57-0

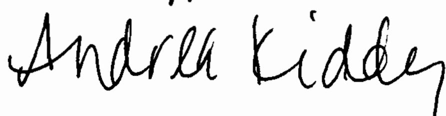
Andrea Kiddy
121 Williams Lane
El Dorado, AR 71730

10 October 2007

To Whom It May Concern:

My son attends ECCEL's Preschool Program in El Dorado, Arkansas. They are a DDTCS/CHMS facility that is a Medicaid based program. He currently receives serves in day habilitation that are outlined in his individualized program plan and related services. Zachary receives OT and ST in addition to the day habilitation. There are no other facilities that could possible serve Zachary and still be his "least restrictive environment". Day habilitation and related services are vital to my son's success.

Sincerely,



Andrea Kiddy

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David Pryor

October 10, 2007

Centers for Medicaid and Medicaid Services
Department of Health and Human Services
Attention: CMS2261-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS2261-P
File Code 2261-P
Medicaid Program; Coverage for Rehabilitative Services
Day Habilitation

Dear Sir or Madam:

In 1989, while representing the State of Arkansas as U.S. Senator, I joined my colleague Rep. Beryl Anthony in passing legislation as a part of the Omnibus Budget Reconciliation Act (OBRA) that prevented the demise of day habilitation services to individuals with mental retardation or with related conditions. Our intent in passing this legislation to prevent elimination of a valuable Medicaid service that was effective in efforts to provide for individuals in the least restrictive setting and to assist in deinstitutionalization of individuals with developmental disabilities was to allow day habilitation to remain a viable community-based service option. For example, in Arkansas we included the day habilitation option in Developmental Day Treatment Clinic Services (DDTCS) model to offer individuals with developmental disabilities and their families an alternative to state-operated institutional care. Many were able to move into communities and benefit from this community-based option and many have never had to be placed in the state-operated Human Development Center. Currently there are over 12,000 individuals and families in Arkansas benefiting from the Day Habilitation option.

I encourage you to withdraw the proposed rule change published in the August 13, 2007 Federal Register, Proposed Rules. The information I received from parents over the years indicates that they choose day habilitation to meet the needs of the individuals and families who desire a community-based option. It enables many parents to remain in the workforce while keeping their loved ones in the community.

1405 N. Pierce, Suite 212
Little Rock, Arkansas 72207
501-661-1775

On a personal note, for several decades I have been closely aligned with Opportunities, Inc. The community support has been a generous allocation of resources, both human and financial. This project, Opportunities, bring the Texas and Arkansas sides of Texarkana together like no other undertaking. It has been a remarkable effort of community dedication that should be a model for our country. To watch the human development of these individuals who are cared for has been one of my life's rewarding experiences. It is precisely the type of effort and partnership that our federal, state, and local communities should undertake.

Respectfully,

David Pryor

Former U.S. Senator 1979 - 1997

Governor of Arkansas 1975 - 1979

U.S. Congressman 1967 - 1973

DP:pls

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Mental Health PEER Connection
3108 Main Street • Buffalo, NY 14214-1384
(716) 836-0822 (voice/TDD)
(716) 835-3967 (fax)

October 10, 2007

Centers for Medicare and Medicaid Services Department of Health and Human Services
P.O. Box 8018 Baltimore, MD 21244-8018
Re: CMS-2261·P

To Whom It May Concern:

The Mental Health PEER Connection (MHPC) is a member of the WNY Independent Living Project, Inc.'s family of agencies is pleased to comment on behalf of its agency and individuals who are dedicated to promoting and strengthening community-oriented rehabilitation services that support recovery from psychiatric disabilities. Based upon our knowledge and experience over the past 26 years, we offer the following comments on the provisions of the proposed regulations related to Medicaid's Rehabilitation Services Option.

Individualized Rehabilitation Plan Signed by the Person Served

MHPC enthusiastically supports the inclusion of a required rehabilitation plan and recovery-oriented goals that is developed with the individual and requires a signature to demonstrate involvement, approval and receipt of the plan [§440.130(d)(3)]. The creation of a rehabilitation plan is good practice and Is necessary for shared decision making and accountability. It is our belief that quality rehabilitation services are strength-based and person-centered, and are built upon the values of choice and self-determination within the cultural context of the individual receiving services.

Person Centered Planning

We are pleased that these values have been applied in the proposed regulations, and hope CMS will consider making person-centered planning a formal requirement of the written rehabilitation plan [§440.130(d)(3)(iii)] beyond the proposed recommendation. In fact, we believe these values should apply to all Medicaid funded services, not just rehabilitation.

The Value of Psychiatric Rehabilitation

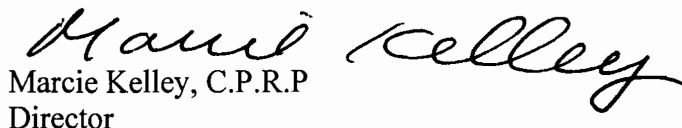
We also appreciate the recognition of psychiatric (or psychosocial) rehabilitation services as an integral component of mental health services and its role in an individual's recovery. The presence (or absence) of psychiatric rehabilitation services directly impacts the achievement of recovery-oriented outcomes. In this context, recovery refers to the process the individual goes through as they rebuild their lives, not just the treatment of symptoms. Certainly, treatment or medical activities should be incorporated within the rehabilitation plan, but are not necessarily the primary driver under the rehab option.

Engagement
Unfortunately, because of prior negative experiences or stigma, same individuals may not be initially ready or willing to become engaged in an intensive and formally documented rehabilitation plan. Therefore, MHPC recommends that CMS consider including the following language to §440.130(d)(3) to recognize the need for and use of early engagement services: "In the event that an individual is initially unwilling or refuses to participate in the development of a rehabilitation plan, early engagement services may be used as a short-term reimbursable expense that encourages a sense of trust, hope and empowerment to improve an individual's participation in rehabilitation goal setting, assessment, planning and/or development activities."
In the absence of a signed rehabilitation plan, early engagement services must document efforts to revise approaches and engage the person to build a mutually satisfying course of action, including documentation of engagement goals and related services. Examples of early engagement services include opportunities to sit in on group activities and meet other people in recovery using the program; educating the individual about the recovery process, recovery outcomes, and the Individual's rights and responsibilities; and motivational interviewing techniques or other explorations of personal interests and values.

Reimbursement Flexibility
MHPC is pleased that the proposed regulations allow for flexibility in how rehabilitation services are paid. Allowing States to specify the methodology under which rehabilitation providers are paid [§441.45(a)(5)] will ensure the continuation of many highly effective programs, such as Assertive Community Treatment, Clubhouses, and Crisis and Transitional Residential Treatment Programs, that tend to bill through a single daily rate or case rate. If executed correctly, these services would focus on the Improvement of the disability and achievement of specific rehabilitative goals, as specified in the rehabilitation plan, and not duplicate services that are intrinsic to programs outside of Medicaid.

Intrinsic Services
Because of this, MHPC recommends that the term "intrinsic" be further clarified within §441.45(b)(1) of the regulations, and suggests that CMS consider defining it in the following way: Intrinsic services are those that are the major focus of another agency based on their statutory requirements. This definition is NOT meant to preclude funding of services under the rehabilitation option which may mirror those by another agency (e.g., housing, employment) but which are provided pursuant to an approved rehabilitation plan as defined in these regulations [§440.130(d)(1)] and are consistent with medical necessity.

Thank you for your consideration of our comments.


Marcie Kelley, C.P.R.P
Director

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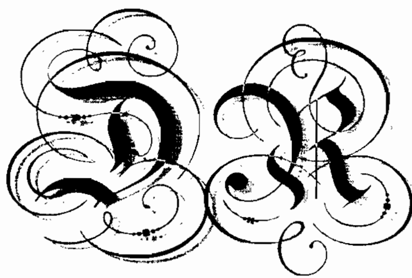


Mr. Daniel Rowland
40 Westminster Road
Rockville Centre, New York 11570

Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8018
Baltimore, MD 21244-8018
Attention: CMS- 2261-P

October 10, 2007

RE: File Code CMS-2261-P

To whom it may concern:

I am writing to express my strong opposition to regulations proposed by Center for Medicare and Medicaid Services (CMS) which would drastically eliminate many clinical services currently provided to individuals with developmental disabilities. These proposed regulations would change the definitions of "habilitation" thereby resulting in excluding necessary speech therapy, occupational therapy and physical therapy from allowable services in Medicaid clinics for individuals with autism and other developmental disabilities.

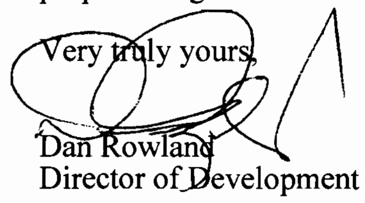
It is estimated that in 2006, nationwide approximately 52,000 people with autism and other developmental disabilities received necessary habilitation services through the clinic and rehabilitation options that are being eliminated by these proposed regulations.

As a result, I strongly oppose the provisions related to excluding federal financial participation (FFP) for habilitation services and urge that this proposed rule be withdrawn. The proposed rule would severely harm people with autism and other developmental disabilities in two major ways:

(1) It eliminates longstanding programs for providing habilitation services to people with autism and other developmental disabilities
(2) It imposes a discriminatory and arbitrary exclusion from receiving many rehabilitative services for people with autism, mental retardation and other developmental disabilities.

Developmental Disabilities Institute (DDI) is one of the largest not for profit providers of services to individuals with autism and other developmental disabilities on Long Island. Over 3,000 clinic visits a year would be eliminated by these proposed regulations at our clinics alone. I believe that states should have the flexibility to continue operating these very necessary habilitation services to individuals with autism and other developmental disabilities. I urge the Secretary to rescind these proposed regulations. Thank-you.

Very truly yours,



Dan Rowland
Director of Development

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October 5, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2261-P
P.O. Box 8018
Baltimore, MD 21244-8018

RE: File Code CMS-2261-P
Notice of Proposed Rule
Medicaid Coverage: Coverage for Rehabilitative Services

Dear Sir or Madam:

Advocacy, Incorporated is the designated protection and advocacy system for the rights of people with disabilities in Texas. Advocacy, Incorporated works to advocate for, protect, and advance the legal, human, and service rights of individuals with disabilities. We submit these comments in response to the Notice of Proposed Rule entitled "Medicaid Program: Coverage for Rehabilitation Services," published in the Federal Register on August 13, 2007.

First of all, we are concerned that these regulations do not comply with Executive Order 13132. Furthermore, contrary to the assertion in the regulation's Preamble, we believe that these regulations will have a significant impact on small business rehabilitation service providers. As a result, we believe that these proposed regulations could result in the denial of coverage for medically necessary services. This is especially true with regard to coverage of services for beneficiaries under 21 who are entitled to all Medicaid services necessary to correct or ameliorate a physical or mental condition, regardless of whether those services are covered for adults. 42 U.S.C. § 1396d(r)(5).

Moreover, the proposed regulations are inconsistent with the statutory purpose of Medicaid coverage of rehabilitation services, which is "to enable each State, as far as practicable. . . to furnish (1) medical assistance . . . and (2) rehabilitation and other services to help . . . families and individuals *attain* or retain capability for independence or self-care . . ." 42 U.S.C. § 1396 (emphasis added). The proposed regulations, on the other hand, leave the distinct and incorrect impression that certain services cannot be covered under Medicaid at all. Specific illustrations and proposed revisions are provided below.

I. Overall Impact

Executive Order 13132 imposes certain requirements on agencies promulgating proposed rules that will impose "substantial direct compliance costs on States," including a requirement that an

agency must either (1) provide the funds necessary for the states to comply with the rule; or (2) consult with state officials during the process of developing the rule prior to promulgation. Exec. Order 13132, § 6(b). CMS asserts that these requirements do not apply because no substantial, direct compliance costs will be imposed on the states. 72 Fed. Reg. at 45209 (Preamble, V.A). We disagree.

It is apparent that implementing these proposed regulations will result in significant costs to states. For example, most states will likely be forced to change their billing and prior authorization procedures. Additionally, states that are currently providing services that would be categorized as day habilitation services under the proposed regulations, would be forced to pay for them with state only funds, or make drastic changes to the way they provide services. Furthermore, the primary purpose of E.O. 13132 is to promote state autonomy and authority. These proposed regulations run counter to that notion because they will significantly limit state flexibility.

Accordingly, CMS should comply with the requirements of Executive Order 13132.

In addition, these regulations narrow the scope of the service and impose requirements that will significantly impact providers. Foe example, the requirements governing therapeutic foster care would require providers to separate and bill for services that were previously "packaged." The discussion of how providers need to separate "incidental" personal care functions from rehabilitation services for billing, record keeping and administration shows how many additional duties will be necessary for providers. 72 Fed. Reg. at 45206 (Preamble, II.F.2).

This statement should be corrected.

II. Conflict with EPSDT

Medicaid's Early and Periodic Screening, Diagnostic and Treatment Service (EPSDT) requirements provide that all Medicaid beneficiaries under age 21 must receive all necessary services listed in 42 U.S.C. § 1396d(a) to correct or ameliorate physical or mental illnesses and conditions, regardless of whether those services are covered under a States' plan. 42 U.S.C. §§ 1396a(a)(43), 1396d(r)(5). There are numerous ways in which the proposed regulations conflict or potentially conflict with the EPSDT requirements.

We suggest an overall restatement of the EPSDT requirement in the regulations.

III. Proposed § 440.130(d)(1)(v)-(vii), (2) - Maintenance v. Restorative services

The discussion of services that maintain, rather than restore, function may lead to inappropriate denials of services that should be covered as rehabilitative. Throughout the preamble and proposed regulations, CMS emphasizes that rehabilitation services must reduce disability and restore function in order to be reimbursable under Medicaid. *See, e.g.,* 72 Fed. Reg. at 45211 (Proposed 42 C.F.R. §§ 440.130(d)(1)(i)(A)). The discussion of a written rehabilitation plan in

the preamble emphasizes the "ultimate goal" of reduction of medical care. *Id.* at 45203 (Preamble, II.C). Moreover, the preamble states that "[i]t is important to note that this benefit is not a custodial care benefit but should result in a change in status." *Id.* At the same time, the proposed regulations acknowledge that maintaining a functional level may be necessary to achieve a rehabilitation goal. *Id.* at 45211 (Proposed 42 C.F.R. § 440.130(d)(1)(vi)).

This discussion creates confusion. The emphasis on change in status and on achievement of specific goals may lead states to deny coverage for medically necessary rehabilitation services, because such services may not lead to immediate results. However, recovery is not necessarily a linear process, a plateau or relapse may be part of the natural progression of recovery. However, the overall emphasis on change in status creates a strong possibility that states will actually apply a more narrow definition than is appropriate.

Moreover, services aimed at maintaining function could fit under service categories other then rehabilitation. For example, assistance with dressing or eating could be covered as a personal care service, as could supervision to prevent injury. This should be recognized both in the preamble and in the regulations.

Recommendation: Add language to proposed regulation § 440.130(d)(1)(vi) that makes clear that the failure to make measurable progress toward a particular goal within a certain time period does not necessarily indicate that a service is not necessary to help achieve a rehabilitation goal.

Add a new subsection (c) to § 441.45, that provides that if a service cannot be covered as a rehabilitative service, states should determine whether the service can be covered under another category of Medicaid services. Also, discussion should be added to Section II.C. of the preamble indicating that maintenance services could qualify for coverage under another category of services and citing examples of other categories.

Delete the language at 72 Fed. Reg. at 45204, Section II.C of the preamble that states that "[i]f it is determined that there has been no measurable reduction of disability and restoration of functional level, any new plan would need to pursue a different rehabilitation strategy . . ."

IV. Proposed § 440.130(d)(1)(vi) – Restorative Services

On August 15, 2007, CMS issued a letter describing peer guidance and explaining that it could be covered under the rehabilitation option. *Dear State Medicaid Director,* Peer Support Services – SMDL #07-011 (August 15, 2007). As acknowledged in the letter, this is an important service for individuals with mental illness and substance abuse services. Given its obvious importance to CMS, States, providers and patients, the specifics of this guidance should be referenced in the regulations.

Recommendation: Section 440.130(d)(1)(vi), which describes "restorative services" should be amended and language added stating that peer guidance is a covered rehabilitation service.

V. Proposed § 441.45(b)(1) – Non-covered Services

The proposed regulations provide that services cannot be provided if they are an "intrinsic element" of a program other than Medicaid. 72 Fed. Reg. at 45212 (Proposed § 441.45(b)(1)). The regulations do not define the term "intrinsic element." This will potentially cause confusion for state Medicaid officials and providers causing erroneous denials of coverage for services. Moreover, these service exclusions will predominantly apply to services for children under age 21, given the nature of the programs implicated. Thus, these children will all be eligible for EPSDT, under which a service should be covered if it is necessary to correct or ameliorate a physical or mental condition, even if it could be covered under another program. The proposed regulation appears to acknowledge this in § 441.45(b)(1)(i) and (ii), but not with sufficient clarity.

The proposed regulation states that therapeutic foster care services cannot be covered, but makes an exception for medically necessary rehabilitation services "that are clearly distinct" from packaged therapeutic foster care services. Since packaged therapeutic foster care services are not defined, it will be difficult to identify services that are not included in that package. Furthermore, in describing adoption services and routine supervision in schools, the regulation does not include the same exception for medically necessary rehabilitation services. 72 Fed. Reg. at 45212 (Proposed § 441.45(b)(1)(iii) – (iv)). Additionally, the term "packaged" is problematic because many services that are covered under Medicaid, such as physicians' services, are packaged. The use of this term will confuse states and create serious administrative issues. The proposed regulations should explain this term and how it would be applicable to other services.

Further, this requirement appears to conflict with provisions regarding Medicaid coverage of related services under the Individuals with Disabilities Education Act (IDEA) and third party payment. In Section I.A. of the preamble, it is noted that Medicaid has been used to fund services that are included under the IDEA. 72 Fed. Reg. at 45202. The Medicaid statute specifically provides that the Secretary cannot prohibit or restrict coverage of Medicaid services simply because the services are included in an individualized education plan for IDEA services. 42 U.S.C. § 1396b(c). The Medicaid statute also requires that State and local agencies administering the state Medicaid plan "take all reasonable measures to ascertain the legal liability of third parties . . ." 42 U.S.C. § 1396a(a)(25)(A). Even if a third party is liable, when EPSDT services are at issue, the Medicaid agency is obligated to pay a claim for services, then pursue reimbursement from the liable third party. 42 U.S.C. § 1396a(a)(25)(E); 42 C.F.R. § 433.139(b)(3)(i) (2007). Therefore, when a service is the responsibility of a third party, the other program is still a third party payer.

Finally, it is important to note that during consideration of the Deficit Reduction Act of 2005 (Pub. L. 109-171), Congress considered *but rejected* an "intrinsic element" test for rehabilitation services. *See* Jeff Crowley, Kaiser Commission on Medicaid and the Uninsured, *Medicaid's Rehabilitation Services Option: Overview and Current Policy Issues*, 1 (August 2007). Thus the "intrinsic element" test does not reflect Congress' intent with regard to coverage of rehabilitation services.

Recommendation: We recommend that § 441.45(b), be omitted because it conflicts with the EPSDT requirements and other parts of the Medicaid statute.
In the alternative we suggest that the regulations omit the intrinsic element test and define and explain in § 441.45(b)(1)(ii) and (iii) what constitutes a "packaged" therapeutic foster care or child care service. Additionally, the phrase "except for medically necessary rehabilitation services" should be added to subsections (iii) and (iv).

Section 441.45(b)(1)(iv) should be amended to clarify that Medicaid coverage should not be denied merely because a service is provided in an individual education plan.

Finally, the regulations should recognize and explain the responsibilities for states regarding third party payers and the third party payers' responsibilities in § 441.45(b)(1).

VI. Proposed § 441.45(b)(2) - Habilitation Services

The proposed regulations explicitly state that habilitation services are not coverable as rehabilitation services, because they are designed to help individuals acquire new functional abilities rather than to restore function. 42 C.F.R. § 441.45(b)(2), *see also* 72 Fed. Reg. at 45205. The discussion and regulation regarding habilitation is problematic.

The discussion appears to be based on the premise that individuals with cognitive or intellectual disabilities could never have a need for rehabilitation services. This premise is overly broad and will lead to the exclusion of appropriate services for this population.

Further, neither the regulations nor preamble acknowledge the different nature of some "related conditions," including epilepsy, autism, and cerebral palsy. 42 C.F.R. § 435.1010 (2007). These diagnoses can cause loss of function that needs to be restored, thus, those individuals need and could benefit from rehabilitation services.

Finally, the proposed regulations do not provide guidance for coverage of services for individuals with dual diagnoses of mental retardation/related conditions and mental illness. This is likely to lead to denial of medically necessary covered services for a population that already faces significant barriers to care.

Recommendation: Add language to § 441.45(b)(2) stating that a diagnosis of cognitive or intellectual disabilities or related conditions does not automatically exclude a person from coverage of mental health services.

Add language to § 441.45(b)(2) clarifying that habilitation services may also be provided under other Medicaid services categories, including but not limited to therapy services, defined at 42 C.F.R. § 440.110 (including physical, occupational, and speech/language or audiology therapy) and medical or other remedial care provided by licensed practitioners, defined at 42 C.F.R. § 440.60.

Clarify that services for individuals with a dual diagnosis of mental retardation/related condition

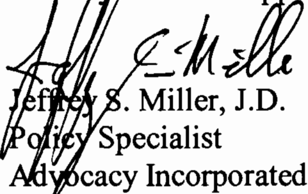
and mental illness may be covered, and provide further explanation of how that coverage can be achieved.

VII. Proposed § 441.45(b)(4)

Services for inmates living "in the secure custody of law enforcement and residing in a public institution" are specifically excluded by the proposed regulations. It is unclear if this is intended to be a narrower category of individuals than those for whom FFP is not available because they are living in a public institution, as defined by 42 C.F.R. § 435.1010 (2007). If so, this would be undesirable. If not, it appears unnecessary and confusing.

Recommendation: omit the phrase "in the secure custody of law enforcement."

Thank you for the opportunity to comment on these proposed regulations.



Jeffrey S. Miller, J.D.
Policy Specialist
Advocacy Incorporated

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October 8, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 21244-1850

Attn: CMS-2261-P
Proposed rule making on the Coverage for Rehabilitative
Services 42 CFR parts 440 and 441
Federal Register (72 FR 45201)

To Whom It May Concern:

The Montana Children's Initiative Provider Association (MCI) is an organization that has advocated for children and families and supported providers for 22 years in Montana. Our membership currently includes 85% of the states mental health and child welfare providers. The MCI member list is attached.

We are very concerned about the proposed rehabilitation rule changes by the Centers for Medicaid & Medicaid Services (CMS). These changes would result in a mandate to Montana that we unbundle our Therapeutic Foster Care (TFC), Therapeutic Family Living (TFL) and Therapeutic Group Care (TGC) services for seriously emotionally disturbed children. In this last fiscal year Montana served over 800 youth in TFC and TFL and over 500 youth were served in 4-8 bed TGC. If implemented, these changes could ultimately destroy Montana's array of out of home services and essentially wipe out all services between foster care and residential treatment.

MCI has been involved with the Montana Department of Public Health and Human Services and the Children's Mental Health Bureau regarding how to unbundle these services. There appears to be some possibility to restructure our Therapeutic Group Care services. It is a very important level of care. Many youth who do not need residential treatment or are stepping down from this level of are, but cannot function in a family setting do well in a community based Therapeutic Group Home, where they can go to school or day treatment and participate in other community activities. However, our Therapeutic Foster Care and Therapeutic Family Living services, where youth live in a family setting could end up being totally dismantled.

Following are the concerns we have regarding the proposed rule changes and the impact on our excellent out of home children's services:

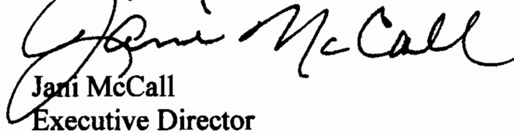
- The basic definition of "rehabilitative services" is retained as: "medical or remedial services recommended by a physician or other licensed practitioner of the healing arts.........for maximum reduction of physical or mental disability or restoration of an individual to the best possible functional level. This definition is confusing when it comes to children, because of their ever-changing developmental levels.
- The definition of requiring all treatment foster parents to meet "qualified providers of rehabilitation services" will likely result in most of them not being able to meet the standards. The qualifications might include education, work experience, training, credentialing, supervision, and licensing. Treatment foster parents come from a variety of backgrounds. The vast majority do not have professional training in human services.
- Currently CMS is maintaining that Therapeutic Foster Care is not considered a medically necessary service. The proposed rule would prohibit reimbursement for this service under the Medicaid Rehabilitation Services benefit, including recruitment, training and other foster care support services;
    - According to SAMSHA, Therapeutic Foster Care is supported as the most effective out of home placement option for children, yet CMS contradicts this, with rule changes that would not allow these support services to be paid for by Medicaid dollars.
    - Therapeutic Family Living services are geared to work with children in their own home and provide the same level of support as TFC, yet the CMS rule changes would not allow these support services to be paid for by Medicaid dollars.
    - The President's Freedom Commission Report supports family driven services and the creation of comprehensive, multi-agency children's system of care options. Yet the CMS rule changes contradict the priorities in this report.
- A written rehabilitation plan (with 17 components) will help ensure state accountability and regular re-evaluation will ensure progress. The plan also requires input from the youth and family.
    - However, the rule does not take into account other plans such as individual treatment plan and how they will be coordinated, to avoid duplication, additional time and additional burden.
- The "Intrinsic To" test, stating that rehabilitation does not include services furnished through a non medical program as either a benefit or administrative activity including services that are intrinsic to elements of programs such foster care, child welfare, education, child care and juvenile justice.
    - According to the Child Welfare League of American, Congress explicitly rejected adopting an 'intrinsic to" test in regards to Medicaid rehabilitative services when finalizing the Deficit Reduction Act, yet it is occurring in these proposed changes.
    - The proposed changes exclude federal financial participation for TFC or TFL, except for "medically necessary rehabilitation services that are clearly distinct from packaged therapeutic foster care services." It is extremely difficult to unbundle TFC and TFL services to meet these terms. TFC TFL gives children the chance to heal and grow in the midst of a family setting.
    - Montana's child welfare system requires that children in care receive all of the services they need, physical, dental and mental health. Most children in the system have experienced some type of trauma resulting from some form of child abuse and/or neglect.

- Montana's Children's System of Care, supported by a SAMSHA grant and the President's New Freedom Commission report on Mental Health acknowledge and promote the need for comprehensive, wrap around and supportive community based services for children and families. If Medicaid dollars no longer pay for these kinds of support services how can we provide the treatment and care they deserve? How can we meet the requirements of our SAMSHA Children's System of Care grant of least restrictive, most appropriate family and community based services?
- Both our child welfare system and our mental health system must ensure the provision of all medically necessary services but cannot cover the costs alone without Medicaid assistance.

We believe that CMS will receive similar comments from virtually all states across the country regarding these changes and the impact on children's out of home services. We ask that CMS not implement the proposed rules as scheduled in June 2008 and that substantial time be given to evaluate the impact of these changes. If this is not done, we will see least restrictive, cost effective community based services dismantled, more children being served at the highest levels of care and Montana, along with many other states, faced with huge general fund budget concerns to offset the loss of Medicaid funding.

Thank you for your cooperation and consideration of these critically important issues. If I can be of further assistance please contact me at 406-256-3585 or janimccall@msn.com.

Sincerely,



Jani McCall
Executive Director

2331 Spruce Street
Billings, MT 59101
406-256-3585 – O
406-256-3847 – F
janimccall@msn.com

Copy: MCI Members
MT DPHHS

JM/jm

The Clubhouse has been there when i lost my husban last year. I've met a lot of new people. I get my own place. and now i'm getting my check. I have been coming to the clubhouse for almost a year. The staff have been really good to me. I have a case manager She help's me with my money, So i don't spend it all in one place. I can ride tacc without having to walk. I have to go to Court On the 8th and some of the staff said if i need Someone the come with me they would go with me. I get medcaid now so i can get my meds. Please don't start the proposed cut in Services to ADventure House.

Trina McSwain
1102 S. Washington St,
Apt. A Shelby N.C. 28150

2261-P

64

October 3, 2007

Centers for Medicaid & Medicare Services
Department of Health and Human Services
Attn: CMS-2261-P
P.O. Box 8018
Baltimore, MD 21244-8018

Aloha,

The latest changes in practice by the CMS and related proposed rule changes, I believe will have a dramatic effect on both local and national levels. Though the plan maybe of good intentions, in actuality the proposal makes mentally ill citizens most vunerable by having forsaken the care structures or supportive foundations presently offered to them.

NAMI notes 73% of the people in need of rehabilitation <u>also</u> need mental health services! Mentally ill people need <u>long term rehabilitation</u> and <u>support</u> from a network of services which are funded in a myriad of ways. The dramatic shift of all mental health funds to be under Medicaid creates chaos in community services of most states.

Under the new proposal, public access to mental health will be diminished without alternative funds to provide the present crucial support network. It is the mentally ill in today's society that are marred with a stigma that often deprived them a future with promise. To create and enforce a lengthy bureaucratic clinical and administrative process and forego the necessary alternative funding provided by states will cause a dramatic decline in mental health services. This mishap speeds the severely or persistently mentally ill into the fast lane towards institutionalization or worst yet, prison!

Recovery from mental illness is a long term process that requires punitive psychosocial services and support. Recovery needs to be "person centered" that offers the necessary focused services as education, employment, housing and vocational preparation.

Clubhouses affiliated with the International Center for Clubhouse Development (ICCD) are known to provide cost effective gambit of services in a community based environment. Clubhouses more than any other program have strong partnerships with the local businesses, educational institutions and other social service providers.

It is imperative that none of the proposed rule changes should go into play until we have a parallel plan to provide the necessary focused services that would no longer be under Medicaid's umbrella. Essentially, the plan must include mental health services and provide for a long term recovery process such as ICCD Certified Clubhouses do. Otherwise we will have forsaken the lives and hopes of millions of mentally ill who need essential support networks such as ICCD Certified Clubhouses to begin the arduous task of rebuilding their lives.

Mahalo for your interest and concern,

ROBYN UYEHARA
3253 DUVAL STREET
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108 East Willow Street
P.O. Box 327
Normal, Illinois 61761-0327
Phone: (309) 452-1170 • Fax: (309) 452-0115

Family Center
Residential Treatment Center
612 Oglesby Avenue
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October 8, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2261-P
P.O. Box 8018
Baltimore, MD 21244-8018

To Whom It May Concern:

Reference : File code CMS-2261-P

The Child Care Association of Illinois is submitting the following comments on the Proposed Rule for coverage for Rehabilitative Services under the Medicaid program, as published in the Federal Register August 13, 2007.

I. BACKGROUND - GENERAL COMMENTS

Impact on Poor Children

The proposed amendments by CMS to protect Medicaid beneficiaries would in effect limit access to Medicaid for currently eligible poor children and we see it as an effort to cut vital federal funds to states by reducing funding for children. We ask that states not be penalized for stepping up to meet the needs of the nation's poor children and families. According to the Medicaid regulations which identifies **mandatory eligibility groups**, "states have some discretion in determining which groups their Medicaid programs will cover and the financial criteria for Medicaid eligibility. To be eligible for Federal funds, states are required to provide Medicaid coverage for most people who get Federally assisted income maintenance payments, as well as for related groups not getting cash payments. Some examples of the mandatory Medicaid eligibility groups include the following:

- Limited income families with children, as described in Section 1931 of the Social Security Act, who meet certain of the eligibility requirements in the state's Aid to Families with Dependent Children (AFDC) in effect on July 16, 1996;
- Recipients of adoption assistance and foster care under Title IV-E of the Social Security Act."

While we welcome rule clarifications and your commitment to protect the fiscal integrity of the Medicaid program, many of these rule changes could be used to narrow or potentially eliminate the very children it was written to help rehabilitate as identified in the mandatory eligibility groups. We strongly recommend that CMS work with child welfare providers, the states, and other federal agencies to create a system of fiscal accountability, which supports best practice for children with mental health needs and

allows for the provision the most appropriate Medicaid rehabilitative services in the least restrictive setting.

To protect the nation's poor children the Child Care Association of Illinois asks for the following considerations.

Importance of Rehabilitative Services for Children in Foster Care and Child Care Institutions

Children that enter the foster care system or are placed in child care institutions under the federal requirements applicable to Title IV-E are at an extremely high risk for both physical and mental health issues as a result of biological factors and the maltreatment they were exposed to at home. 80% of children in out of home care meet the clinical criteria for behavioral problems or psychiatric diagnosis.

When children are removed from their home base and placed in state custody, child welfare agencies funded through Title IV-E are responsible for meeting their health and mental health needs, and virtually all children in foster care and child care institutions are eligible for and obtain health care services through Medicaid.

Funding for those most applicable Rehabilitative services have increasingly been accessed by states – especially for children with mental illness – for two reasons. The increase was promoted in part by the recommendations from the President's New Freedom Commission on Mental Health, issued in 2003, to improve the nation's mental health system. Secondly, the Children's Federal Services Review (CFSR) has identified mental health services as the major area of deficiency that is not being met within the child welfare system funded with Title IV-E.

II. PROVISIONS OF THE PROPOSED RULE

C. Written Rehabilitation Plan

In Section 440.130(d)(3), it adds a requirement that covered rehabilitative services for each individual must be identified in a written rehabilitation plan.

Concerns:
We are concerned about the extent of the requirements that must be included in the written rehabilitation plan. This would place an administrative burden on Medicaid providers in order to address the overall extent of all requirements.

The plan requirement to indicate the anticipated providers of the services and the extent to which the services may be available from alternate providers of the same service would be administratively burdensome.

Recommendation: Substitute for the requirement that the plan list the potential providers of the same service requirement that the plan include an assurance that the individual

received this information to the extent the service planning team is aware of all existing providers.

F. Requirements and Limitations for Rehabilitative Services

2. Limitations for Rehabilitative Services – Intrinsic Elements

Under this section it explicitly states that rehabilitation does not include services "furnished through a non medical program as either a benefit or administrative activity including services that are intrinsic to elements of programs other than Medicaid, such as foster care, child welfare, education, child care ..... juvenile justice. (Proposed Section 441.45 (b) (1) through (b) (8). The proposed rule seems grounded in the assumption that rehabilitation services serve as "intrinsic elements" within a series of other federally funded programs, and that states are duplicating their funding streams in seeking support from Medicaid for these services. This leaves the questions of what is considered to be "intrinsic to" a program. How would that be defined?

Concern: Congress explicitly rejected adopting an "intrinsic to" test in regards to Medicaid rehabilitative services when debating and finalizing the Deficit Reduction Act, so the authority to make this application to Medicaid Rehabilitation Services would need to be done through change in the law and not through regulation.

Concern: While it is helpful to clarify what is covered by Medicaid and what is covered by other federal programs, the proposed regulation and its "intrinsic to" test does not properly consider the child welfare system funded under Title IV-E and the application of Medicaid programs to children's services. The child welfare system is required to ensure that the children in their care get the services they need, including medical and mental health. The results of the CFSR's of the 50 states indicate that state child welfare agencies are already struggling to meet these needs largely because the mental health system as reported by the President's New Freedom Commission is "fragmented and in disarray".

If the proposed "intrinsic to" test is applied to child welfare and Medicaid resulting in the requirement that the services needed by the child in care would come only from the child welfare system, this would eliminate critical mental health services that the CFSR's have even identified. If Medicaid is not there to assist, what will be done to infuse greater dollars into the Mental Health system so that the services that are needed are being provided and available?

Recommendation: We would propose the removal of the reference "intrinsic to" in the rule and use the basic definitions from the other federal programs as the guideline for determining the coverage of services. In the definition for Title IV-E it specifically provides for payment for a child placed in a foster family home or child care institution and that these children are Medicaid eligible and therefore eligible for Medicaid defined services. As stated by the Code of Federal Regulations, Title 45, Chapter XIII, Part 1355.20, Title IV-E covers the cost of food, clothing, shelter, daily supervision, school supplies, a child's personal incidentals, liability insurance with respect to a child and reasonable travel for a child's visitation with family or other caretakers. For child care

institutions it must also “include the reasonable costs of administration and operation of such institutions as are necessarily required to provide the items described in the preceding sentence”.

The Code of Federal Regulations at 1356.60 Fiscal Requirements (Title IV-E) specifically prohibit States from claiming Title IV-E federal financial participation (FFP) for medical or rehabilitative services as “Allowable administrative costs do not include the costs of social services provided to the child, the child’s family or foster family which provide counseling or treatment to ameliorate or remedy personal problems, behaviors or home conditions.”

Mental health services are a critical portion of the services that need to be made available to children in foster care and child care institutions but are not covered under Title IV-E and should be covered by Medicaid if they meet the Medicaid regulations.

2. Limitations of Rehabilitative Services – Provider Choice

Section 441.45 (b) (1) emphasizes language that requires that “the individual must have free choice of providers”.

Concern: The clients in the child welfare system are children and adolescents who are wards of the state and do not choose these services amongst a list of available providers. For those children, the choice should include birth parent, the child who is old enough, and legal guardian.

Definitions for Rehabilitation Services versus Habilitation Services

Section 441.45(b)(2) speaks to a distinction between the terms “habilitation” and “rehabilitation”. Rehabilitation refers to measures used to restore individuals to their best functional levels. It states that individuals receiving rehabilitation services must have had the capability to perform an activity in the past rather than to actually have performed the activity.

Section 441.45(a)(2) states that rehabilitative services claimed for Medicaid payment are only those provided for the maximum reduction of physical or mental disability and restoration of the individual to the best possible functional level.

Concern: These sections of the proposed rule as with numerous other sections of the proposed rules have language that is geared more for adults than for children. In children’s services, we have to be sensitive to the developmental levels of children. In such cases rehabilitative services are geared to move children to expected levels they have not reached. Rehabilitative services should be used to achieve these type of functional goals for children. Such rehabilitative steps are not geared to restoring a child to a previous level of functioning as with an adult.

Recommendation: Language should be included that references rehabilitative services are also used to achieve an “expected level” of development for children.

<u>Exclusion of Services Provided to Residents of an Institution for Mental Disease</u>
In section 441.45 (b) (4) it is proposed to exclude payment for services that are provided to residents of an institution for mental disease (IMD) including residents of a community residential treatment facility of over 16 beds, that is primarily engaged in providing diagnosis, treatment or care to person with mental illness, that does not meet the requirements at Section 440.160.

<u>Concern</u>: It appears that language here is more readily applicable to the adult population in determining what is an IMD. In the child welfare system, funding is provided through Title IV-E to child care institutions as referenced in 45 CFR Chapter 13 Part 1355 and 1356 and, although the interchange of wording used when speaking about them may at times include residential treatment facility, they are not licensed as a residential treatment facility within the child welfare system. Child welfare programs are licensed as child care institutions per the language of the IV-E federally funded program and not as psychiatric under 21 residential treatment facilities. Title IV-E pays for room and board costs for the placement of children in foster family homes or child care institutions.

<u>Recommendation:</u> According to the definitions for Title IV-E under the Social Security Act (45 CFR Chapter 13 Part 1356) for foster care and child care institutions, these settings would be allowable for Medicaid services if the state licensing provisions (Title 89: Social Services, Chapter III, Dept. of Children and Family Services, Subchapter e: Requirements for Licensure, Part 404) are so established within a state and the services provided meet the definitions for Medicaid rehabilitative services. The inherent intent of the child care institution is to improve the level of functioning of the child so that they would be moved to a less restrictive setting so this would meet the definitions for rehabilitative services.

<u>Any child welfare program licensed as a child care institution should not be included in the language of a community residential treatment facility referenced in section 441.45 (b) (4). The reference to an IMD should not apply to child care institutions as defined by state licensing rule.</u>

<u>E. Settings</u>

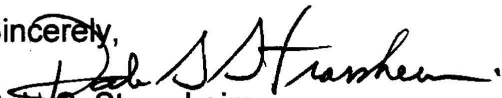
Also under section 440.130(d)(5), it is proposed that rehabilitative services may be provided in a facility, home or other setting.

<u>Recommendation:</u> Child care institutions should be included as an example of one of these settings. Inpatient is associated with a psychiatric facility and child care institutions do not meet that definition according to licensing regulations of the state (Title 89: Social Services, Chapter III, Dept. of Children and Family Services, Subchapter e: Requirements for Licensure, Part 404) and should not meet that definition in order to provide a level of care needed in a community based setting, but not within the inpatient setting of a hospital. It is agreed that rehabilitative services do not include room and board in an institutional setting as that is paid through other federal funding in the child welfare system such as Title IV-E. Rehabilitative services

provided within the child care institution setting should be eligible for Medicaid if they meet the definitions.

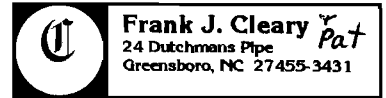
Thank you for the opportunity to comment on the proposed regulation.

Sincerely,



Dale S. Strassheim
President/CEO
The Baby Fold

66



To Whom It May Concern:

As both board members of Sanctuary House in Greensboro, NC, and members (17yrs!) of NAMI, (National Alliance on Mental Illness), we are very concerned about the Proposed Rule to amend the definition of Medicaid Rehabilitative Services as published in the Federal Register, Aug. 13, 2007.

We are parents of our 35 yr. old son, who suffers from schizo-affective disorder. Until he became a member of Sanctuary House, (Greensboro's wonderful psychosocial rehabilitation program), -- based on the Clubhouse Model, he was not able to attain his personal and professional goals. Since becoming a member he's been stable and able to hold down a permanent job. (on his 4th year!)

We are very concerned about this proposal. Please consider the impact these policy changes will have on adults with serious mental illness. The mentally ill need the services of Clubhouse programs to reach optimal level of functioning.

Sincerely,
Frank and Pat Cleary

To Whom It May Concern,

It is imperative that CMS withdraw, revise and re-issue the regulations proposed under Section 441.45(b)(2), with greater clarity as to the implications for children and adolescents with special needs who are currently receiving necessary medical services here in Pennsylvania.

As written, these proposed regulations raise questions as to whether the federal government will use them to force Pennsylvania to restrict these vital services for our children.

It is also urged that CMS provide opportunity for public comment.

Sincerely,

Douglas and Sally Abbonizio
1302 Farren Ln
West Chester, PA 19380
610-701-9258

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October 5, 2007

Centers for Medicare and Medicaid Services
US Dept. of Health and Human Services
Attn.: CMS-2261-P
PO Box 8018
Baltimore, MD. 21244-8018

To Whom It May Concern:

In regard to regulation CMS-2261-P, please note that as a professional in the field of human services and a person having a family member with a severe disability I strongly object to planned cuts in Medicaid allocations. The use of Medicaid for rehabilitative services, particularly residential and day habilitation, is a key component in the continuum of care for our most vulnerable citizens. Abolition of these funds will not only harm these human beings, but may set the whole field of developmental disabilities back 25 years. The Medicaid funding system has been the primary funding vehicle to support de-institutionalization in New York Sate and across our nation....this cannot be denied.It is unconscionable that consideration would occur toward removing this funding support from these people...what would replace it?

Removal of Medicaid funded rehabilitative services may be an attractive option to curtail government spending....but at what cost? This may actually be a mater of life and death for some people. I ask you to please recognize the seriousness of this situation....our most vulnerable citizens must have access to this form of community support.

I appreciate your consideration of this request.

Sincerely,

Edward Martin

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A Clubhouse Model Rehabilitation Program

Center for Medicare & Medicaid Services
Attention: CMS-2261-P
PO Box 8018
Baltimore, MD 21244-8018
Reference: File code CMS 2261-8018

To Whom It May Concern:

My name is Phil Wintermute, and I have worked in the community mental health field for more than twelve years now, most of that time as part of a program in Durham, NC known as Threshold. Threshold is a Clubhouse Model psychosocial rehabilitation day program, to use the jargon of our field. I want to take this opportunity to tell you about what we do here and in other similar programs, and why the proposed CMS regulation changes will have such a negative impact on our communities.

Clubhouse programs like Threshold are part of the community-based rehabilitation system that was going to take over when we realized that our older paradigm (long-term institutional care in state hospitals) was not only outdated but really quite inhumane. New medications and progressive thinking indicated that people with mental illness would be much more appropriately served in the community, and we as a nation agreed that we would do so. Clubhouse programs have been one of the few that have truly addressed this need and kept that promise.

Some of the things I have learned in my years at Threshold:

- Progress is gradual- individuals with severe mental illness are able to achieve equilibrium and to improve, but these things take time. Time-limited services are inappropriate and ineffective.
- The clubhouse is often the only stabilizing factor in people's lives. Under our current state of mental health "reform", any sense of continuity in other community services (case management, therapy, etc.) has been completely lost.
- The focus on documentation per contact for rehabilitation puts the focus on paperwork and not people work. Every minute spent on documentation, requests for authorization, etc. is a minute taken away from direct service.
- The idea that mental health consumers who receive one service no longer need others is absurd. Supporting individuals with mental illness is complicated and calls for input from a variety of sources to have any hope of succeeding.

In conclusion, I urge you to reconsider these changes in the rules governing Medicaid reimbursement for rehabilitation services. Please understand that if implemented, the proposal would mean the end of Threshold and other clubhouse programs dependent on Medicaid dollars. This in turn would undoubtedly result in, at minimum, widespread deterioration of those who depend on us for support. We have come too far to go back to dehumanizing warehousing as our "best practice" in our approach to mental health. We owe our brothers and sisters who daily struggle with this devastating illness much better than that.

Sincerely,

Phil Wintermute
Employment Director

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Telephone: (919) 682-4124 Facsimile (919) 956-7703

LaPorte County's Complete Mental Health Resource
450 St. John Road, Suite 501 • Michigan City, IN 46360 • (219) 879-4621 • (800) 982-7123 • Fax (219) 873-2388 • www.swansoncenter.org

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September 26, 2007

Centers for Medicare & Medicaid Services
Dept of Health and Human Services
Attention: CMS-2261-P
P.O. Box 8018
Baltimore, MD 21244-8018

To Whom It May Concern:

Reference: File code CMS-2261-P

Swanson Center is submitting the following comments on the Proposed Rule for Coverage for Rehabilitative Services under the Medicaid program, as published in the Federal Register, August 13, 2007.

We are a not-for-profit comprehensive community mental health center located in LaPorte County, Indiana. Our Center is organized to provide comprehensive mental health and substance abuse services to persons of all ages. The comprehensive mental health and substance abuse services are provided to children, adolescents, adults, elderly and their families with special emphasis on persons most disabled. Swanson Center has been serving the mental health and substance abuse needs of the citizens of LaPorte County for over thirty-eight years.

Out main offices are located at the Marquette Office Building 450 St. John Road in Michigan City, Indiana 46360. Clinical Services at this location include (a) Medical and Psychiatric Services, (b) Outpatient services for all ages, (c) Passages (substance abuse program), (d) Community Support Program (case management), (e) ACT (assertive community treatment), (f) Adult Day Treatment (partial), and (g) BEST program (supportive employment). Administrative Services include: (a) Office of the Executive Director, (b) Fiscal Administration, (c) Human Resources, (d) Health Information Management Services, (e) Management Information Systems (MIS), and (f) Prevention Services. Also located in Michigan City is Ventures, a Day Treatment Program for children/adolescents, at 301 East 8th Street. Shorewood Place, our Supervised Group Living Program, at 975 S. Carroll Avenue, and Southwind, our Clustered Apartment Program, at 214 Westwind Drive. We also maintains a site in LaPorte at 1230 State Road 2 West, Suite B., 46350. This site offers the following clinical services: (a) Medical and Psychiatric

Rich Past, Bright Future

Activity Center for Older Adults • (219) 326-5354 • Fax (219) 873-2388
LaPorte Counseling Services • (219) 362-2145 • Fax (219) 362-1143
Michigan City Counseling Services • (219) 879-4621 • Fax (219) 874-4538
Passages • (219) 873-2395 • Fax (219) 874-4538
Psychiatric Services • (219) 877-3202 • Fax (219) 874-4538

Services, (b) Outpatient Services for all ages, (c) Substance Abuse Counseling/Programs, (d) Case Management, and (e) ICM (Intensive Case Management/Therapy Program). The Center operates the Activity Center for Older Adults (ACOA) located on 901 State Street in LaPorte Indiana 46350. This Activity Center serves the senior citizens of LaPorte County and particularly those who reside in the city of LaPorte.

The primary funding sources for our agency is Medicaid, Medicare, Private Insurance, and our Hoosier Assurance Plan through the Indiana Department of Mental Health and Addictions. The Center also accepts private pay , but this accounts for very little of our funding. We served 2,725 clients last fiscal year and will serve at least that many this year.

We have significant concerns with the proposed regulations, as they will create barriers to the recovery process for the children and adults that our agency serves. We would like to comment on the following four areas of the proposed rule:

440.130(d)(1)(vi) Definition of Restorative Services

This definition stipulates that restorative services are those that enable an individual to perform a function, and that the individual does not have to have actually performed the function in the past. This language is critical, as loss of function may have occurred long before restorative services are provided. This would be particularly true for children, as some functions may not have been possible (or age-appropriate) at an earlier date. The regulation needs modification to make the meaning of this section clearer.

This definition also includes as appropriate rehabilitation services those services designed to maintain current level of functioning but only when necessary to help an individual achieve a rehabilitation goal. While rehabilitation services should not be custodial, for people with serious mental or emotional disabilities, continuation of rehabilitative services are at times essential to retain their functional level. Most severe mental illnesses are marked by cyclical periods of sharp symptom exacerbation and remission, and the long-term clinical course of these conditions is difficult to determine. As an illustration, *Mental Health: A Report of the Surgeon General*, notes that for people living with schizophrenia, "..a small percentage (10 percent or so) seem to remain severely ill over long periods of time (Jablensky et al., 1992: Gerbaldo et al., 1995). While these individuals can significantly improve, "most do not return to their prior state of mental function." (Mental Health: Report of the Surgeon General, 1999, pg. 274).

Given this sobering clinical data, failure to provide a supportive level of rehabilitation would result in deterioration necessitating a reinstatement of intensive services. We are concerned that states and providers will interpret the current proposed regulation as prohibiting the coverage of services necessary for retention of improved functioning as well as maintaining the highest possible functional level, leading individuals to deteriorate to the point where they will be eligible for services. This serves no one's interest.

Section 1901 of the statute specifically authorizes funds for "rehabilitation and other services" to help individuals "retain" capability for independence and self-care. This provides authority for CMS to allow states to furnish services that will maintain an individual's functional level.

Similarly, CMS in the Medicare program explicitly acknowledges the importance of maintenance of current functioning as an acceptable goal:

> For many other psychiatric patients, particularly those with long-term, chronic conditions, control of symptoms and maintenance of a functional level to avoid further deterioration or hospitalization is an acceptable expectation of improvement. "Improvement" in this context is measured by comparing the effect of continuing treatment versus discontinuing it. Where there is a reasonable expectation that if treatment services were withdrawn the patient's condition would deteriorate, relapse further, or require hospitalization, this criterion is met."
>
> Medicare Hospital Manual, Chapter II, Section 230.5 Hospital Outpatient Psychiatric Services; Medicare Intermediary Manual, Part 3, Chapter II, Section 3112.7 Outpatient Hospital Psychiatric Services.

Additionally, The preamble and section 441.45(b) of the proposed rules exclude prevocational services. However, rehabilitative services should include prevocational services when they are provided to individuals that have experienced a functional loss has a specific rehabilitation goal toward regaining that functioning. Examples of these skills include cognitive interventions such as working at an appropriate pace, staying on task, increased attention span, increasing memory, as well as other communication and social skills that are necessary as pre-vocational work and for daily living, such as taking instructions and/or guidance, and asking for help.

Recommendation:

Further clarify that a child need not demonstrate that he or she was once capable of performing a specific task in the past if it were not possible or age-appropriate for the child to have done so. Specifically, the language should state that restorative services include services to enable a child to achieve age-appropriate growth and development and that it is not necessary that the child actually performed the activity in the past. (Note, this phrasing is taken from current CMS regulation of managed care plans at 42CFR 438.210(a) (4) (ii) (B)). An example of a child who was developmentally on track to perform a function, but did not because it was not yet age-appropriate would be helpful. Currently, the regulation only has an example of an adult.

Secondly, revise the definition of when services may be furnished to maintain functioning to include as an acceptable goal of a rehabilitation plan the retaining of functional level for individuals who can be expected to otherwise deteriorate.

Clarify that pre-vocational services are allowable services when appropriately tied to a rehabilitation goal.

440.130(viii)(3) Written Rehabilitation Plan

We do urge some amendments (see below). In addition, there are some issues where the regulation is unclear and issues are unaddressed. Without attention to our suggestions, this new requirement will add significantly to the administrative time and expense of agencies serving individuals in need of rehabilitative services.

For example, how does CMS expect providers to indicate progress towards the goals in the rehabilitation plan? Need there be a progress note for every encounter? (Since CMS is currently requiring providers to account for and bill services in 15-minute increments, a progress note for every encounter will become a major burden, especially when services are delivered to a group.) We would recommend that progress notes be required at least monthly, leaving it to states to require, or providers to make, more frequent notes in cases where that may be appropriate. The guiding factor should be that the service record includes information that is necessary for clinical purposes and that this information is presented in a way that meaningfully demonstrates the nature and course of services being provided.

Is it allowable for a service planning team to create a single plan of services that address both treatment issues and rehabilitation issues? Frequently in mental health service delivery clinical issues (such as medication and therapy) are planned in conjunction with rehabilitation needs (skill building, etc.). Requiring two separate planning processes and two separate planning documents is burdensome not only on providers but also on the individual consumer. Clearly, multiple service plans do not facilitate coordination or accountability. The regulation does not prohibit a single plan of service, but it would be extremely helpful to the field if CMS could clarify that this is indeed preferable.

We are puzzled by the requirement that the plan include information on alternate providers of the same service. In almost all communities, the number of providers willing to accept Medicaid reimbursement is small. This reality is even more problematic in rural and frontier areas of the country. Expecting staff responsible for planning to now become familiar with alternate providers is an unreal expectation.

Person-centered planning requires the active participation of the individual. CMS further recommends the involvement of the consumer's family, or other responsible individuals. However, requiring the signature of the client or representative in some rare cases may be problematic. There are two factors to consider.

First, severe mental illness is episodic, and it is not always possible to determine when an exacerbation of the illness may occur. There may be instances in which a person, because of the

symptoms of their illness, may not believe they are sick or comply with the signing the treatment plan, and it is also true, that at this point in the individual's life, retention of services are critical to prevent hospitalization, incarceration, or other public or personal safety consequences. There is also no guarantee that the individual has appointed a representative, or that the consumer in crisis could identify this person. Therefore, CMS should allow for the documentation by the provider who meets state requirements of reasons that the client, or their representative is not able to sign the treatment plan.

Recommendations:

We recommended inclusion of the following requirements regarding the written rehabilitation plan:

- that this plan be written in plain English so that it is understandable to the individual.
- that the plan include an indication of the level of participation of the individual as well as his or her concurrence with the plan. CMS should allow for the documentation by the provider who meets state requirements of reasons that the client, or their representative is not able to sign the treatment plan.
- that the plan of services be based on a strengths-based assessment of needs;
- that the plan include intermediate rehabilitation goals;
- that, as indicated, the plan include provisions for crisis intervention;
- that the plan include individualized anticipated review dates relevant to the anticipated achievement of long-range and intermediate rehabilitation goals;
- substitute for the requirement that the plan list the potential alternate providers of the same service a requirement that the plan include an assurance that the individual has received this information (to the extent the service planning team is aware of all existing providers.

CMS should also clarify that a single treatment and rehabilitation plan is acceptable and encourage a single planning team and service planning meetings.

Section 441.45: Rehabilitative Services

441.45(a)(2)

This section limits rehabilitative services to those furnished for the maximum reduction of physical or mental disability and restoration of the individual to their best possible functional level, as defined in the law. However, it would be helpful to reiterate here when services may be furnished to retain or maintain functioning (see comments above).

It would also be valuable to include the language in the preamble (page 45204) regarding how to determine whether a particular service is a rehabilitation service, based on its purpose.

Recommendation:

Insert additional language into 441.45(a)(2) to describe when services may be furnished with the goal of retaining or maintaining functioning.

Insert additional language into this section (from the preamble) to state that it is helpful to scrutinize the purpose of the service as defined in the care plan in order to determine whether a specific service is a covered rehabilitative benefit.

441.45(b) Non-covered services

This section introduces a whole new concept into Medicaid, one that conflicts with federal statutory requirements. It denies Medicaid coverage for covered services to covered individuals if such services are furnished through another program, including when they are considered "intrinsic elements" of that program. There are many mechanisms that states and localities use to fund mental health services for persons who are uninsured or underinsured. These programs frequently operate on capped appropriations distributed through grants to providers. This is a very different situation from when an individual has other insurance (where the insurer has a contracted legal liability to pay) or when an agency has already received a federal payment to meet a specific need of a particular person (such as through Title IV-E for certain case management services).

There is little clarity in the regulation on how this provision would be applied as the regulation provides no guidance on how to determine whether a service is an "intrinsic element" of another program.

We can see only two situations in which Medicaid might have been paying for services that fall under this test. Either a provider bills Medicaid for a service which is not a Medicaid-covered service – in which case this is a fraud-abuse issue and does not warrant a change in rule for all providers and systems. Or, CMS is concerned that non-medical programs are furnishing Medicaid covered services (and meeting all Medicaid requirements) but have other resources available to them for providing the service (even though these other resources are generally targeted to non-Medicaid individuals). In the latter case, what is the legal basis for denying federal financial participation for the Medicaid-covered individual?

Furthermore, few of the other cited programs have a clear legal obligation to provide these services or have the resources to do so. Without revision, this new rule would conflict with the federal statutory mandate to provide all medically necessary services covered by the state Medicaid plan, and for children, all medically necessary services covered by 42 U.S.C. § 1396d(a). See 42 U.S.C. §§ 1396a(a)(10), 1396?? (1396d(r)). The net result of this new rule will be that Medicaid-eligible individuals will be denied services, both by Medicaid and by the other cited program (due to lack of resources in the other program). Thus, the rule effectively denies them medically necessary Medicaid services, in direct contradiction of the statute.

Recommendation:

We strongly recommend that this entire section be dropped, because it conflicts with the Medicaid statute.

Alternatively, the section should be clarified and narrowed so as to specifically focus on situations where an entity (e.g. an insurer) has a specific legal obligation to pay for the services for the specific Medicaid-covered individual. Programs operated through capped or discretionary appropriations from states or localities should be specifically excluded from this provision.

Some subsections of Section 441.45(b) include language that ensures that children in the other settings that are cited (therapeutic foster care, foster care or child care institutions for a foster child) can nonetheless receive medically-necessary rehabilitation services if those services are provided by qualified Medicaid providers. This phrase should be inserted under paragraph (b)(1) so that it will apply to all of the subsections (i) through (iv).

The preamble states that Medicaid-eligible individuals in other programs are entitled to all rehabilitative services that would have been provided to individuals outside of those other programs. The preamble also makes clear that Medicaid rehabilitative services must be coordinated with services furnished by other programs. The regulation should include this language.

It is especially important that mental health providers be able to work with children and adults with serious mental disorders in all appropriate settings. For children, the school day can be an especially critical time. While classroom aides may not be eligible mental health providers, the presence of a mental health provider in the classroom to address a specific child's functional impairments should be a covered service.

Similarly, a child with a serious mental disorder being reunified with its family may have specific issues directly stemming from the mental disorder. Mental health rehabilitation services to address these problems (as distinct from generic reunification services) should be covered.

To the extent that any of these proposals become final, CMS must work with States to develop implementation timelines that account for legislative review of waivers in states where this is

necessary as well as adequate time for administrative and programmatic changes at both the state and provider agency level. The development of new forms as well as staff training, administrative processes all pose significant challenges at the Agency level. At a minimum, States should be granted a one-year planning and implementation period from the time of approval of the State Plan Amendment by the Agency.

Thank you for the opportunity to comment on the proposed regulation.

Sincerely;

Kumud Aggarwal, MD
Executive Director
Swanson Center

Alliance

of Child Caring Service Providers

2525 East 22nd Street
Cleveland, Ohio 44115
tel 216/696-5800 ext 1132
direct/fax 216/694-7032
Email: gceleste@
applewoodcenters.org

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October 8, 2007

Office of Medicaid and Medicare Services
Department of Health and Human Services
Attn: CMS-2261-P, P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS 2261-P/72 Fed. Reg. 4520, Proposed CMS Rule Regarding Coverage for Rehabilitative Services

To Whom It May Concern:

I write on behalf of the Alliance of Child Caring Service Providers to share questions and concerns regarding CMS's proposed rule for Rehabilitative Services.

As an association of children's behavioral health and child welfare providers, we believe that there is a shared mission between Medicaid and child welfare services to provide not only for the basic safety of children in foster care, but also to improve their overall well-being, including both physical and mental health. As such, it is essential that the federal government continue to allow and adequately fund the use of Medicaid rehabilitative services so that the health care needs of children in foster care are properly addressed. While the majority of the philosophy behind the proposed rule is commendable (i.e. focus on family-centered and early intervention services) and some valuable improvements are made, we have several comments.

Exclusion of Habilitation Services and Need for Clarity of Application of "Rehabilitation" to Children and Adolescents: The proposed rule would exclude federal financial participation (FFP) for habilitation services including those provided to individuals with mental retardation or "related conditions". While the proposed rule clarifies that most physical impairments and mental health and/or substance abuse related disorders are *not* included in the scope of "related conditions" (and therefore, would still be eligible as rehabilitative services), further clarity is needed on how the definition of rehabilitative services applies to children and adolescents, particularly those with serious emotional disturbances. Principles of child and adolescent development are not reflected in the language of the proposed rule. The "restoration of functioning" concept is unclear in how it distinguishes children and youth from adults. Are the ever-changing developmental stages of children taken into account?

Gabriella Celeste
Executive Director

Achievement Centers for Children
Alliance Human Services, Inc.
Applewood Centers, Inc.
Bair Foundation
Beech Brook
Bellefaire J.C.B.
Berea Children's Home
Catholic Charities Services - Parmadale
Center for Families & Children
Children's Community Access Program
Christian Children's Home of Ohio
Cleveland Christian Home, *partner of Community Care Network*
Cleveland Clinic Children's Rehabilitation Hospital
Continue Life, Inc.
Diversion, Inc.
Homes For Kids
House of New Hope
In Focus of Cleveland, Inc.
Lutheran Metropolitan Ministry
National Youth Advocate Program
North East Ohio Health Services
Options for Families & Youth
Pathway Caring For Children
Positive Education Program
Pressley Ridge
Specialized Alternatives for Youth
The Twelve, Inc.
The Village Network

Exclusion of Services Provided to Residents of an Institution for Mental Disease (IMD): The proposed rule would exclude federal financial participation (FFP) for services provided to residents of an institution for mental disease (IMD) who are under the age of 65, including residents of community residential treatment facilities with more than 16 beds. [Proposed Section 441.45(b)(5), pages 34-35] As such, we are very concerned that medically necessary behavioral health services (separate from room and board costs) provided by such community residential facilities to children would not be considered rehabilitative services and therefore would not be reimbursed.

Adoption of an "Intrinsic Elements" Test and the Potential Increased Burden on the Child Welfare System: This section explicitly states that rehabilitation does *not* include services "furnished through a non medical program as either a benefit or administrative activity including services that are intrinsic to elements of programs other than Medicaid, such as foster care, child welfare, education, child care…juvenile justice." [Proposed Section 441.45(b)(1)] While no definition or guidance is offered as to what "intrinsic to" means, whatever services that are deemed "intrinsic to" programs other than Medicaid would simply *not* be eligible for payment under Medicaid. Individuals in other programs (such as foster care, family preservation and reunification services, and adoption) would still be technically eligible to receive rehabilitative services, but without federal financial participation from Medicaid, access to such services would surely be impacted.

While it is helpful to clarify what is covered by Medicaid and what is covered by other federal programs and we appreciate the importance of rectifying any improper reliance on Medicaid, the proposed regulation and its "intrinsic to" test does not properly consider the child welfare system given the immense challenges it faces in serving vulnerable children. The child welfare system is required to ensure that the children in their care get the services they need, including medical (physical and dental) and mental health. Most children that come into the child welfare system have experienced some level of trauma which is often compounded by their removal from their home. These children have significant needs that require supportive services in order to recover. Both the Medicaid and child welfare systems seek to and must ensure the provision of medically necessary services, but child welfare agencies should not be required to shoulder the load alone. If Medicaid is not there to assist, what will be done to infuse greater dollars into the mental health system so that the services that are needed are being provided and available?

Written Rehabilitation Plan Requirement: The section enumerates seventeen specific requirements that the written plan would have to meet. [Proposed Section 440.130(d)(3)] While the requirement for the written rehabilitation plan that will guide the services to be delivered makes sense, it does not take into account that the child/adult potentially has other existing plans. It does not discuss if and how the written rehab plan would be coordinated with other existing plans so that the

child's needs may be appropriately and efficiently addressed. As such, it could create additional burdens on all concerned. By requiring input from the individual, the individual's family, the individual's authorized health care decision maker and/or persons of the individual's choosing up front, everyone's voice is heard and a true person- and family-centered approach is pursued. However, for a child in foster care, under state custody receiving rehabilitative services, who has the authority to choose and who should be involved in the decision-making process? What happens when the family is not accessible or chooses not to participate? What is the standard that providers will be held to (i.e. will documented *reasonable attempts* to involve listed persons fulfill the requirement)?

Finally, this proposed rule reflects a federal policy that has a couple of troubling, and perhaps unintended consequences which we want to bring to your attention: a turning away from evidence-based and proven effective practices ("bundled services" are at the core of proven-effective treatments such as multi-systemic therapy, assertive community treatment teams and therapeutic foster care), and cost-shifting administrative and financial burdens to the state and local level which, without proper infrastructure and assistance for program administrators up front, will likely result in less access to services for those in need.

Thank you for the opportunity to provide input – we appreciate your consideration of our comments. Please contact me at 216-694-7032 or gceleste@applewoodcenters.org if you require any further information or if there is any future information or responses regarding this proposed regulation.

Sincerely,

Gabriella Celeste
Executive Director
Alliance of Child Caring Service Providers
2525 East 22nd Street
Cleveland, Ohio 44115

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Centers for Medicare & Medicaid Services
Department of Health & Human Services
P.O. Box 8018, Baltimore, MD 2144-8018.

ATTENTION: CMS-2261-P

To Whom It May Concern:

On August 13th, CMS published rules narrowing what would be allowed for billing under (Medicaid Rehab Option) MRO rules. From my point of view, there are some improvements contained in those proposed regulations, and yet two areas of those regulations are particularly worrisome. The most positive aspect of the proposed rule changes has to do with the increased involvement of the consumer and their family in the treatment planning process. This will guarantee a strong partnership strategy. With this improvement, however, provisions need to be made for those instances when there is forced treatment.

The first area of concern has to do with services Medicaid labels as "intrinsic elements of programs other than Medicaid". (Federal Register, Vol. 72. No, 155, page 45205). With these restrictions, CMS is stating that Medicaid will not pay for mental health services provided as a part of other programs or systems.

This practice is currently widespread around the country and in Indiana. Up until the last 12 months, Indiana FSSA Secretary Mitch Roob frequently advocated that Mental Health Centers partner with Child Welfare providers to provide some of the services to the Child Welfare system through MRO. Park Center formed two such partnerships, and through these partnerships was able to bring more federal dollars into those programs. Mental health treatment services are now being provided in those locations as a part of their programs. CMS is now proposing that such practices are no longer acceptable. While I don't have strong feelings if that is a good thing or a bad thing, it will have a tremendous impact on Counties, as various providers look to County Councils to make up the funding gaps. If CMS decides to proceed with the rules as written, it is very important that a delayed implementation is put into place. This change will have a profound impact, and Counties will need to increase their taxes in order to take this increased financial burden.

The second area of concern I have is related to acute vs. chronic care. The proposed MRO regulations exclude maintenance care in the community. While most of Park Center's care to adults is for those individual who are still making improvements, we serve a significant number of adults who have spent years in

State Hospitals. We provide them medications each day, and lots of wrap around services either in Group Homes or through ACT services in the community. The narrowed regulations would disallow services to those more chronic clients. This would reduce Park Center's revenue by at least $2 million. While this second concern does not immediately impact the Counties, it will result in programs closing, and more individuals in jails or on the streets.

Clearly, states across the country have cost shifted much of the cost burdens for mental health services to the federal government. Obviously, the federal government is now trying to shift some of that back. Foremost, I would request that the narrowed regulations are not implemented. If they are, it will lead to vastly reduced mental health care in the community. However, if the new rules are implemented, I would request that there is a reasonable lead time so program closures and other transitions can happen as smoothly as possible.

Thank you for your consideration.

Paul Wilson, MSSW, MHA
President and CEO
Park Center
260-481-2721

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STATE OF NEW HAMPSHIRE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DIVISION OF COMMUNITY BASED CARE SERVICES

129 PLEASANT STREET, CONCORD, NH 03301
603-271-8560 1-800-852-3345 Ext. 8560
Fax: 603-271-4912 TDD Access: 1-800-735-2964

Nicholas A. Toumpas
Acting Commissioner

Nancy L. Rollins
Director

October 8, 2007

Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-2261-P
P.O. Box 8018
Baltimore, Maryland 21244-8018

To Whom It May Concern:

State of New Hampshire
Comments on Coverage for Rehabilitative Services Proposed Rules
42 CFR Parts 440 and 441
CMS-2261-P

Non-covered services: 441.45(b)

This section introduces a whole new concept into Medicaid, one that conflicts with federal statutory requirements. It denies Medicaid coverage for covered services to covered individuals if such services are furnished through another program, including when they are considered "intrinsic elements" of that program. There is little clarity in the regulation on how this provision would be applied, as the regulation provides no guidance on how to determine whether a service is an "intrinsic element" of another program.

There appear to be only two situations in which Medicaid might have been paying for services that fall under this test. Either a provider bills Medicaid for a service which is not a Medicaid-covered service B, in which case this is a fraud-abuse issue and does not warrant a change in rule for all providers and systems. Or CMS is concerned that non-medical programs are furnishing Medicaid-covered services (and meeting all Medicaid requirements) but have other resources available to them for providing the service (even though these other resources are generally targeted to non-Medicaid individuals). In the latter case, what is the legal basis for denying federal financial participation for the Medicaid-covered individual?

Furthermore, few of the other cited programs have a clear legal obligation to provide these services or have the resources to do so. Without revision, this new rule would conflict with the federal statutory mandate to provide all medically necessary services covered by the state Medicaid plan, and for children, all medically necessary services covered by 42 U.S.C. § 1396d(a). See 42 U.S.C. §§ 1396a(a)(10), 1396d(r). The net result of this new rule will be that Medicaid-eligible individuals will be denied services, both by Medicaid and by the other cited program (due to lack of resources in the

other program). Thus, the rule effectively denies them medically necessary Medicaid services, in direct contradiction of the statute.

New Hampshire is concerned that children in foster care, child welfare, and juvenile justice (juveniles that are not placed in secure detention or wilderness facilities) may be unfairly restricted from receiving medically necessary rehabilitative services for the sole reason that these children are involved with foster care, child welfare or juvenile justice systems. The proposed rule does not define "intrinsic elements of programs other than Medicaid." The Code of Federal Regulations at 1356.60 Fiscal Requirements (Title IV-E) specifically prohibit States from claiming Title IV-E federal financial participation (FFP) for medical or rehabilitative services as "Allowable administrative costs do not include the costs of social services provided to the child, the child's family or foster family which provide counseling or treatment to ameliorate or remedy personal problems, behaviors or home conditions." In addition, the Child Welfare Policy Manual at 8.1B Title IV-E Administrative Functions/Costs, Allowable Costs – Foster Care Maintenance Payments Program in the answer under Question #1 further clarifies by stating "Examples of non-reimbursable services include counseling, homemaker or housing services and assisting in reuniting families. These services are not reimbursable regardless of the credentials or training of the provider, e.g. these services provided by a caseworker are unallowable. Further, they are not reimbursable regardless of whether they are provided on a single occasion or as part of a series." Further in the same section of the Child Welfare Policy Manual under Question #4 it is stated "In accordance with sections 474(a)(3) and 475 (4) of the Social Security Act and 45 CFR 1356.60 (c), administrative costs for the processing and management of health care services for foster children under Title IV-E are not allowable." Section 475(4) of the Social Security Act defines the term "foster care maintenance payments" as "payments to cover the cost of (and cost of providing) food, clothing, shelter, daily supervision, school supplies, a child's personal incidentals, liability insurance with respect to a child and reasonable travel to the child's home for visitation." Clearly the major funding source for child welfare outside of Medicaid is Title IV-E, which strictly prohibits payment for medical, or social services provided to children in foster care, child welfare or juvenile justice.

Recommendation:

New Hampshire strongly recommends that this entire section be dropped, because it conflicts with the Medicaid statute.

Alternatively, the section should be clarified and narrowed so as to focus on situations where an entity (e.g. an insurer) has a specific legal obligation to pay for the services for the specific Medicaid-covered individual. Programs operated through capped or discretionary appropriations from states or localities should be specifically excluded from this provision.

The preamble states that Medicaid-eligible individuals in programs run by other agencies are entitled to any rehabilitative service that would have been provided to individuals outside of those other programs. The preamble also makes clear that Medicaid rehabilitative services must be coordinated with services furnished by other programs. The regulation should include this language.

It is especially important that mental health providers be able to work with children and adults with serious mental disorders in all appropriate settings. For children, the school day can be an especially critical time. While classroom aides may not be eligible mental health providers, the presence of a mental health provider in the classroom to address a specific child's functional impairments should be a covered service.

Similarly, a child with a serious mental disorder being reunified with its family may have specific issues directly stemming from the mental disorder. Mental health rehabilitation services to address these problems (as distinct from generic reunification services) should be covered.

New Hampshire recommends that the Final Rule clearly state that children in foster care, child welfare or juvenile justice are entitled to receive medically necessary rehabilitative services and that such children are not prohibited from receiving rehabilitative services based on the sole fact that they are involved in the foster care, child welfare or juvenile justice systems.

Therapeutic Foster Care: 441.45(b)(1)(i)-

The regulation denies payment for therapeutic foster care as a single program, requiring instead that each component part be separately billed.

Therapeutic foster care is the least restrictive out-of-home placement for a child with a serious mental disorder. Therapeutic foster care is a widely covered evidence-based practice with more than half a dozen controlled clinical trials demonstrating improved outcomes (see the Report on Mental Health from the U.S. Surgeon General). The alternative for most such children would be immediate placement in an institutional setting, such as a residential treatment program or psychiatric hospital, at significantly higher expense.

If states are not able to create a package of covered services such as therapeutic foster care and pay on that basis, this will result in inefficiencies and raise administrative costs.

Recommendation:

Therapeutic foster care should be listed as a covered rehabilitation service for children with serious mental disorders at imminent risk of placement in a residential treatment facility. States should be given the discretion to define therapeutic foster care as a single service and pay through a case rate, daily rate or other appropriate mechanism.

Language should also be included in 441.45(b)(1)(i) to clarify that any covered rehabilitation service may always be furnished by mental health rehabilitation providers to children in therapeutic foster care.

Rehabilitative Services: 441.45(a)(2)-

This section limits rehabilitative services to those furnished for the maximum reduction of physical or mental disability and restoration of the individual to the best possible functional level, as defined in the law. However, it would be helpful to reiterate here when services may be furnished to retain or maintain functioning.

It would also be valuable to include the language now in the preamble (page 45204) regarding how to determine whether a particular service is a rehabilitation service, based on its purpose.

Recommendation:

Insert additional language into 441.45(a)(2) to describe when services may be furnished with the goal of retaining or maintaining functioning.

Insert additional language into this section (from the preamble) to state that it is helpful to scrutinize

the purpose of the service as defined in the care plan in order to determine whether a specific service is a covered rehabilitative benefit.

Definition of Restorative Services: 440.130(d)(1)(vi)-

This definition stipulates that restorative services are those that enable an individual to perform a function, and that the individual does not have to have actually performed the function in the past. This language is critical, as loss of function may have occurred long before restorative services are provided. This would be particularly true for children, as some functions may not have been possible (or age-appropriate) at an earlier date. The regulation needs modification to make the meaning of this section clearer.

This definition also includes as appropriate rehabilitation services designed to maintain current level of functioning but only when necessary to help an individual achieve rehabilitation goal. While rehabilitation services should not be custodial, for people with serious mental or emotional disabilities, continuation of rehabilitative services is at times essential to retain their functional level. Failure to provide a supportive level of rehabilitation would result in deterioration, necessitating a reinstatement of intensive services. There is concern that states and providers will interpret the current proposed regulation as prohibiting coverage of services necessary for retention of improved functioning and for maintaining the highest possible functional level, leading individuals to deteriorate to the point where they will be eligible for services. This serves no one's interest.

Section 1901 of the statute specifically authorizes funds for "rehabilitation and other services" to help individuals "retain" capability for independence and self-care. This provides authority for CMS to allow states to furnish services that will maintain an individual's functional level.

New Hampshire has concern with the above language, as children's developmental issues must be considered when determining whether a service is "habilitation" or "rehabilitation." It is well documented in various studies that children in placement suffer from developmental delays in much greater numbers than children who are not in the foster care system as a result of the neglect or abuse that brought them into the foster care system. These same children, had they not experienced the neglect or abuses, may never have experienced such developmental delays. Insisting that there be a black and white distinguishing of medically necessary services as either "habilitation" or "rehabilitation" based on whether or not the medical services will restore a child to their best functional level or help a child to acquire new functional abilities will increase an already extensive administrative burden in providing children with rehabilitation services as a result of the requirements contained in this proposed rule.

Recommendation:

Further clarify that a child need not demonstrate that he or she was once capable of performing a specific task in the past if it was not possible or age-appropriate for the child to have done so. Specifically, the language should state that restorative services include services to enable a child to achieve age-appropriate growth and development and that it is not necessary that the child actually performed the activity in the past. (Note, this phrasing is taken from current CMS regulation of managed care plans at 42CFR 438.210(a)(4)(ii)(B)). An example of a child who was developmentally on track to perform a function, but did not because it was not yet age-appropriate would be helpful. Currently, the regulation only has an example of an adult.

Second, revise the definition of when services may be furnished to maintain functioning to include as an acceptable goal of a rehabilitation plan the retaining of functional level for individuals who can be expected to otherwise deteriorate.

Related Medicaid Rehabilitation Issues:

1) Payment and Accounting for Services

Although not specifically described in this regulation, recent CMS insistence on accounting and billing for services through 15-minute increments and denying payment through daily rates, case rates and similar arrangements is supported by language in the regulation, at least by inference.

These new shifts in rate-setting methodology are not efficient and, moreover, are extremely detrimental to the provision of the evidence-based mental health services that are increasingly being offered as a package of intertwined interventions delivered flexibly. These services include assertive community treatment, multisystemic therapy, day rehabilitation services, therapeutic foster care and others.

There are alternative ways to hold states accountable for ensuring that non-covered activities are not reimbursed. For example, it is possible to devise rate structures that do not pay providers for time spent on non-covered activities, but that remove the currently imposed extreme administrative burden.

The requirements in this regulation regarding service planning and documentation are relevant here. The new rules should negate the need for overly prescriptive micro-management of Medicaid providers.

Recommendation:

It is strongly urged that CMS work with other federal agencies, states and the field to devise payment methodologies that support the best practice and the most successful outcomes for children and adults with mental disorders. Recent announcements about limiting payment to single fees for single activities and interventions should be withdrawn.

2) EPSDT Mandate

The regulation appears to ignore the Title XIX mandate that children under age 21 are eligible for all federal Medicaid-covered services, regardless of whether that service is defined in the state plan or covered for adults. In several places, the regulation needs to be amended to reflect the EPSDT provision.

Recommendation:

Section 441.45(a), insert a new paragraph clearly stating that states must ensure that children receive all federally covered Medicaid rehabilitation services when medically necessary to correct or ameliorate a physical or mental illness or condition.

Section 441.45(b) (4), which refers to services having to be targeted under the state's plan, should be amended to reference EPSDT for children.

Section 441.45(a)(5) should clarify that even when the state plan does not include certain rehabilitative services, these services must nonetheless be made available to children when medically necessary.

Sincerely,

Nancy L. Rollins
Director, Division of Community
Based Care Services

Cc: The Honorable John H. Lynch, Governor of New Hampshire
The Honorable Judd Gregg, U.S. Senate
The Honorable John E. Sununu, U.S. Senate
The Honorable Carol Shea-Porter, U.S. House of Representatives
The Honorable Paul W. Hodes, U.S. House of Representatives
The Honorable Sylvia Larsen, President of the N.H. Senate
The Honorable Terie Norelli, Speaker of the N.H. House of Representatives
The Honorable Lou D'Allesandro, Chair, N.H. Senate Finance Committee
The Honorable Marjorie Smith, Chair, N.H. House of Representatives Finance Committee
The Honorable Iris W. Estabrook, Chair, N.H. Senate Health and Human Services Committee and, N.H. Senate Education Committee
The Honorable Cindy Rosenwald, Chair, N.H. House of Representatives, Health and Human Services Committee
The Honorable Emma Rous, Chair, N.H. House of Representatives Education Committee

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Amy Gleason
Riverside Industries, Inc.
One Cottage Street
Easthampton, Ma. 01027

October 9, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-2261-P
P.O. Box 8018
Baltimore, MD. 21244-8018

RE: File Code CMS-2261-P

To Whom It May Concern:

I am writing to comment on the notice of proposed rulemaking (NPRM) with respect to Medicaid coverage of rehabilitative services that was published in the Federal Register on August 13, 2007. I am writing on behalf of Riverside Industries, Inc. in Easthampton, Massachusetts, a non-profit organization that supports individuals with developmental disabilities in both day habilitation and employment.

Riverside exists to serve people with perceived limitations and typical ambitions. We encourage those we serve to be participating members of their communities. We ensure that people maximize their abilities through therapeutic options. Riverside Industries has a history of over three decades of providing quality services. Our day habilitation has doubled in size over the last ten years, where we now serve 95 individuals. These individuals receive comprehensive individualized services Monday through Friday 9:00 – 3:00.

The positive impact for people who attend our day habilitation is hugely significant and repeatedly conveyed to us via satisfaction surveys and other forms of regular communication. Providing a variety of clinical consults as well as some direct therapies enables us to give people the opportunity to develop skills as well as gives people a sense of independence and self-esteem. Being able to get out of a wheelchair and walk using adaptive equipment, utilizing an augmentative communication device to express yourself, given the opportunity to feed yourself with the assistance you need, and learning to control your emotions in order to adapt to the many demands of everyday life are some examples of ways people have benefitted from our day habilitation services.

We strongly oppose the provisions related to excluded federal financial participation (FFP) for habilitation services, and urge you to withdraw this proposed rule.

The proposed rule would be detrimental to people with developmental disabilities in two ways: it would eliminate established programs that provide day habilitation services and it would impose discriminatory exclusion from receiving many rehabilitation services for people with mental retardation and other related conditions.

The proposed rule does not specify which day habilitation services a state may cover and we believe the prohibition on habilitation services of the Social Security Act exceeds the regular authority granted by Congress. We agree with the Secretary that state programs operated under the rehab and clinic options should set high standards for delivering active treatment and for innovating to develop programs for people with developmental disabilities that maximize their abilities to attain, maintain, and retain their maximum ability to function, consistent with the original conception for rehabilitation, as found in section 1901 of the Social Security Act.

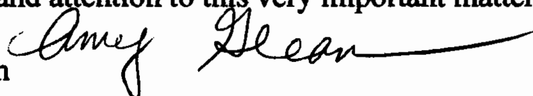
We believe that states should have flexibility to continue operating habilitation programs under the longstanding state plan options.The disability community opposed aspects of section 1915 (i) in the Deficit Reduction Act that permit enrollment caps and do not extend an entitlement to services. Nonetheless, this option was intended to give states added flexibility and was not intended to supplant the rehab and clinic options by requiring states to shift to more restrictive coverage authorities. It should also be noted that the 1915 (c) waiver programs are known for having long and large waiting lists.

We strongly recommend that the proposed exclusion of FFP for habilitation services under the clinic and rehab options not be implemented.

As far as the discriminatory and arbitrary exclusion from receiving many rehabilitation services for people with mental retardation and related conditions: We strongly oppose the proposed rule's definition of habilitation services [see section 441.45(b)(2)] as including "services provided to individuals with mental retardation and related conditions." This population exclusion violates a fundamental principle of Medicaid, that medical assistance be provided to one Medicaid beneficiary shall not be less in amount, duration, and scope than the medical assistance made available to any other Medicaid beneficiary {see section 1902 (a) 10(B) of the Social Security Act}.

We urge the Secretary to rescind this constraint on rehab options that is so blatantly stigmatizing and discriminatory to people with developmental disabilities.

Thank you for your time and attention to this very important matter.



Amy Gleason
Director, Day Habilitation
Riverside Industries, Inc.

2261-P 75

October 8, 2003

530 Kent St.
Chestertown, MD 21620

Many in this area are extremely concerned that Federal Government discussions of changes in mental health community services (cuts) would have a very damaging impact on services offered in this area.

Our own family and many others have benefitted from the skilled care of the Crossroads Program at the Chestertown, MD and Centreville, MD locations.

It is our sincere hope that this institution continue to receive financial support.

Sincerely,
W. Robert and
Margaret Fallaw

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Thomas Lerchen, President

Dohn Hoyle, Executive Director

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-2261-p
P.O. Box 8018
Baltimore, MD 21244-8018

Re: File Code CMS-2261-P

To Whom is May Concern:

On behalf of our 35 local chapters and our many thousands of members,
We are commenting on the notice of proposed rule making (NPRM) regarding Medicaid coverage of rehabilitation services publishes on 8/13/07 in the Federal Register.

The Arc Michigan has as its mission, "Empowering our local chapters to assure that persons with developmental disabilities are fully included and are contributing members of their communities." To achieve this end, habilitation services are imperative. We strongly oppose the discrimination against persons with developmental disabilities which results from the removal of habilitation services from Medicaid coverage under the rehabilitation and clinic options.

The therapeutic services which have been provided under this option in Michigan have assisted a great many individuals to move from large congregate settings to their communities and to "get a life." This proposed arbitrary exclusion of persons with developmental disabilities is harmful to our effort and to Michigan being a leader in this field.

We also vehemently disagree that waivers under Section 191 (c) or the Home and Community-Based Services State Plan option under Section 1915 (i) could be equivalent or appropriate substitutes. These options would significantly limit the number of person eligible by removing coverage under the core State Plan and make the services discretionary.

We fervently hope that the proposed end to Federal Financial Participation for habilitation services, under the clinic and rehabilitation option, will not be implemented. The Secretary should rescind these proposed rules.

Sincerely,

Dohn Hoyle
Executive Director
The Arc Michigan
1325 S. Washington Ave.
Lansing, MI 48910

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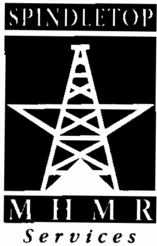

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Affirmative Action Employer

October 8, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS-2261-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: File Code CMS-2261-P. Proposed Regulations on Coverage for Rehabilitative Services

Dear Sir or Madam:

I am the Chief Executive Officer of Spindletop MHMR Services and am grateful for the opportunity to comment on the proposed rules regarding coverage for rehabilitative services under the Medicaid program.

We are a large Community Mental Health Center that provides comprehensive community based services to individuals living with serious mental illnesses and their families. Many of our clients have personally experienced the effectiveness of rehabilitation services and have been able to live, work and participate in their communities as a direct result of these services.

Research confirms that individuals with serious mental illnesses who receive rehabilitation services achieve better outcomes, such as stable housing and employment. They also experience fewer hospitalizations and less involvement with the criminal justice system. I have over 27 years experience providing services under the Rehab option in two states and I know how effective these services can be. Yet, despite these well documented findings, these services remain out of reach for the vast majority of individuals with mental illnesses and their families.

I am writing to express the concern of my organization about regulatory changes being developed by the Centers for Medicare and Medicaid Services (CMS) that are likely to narrow the scope of rehabilitation services covered by Medicaid.

This letter will supplement the formal response filed by the National Council of Community Behavioral Health Care of which this center is a member.

The rehab option in the Medicaid program is widely used by Texas to fund community-based mental health services. In fact, this option is most commonly used to underwrite mental health services including community-living skills training, medication management, crisis services, day programs and employment related services.

For this reason, we are particularly concerned that any new regulations governing rehabilitation services facilitate the provision of these services and in no way discourage systems and providers from increasing the availability of these critical services. Many of my peers are very troubled by the estimate in the proposed regulation that these rules would remove 2.2 billion dollars from an already under-resourced service system.

I urge you to refrain from any regulatory activity that either narrows the definition of reimbursable services under the rehabilitation option or lessens Medicaid reimbursement for rehabilitation services.

Sincerely,

N. Charles Harris, Ph.D.
Chief Executive Officer
Spindletop MHMR Services
Beaumont, Texas

cc: Joe Lovelace

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The Arc

Of Schuyler County

James E. Wilson,
Executive Director

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Fax: 607-535-2666

www.arcofschuyler.org

Chapter NYSARC, Inc.
United Way Agency

October 8, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS-2261-P
PO Box 8018
Baltimore, MD 21244-8018

Re: File Code CMS-2261-P

To Whom It May Concern:

We are writing to comment on the notice of proposed rulemaking (NPRM) with respect to Medicaid coverage of rehabilitative services that was published in the Federal Register on August 13, 2007. We are commenting on the impact of the proposed rule on people with intellectual and other developmental disabilities and access to habilitation services. These comments are submitted on behalf of The Arc of Schuyler. Our not for profit organization provides a variety of supports and services for individuals with intellectual and other developmental disabilities in New York State, including Schuyler and contiguous counties. Within the 30 years of providing services, we have seen first hand the dramatic improvement that occurs in a person's life when they are able to access habilitative and rehabilitative services in their community. These are vital supports that directly impact a person's independent living development, behavior development, communication development and sensorimotor development. Individuals with developmental disabilities and their families would be devastated if these services were no longer available. We strongly oppose the provisions related to excluding federal financial participation (FFP) for habilitation services. We urge you to withdraw this proposed rule.

The proposed rule would severely harm people with intellectual and other developmental disabilities in two major ways: (1) it eliminates longstanding programs for providing day habilitation services to people with developmental disabilities, and (2) it imposes a discriminatory and arbitrary exclusion from receiving many rehabilitative services for people with intellectual disabilities/mental retardation and related conditions.

We believe that this proposed restriction violates the intent of the Congress to protect access to day habilitation services for people with developmental disabilities when it enacted Section 6411(g) of the Omnibus Budget Reconciliation Act of 1989, P.L. 101-239 (OBRA '89). In enacting this provision of law, the Congress was clearly intending to protect access to day habilitation programs for people with intellectual disabilities/mental retardation and related conditions. It establishes that the Secretary may not deny federal financial participation (FFP) for habilitation services unless the Secretary promulgates a final regulation that "specifies the types of day habilitation and related services that a State may cover...on behalf of persons with mental retardation or with related conditions."

In contradiction to the plain language of Section 6411(g) of OBRA '89, the proposed rule does not specify which day habilitation services that a state may cover. Instead, the proposed regulation would prohibit provision of any habilitation services under

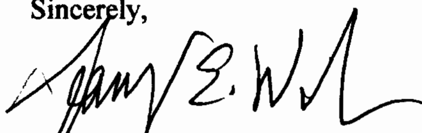
paragraphs (9) and (13) of section 1905(a) of the Social Security Act. We believe that this NPRM exceeds the regulatory authority granted by the Congress and must be withdrawn.

We also believe this is a discriminatory and arbitrary exclusion from receiving rehabilitative services for people with mental retardation and related conditions. We strongly oppose the proposed rule's definition of habilitation services [see Section 441.45(b) (2)] as including "services provided to individuals with mental retardation and related conditions." Coupled with the prohibition on habilitation services, this effectively excludes a population from services in violation of a fundamental principle of Medicaid, that medical assistance provided to one Medicaid beneficiary shall not be less in amount, duration, and scope than the medical assistance made available to any other Medicaid beneficiary [see Section 1902(a)(10(B) of the Social Security Act].

We urge the Secretary to rescind this constraint on rehabilitative and clinic option services that is so blatantly stigmatizing and discriminatory to people with intellectual and other developmental disabilities.

Thank you for your attention to this important matter.

Sincerely,



James E. Wilson
Executive Director

mj

Enclosure

cc: Congressman Randy Kuhl

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Carolinas Rehabilitation

October 9, 2007

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-2261—P
Mail Stop C4—26—05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attn: CMS—2261--P
Medicaid Program; Coverage for Rehabilitation Services

Dear Sir/Madam:

On behalf of Carolinas Rehabilitation, I would like to submit comments to the Centers for Medicare and Medicaid Services (CMS) on its Medicaid proposed rule on rehabilitation services published in the August 13th *Federal Register.* The changes proposed in this regulation would have a negative impact on our hospital and the children we serve. We ask that you make necessary changes to the proposed rule to ensure that children with special health care needs continue to receive critical rehabilitation services.

Medicaid is the single largest payer for children's hospitals and the single largest insurer for children. Children's hospitals devote more than half of their care to children insured by Medicaid and more than three-fourths of their care to children with chronic or congenital conditions. At Carolinas Rehabilitation, 50% of our patients are insured by Medicaid and 100% of them have serious and complex health care conditions. More than one-fourth of all children and one-third of all children with disabilities are insured by Medicaid. The rehabilitation service category has ensured that children in our state with chronic conditions have access to an array of physical and mental health services required for their conditions.

Comments on Proposed Rule on Medicaid GME

Although Medicaid is the major insurer for children and in particular children with disabilities, the proposed regulation fails to consider how the changes would affect the children our hospital cares for every day. Children admitted to our hospital have fallen victim to traumatic injuries as a result of traumatic accidents, child abuse and congenital conditions. Over 50% of our patients have suffered a life altering and permanent brain injury or spinal cord injury. These complex injuries require an expert team of professionals to help both patient and parents through the rehabilitation process and prepare them for the challenges they face for the rest of their lives. These children face

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a life of not only physical and emotional challenges, but a host of complex medical issues that require continued care from medical/health professionals. The proposed regulation does not acknowledge the unique needs of these very vulnerable children, but attempts to make broad policy for all groups without considering how it could specifically affect children.
Carolinas Rehabilitation's largest concern with the proposed rule is that it threatens the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit for children. EPSDT guarantees that children insured by Medicaid receive all medically necessary services as determined by their health care provider. Absent a clarification that children would not be affected because of EPSDT, the proposed rule would limit the definition of rehabilitation services and therefore threaten the health care of children. N.A.C.H. recommends that CMS add language into the regulation to clarify that children will continue to receive all medically necessary care, including all necessary rehabilitation services, as required by EPSDT.

Our hospital also has the following specific objections to the rule:

- **The proposed regulation asserts that rehabilitation services would not include services that are "intrinsic elements" of programs other than Medicaid, such as foster care, child welfare, education, and child care.** Since many of the programs highlighted in the regulation focus on children, this would have a disproportionate impact on children, specifically children in foster care or receiving other social or educational services. The regulation does not provide the criteria for what constitutes an "intrinsic element" of another program. Traditionally, Medicaid has worked closely with a multitude of programs to ensure that children get the services that they need. This new requirement would not allow federal match for services that are determined to be part of another program. Due to a lack of resources, the other programs will not be able to pay for these services without Medicaid as a partner.

  We recommend that this requirement be removed from the regulation. In order to implement such a change, the U.S. Department of Health and Human Services would need to identify other funding sources that would be able to sustain services without federal Medicaid funding. Most of the programs specified in the regulation would not have adequate resources to provide the needed services without additional funding. The result would be children not receiving medically necessary physical and mental health services.

- **The regulation does not clearly state that rehabilitation services could be provided to retain or maintain function.** In many cases, children with neuromuscular conditions, such as spina bifida or muscular dystrophy, and those with serious hearing problems or development delays require rehabilitation services that help them retain or maintain a certain function level. Many of these children would experience deterioration of their conditions without rehabilitation services.

  The preamble to the regulation does state that services could be provided to retain or maintain function if necessary to help an individual achieve a certain rehabilitation goal

as outlined in their rehabilitation plan. The regulation does not include any details on what constitutes a rehabilitation goal.

Carolinas Rehabilitation recommends adding regulatory language to clarify that rehabilitation services would include services needed to retain or maintain function. In addition, we would suggest that CMS add a definition of a rehabilitation goal for children that would include retaining or maintaining function.

- In the preamble to the regulation, CMS says that rehabilitation focuses on restoring individuals to their best functional levels. This requirement would be particularly troublesome for children because some functions may not have been possible (or age appropriate) at an earlier date. Once again, the proposed regulation fails to recognize that children have unique needs that need to be addressed.

  We recommend adding language to specify that children need not demonstrate that they were once capable of performing a specific task in the past if it was not age appropriate for the children to have done so.

We appreciate the opportunity to present our comments and would be pleased to discuss them further. For additional information, please contact me at 704-355-4370 or Robert.Larrison@carolinashealthcare.org. Thank you for your consideration.

Sincerely,

Robert G. Larrison, Jr., FACHE
Assistant Vice President

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South Carolina Association of Children's Homes and Family Services

October 10, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-2261-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD21244-1850

Re: CMS 2261-P; Comments on Proposed Rule *Medicaid Program; Coverage for Rehabilitative Services*

To Whom it May Concern,

The South Carolina Association of Children's Homes and Family Services (SCACHFS) represents 52 child- and family-serving member agencies across the state of South Carolina. We present these comments on the Proposed Rule for the Medicaid Program's Coverage of Rehabilitative Services (CMS-2261-P) published in the Federal Register on August 13, 2007 (72 Fed. Reg. 45201).

SCACHFS believes that CMS is well intended and its goal is to make the Medicaid program more efficient and effective. The general intent of this rule is to make rehabilitative services more person-centered and focused on positive, effective outcomes. It is our opinion, however, that these regulations may greatly restrict access to vital community-based services for the population of children that our agencies serve - children who are involved with the child welfare system and in our nation's foster care system.

In addition, SCACHFS is troubled by the Regulatory Impact Analysis's certification that CMS-2261-P "would not have a direct impact on providers of rehabilitative services that furnish services pursuant to section 1905(a)(13) of the Act." It is difficult to imagine that such sweeping regulatory changes would have no impact on providers.

It appears that CMS is admitting that they do not know that true impact of these regulations as they state "we do not know nor can we predict the manner in which states would adjust or respond to the provisions of this rule." States have always regarded Medicaid as a federal-state partnership, providing health care for those deemed eligible, including children in foster care, and we fear the result if such a substantial amount of Federal funding is withdrawn.

National statistics indicate that over a half million children are in out-of-home care. In South Carolina, member agencies of the SCACHFS serve over 13,000 children per year. Approximately 10-15% of these children have a diagnosis of mental illness. Research has

133 Powell Drive, Lexington, SC 29072 • Phone (803) 996-5437 • FAX (803) 996-5438 • scachfs@sc.rr.com • www.SCChildandFamily.org

confirmed that many children who enter the foster care system are at an extremely high risk for both physical and mental health issues as a result of biological factors and/or the maltreatment.

On behalf of our membership, SCACHFS sincerely appreciates the opportunity to comment on this proposed regulation. We look forward to working with you to ensure that the best policies are put in place for our nation's children.

PROVISIONS OF PROPOSED RULE:

Section 440.130: Diagnostic, screening, preventative, and rehabilitative services

440.130(d)(1)(iii), Qualified providers of rehabilitative services: We agree with CMS that providers of rehabilitative services must be adequately prepared to deliver services, but we urge that States be granted the latitude necessary to ensure that services would not be restricted as a result. For instance, States' recognition of therapeutic foster parents as qualified providers should remain untouched.

440.130(d)(1)(v), Rehabilitation plan: The requirement for a written rehabilitation plan will help ensure accountability, but the plans must be flexible enough to reflect the current functional level, developmental stage and emotional level of the child. Providers therefore should be granted ample flexibility to adjust children's rehabilitation plans in the form of crisis planning so that prior steps forward are not negated.

In regards to the plan needing to be developed with input from "the individual, individual's family, the individual's authorized decision maker and/or of the individual's choosing," We agree in theory with the person- and family-centered approach taken, but we must remind CMS that children involved with the child welfare and foster care systems frequently come from totally dysfunctional families who are not able to participate in the planning for their child's mental or physical health needs. Similarly, much of this population has limited contact with certain members of their family, so we urge language be added to ensure that "family" is broadly interpreted to include guardians and/or caregivers responsible for the child's wellbeing (including, but not limited to, foster parents, kinship caregivers, and group or residential care staff).

440.130(d)(1)(vi), Restorative services: Restorative services and thus covered rehabilitative services, under the proposed definition, are contingent upon the individual having experienced a functional loss and having had the *ability* to perform the function in the past (and not necessarily having actually performed it). This definition will not work for children and their special circumstances. Children may not have been able to perform some function in the past because it was not age-appropriate. Restorative and rehabilitative services must be available to allow that child to reach appropriate developmental milestones..

SCACHFS agrees that rehabilitative services' goal is not just to maintain functioning, but to move the individual toward recovery. It is difficult, however, to continue the individual—in our case a vulnerable child or youth—on the path towards *meaningful* recovery if at the moment the originally stated goal is met, services and accompanying funds are withdrawn. Maintaining

functioning should be a permissible goal under the rehabilitation plan if the child/youth's would otherwise deteriorate.

440.130(d)(2), Scope of services: This provision maintains the definition of rehabilitative services as "medical or remedial services," but to more accurately reflect the entire proposed regulation that encompasses certain "restorative services" as covered rehabilitative services (440.130(d)(1)(vi)), the phrase "restorative services" should be added.

440.130(d)(3), Written rehabilitation plan: SCACHFS supports the written rehabilitation plan's goals of transparency and ensuring that "services are designed and coordinated to lead the goals set forth in the statute and regulation" and the general avenues taken to achieve those goals. We submit only the following clarification questions and recommendations:

CMS should allow the written rehabilitation plan should be able to be integrated with any concurrent health plans or child welfare service plan for the child and family. This will lessen administrative burden and by crossing system lines, work towards a more integrated, effective structure for the child.

SCACHFS appreciates the desire to have surrounding parties involved in the development, review, and modification of the plan goals and services, but hopes to have language added that acknowledges the very different situation held by children involved with the child welfare and foster care systems. These children, especially those who have had parental rights terminated and are in the custody of the state, may not have familial support or input to turn to. We therefore recommend adding to 430.130(d)(3)(ii) and (iii) (or alternatively, to a new subsection) the following language: "For a recipient involved with the child welfare or foster care systems, input or guidance in the development, review, and modification of plan goals and services may be obtained from the child's parents when appropriate, guardians, and/or caregivers responsible for the child's wellbeing (including, but not limited to, foster parents, kinship caregivers, and group or residential care staff)."

Along similar lines, while CMS is properly hoping for a person-centered process by requiring the involvement of the individual in the development, review, and modification of the plan, a child may not always be competent to participate. Language or a new subsection should be inserted stating that "A child under 18 should be actively involved in the development, review, and modification of the plan if deemed developmentally ready and appropriate."

If the child is deemed competent to participate in the process, any materials provided to the child to inform him/her should be age- and developmentally appropriate and the plan should be thoroughly explained to the child. The plan, on a more general note, should be culturally appropriate and plainly understandable by those who are involved.

In regards to 440.130(d)(3)(xi) that requires the written plan to indicate the extent to which services may be available from alternate providers, a standardized list of alternate providers should be acceptable (to lessen administrative burden of repeating this process).

440.130(d)(3)(xii) requires the written plan to include the individual's "relevant history, current medical findings, contraindications, and identify the individual's care coordination needs." This is important, but is not always possible. Because the children who SCACHFS and its members serve are often moved frequently through the system and between placements and because of other uncontrollable factors such as lapses in health care, relevant history and current medical findings may not be accessible. The child may not have even had a primary care doctor. This subsection should emphasis that the written plan should reference these documents ***when possible.***

441.45(b), Newly Deemed Non-Covered Services, Intrinsic Element Standard:

SCACHFS recognizes that CMS's intentions are to clearly define the funding programs so that providers can correctly bill Medicaid. However, we question the inclusion of an "intrinsic element" standard, as an appropriate solution to this problem. This decision could have a tremendous negative impact if implemented.

Rather than making such sweeping changes through rulemaking, SCACHFS believes that these important decisions that impact vital community-based services should be debated thoroughly and done through the legislative process. It is our understanding that some of this debate already occurred when Congress deliberated over the Deficit Reduction Act of 2005 (DRA, P.L 109-171). During that process, Congress specifically rejected adopting the "intrinsic elements" test for Medicaid rehabilitative services that CMS-2261-P would put in place. This indicates that Congress foresaw the dangers of such language and instead, desires for Medicaid rehabilitative services to remain a strong and viable stream of care. This language proposed in 440.145(b) seems to do the exact opposite, as it will ultimately burden already struggling systems and restrict access to services for some of the most vulnerable segments of the Medicaid beneficiary population, including children in foster care.

We are further concerned that 440.45(b) provides no guidance on how to determine whether a service is an "intrinsic element" of a program other than Medicaid and rather, seems to charge ahead, listing certain public programs such as child welfare and foster care as likely targets. The child welfare system's role is to respond to reports of abuse and neglect, help at risk families, and help secure permanent, safe, and secure homes for children. Part of this equation is to assist children who have suffered trauma in the recovery process and to help locate adequate services when the child has been removed from his/her family. Child welfare, however, is not qualified to provide certain services and because the system instead merely acts as a go-between, Medicaid rehabilitative services are *not* "intrinsic to" child welfare.

Similarly, Medicaid rehabilitative services are not "intrinsic to" foster care. Title IV-E, Section 475(4) of the Social Security Act and the Code of Federal Regulations, Title 45, Chapter XIII, Part 1355.20 state that foster care maintenance payments are "to cover the cost of (and the cost of providing) food, clothing, shelter, daily supervision, school supplies, a child's personal incidentals, liability insurance with respect to a child, and reasonable travel for a child's visitation with family, or other caretakers." Clarifying further that rehabilitative services are not intrinsic to foster care, the Code of Federal Regulations prohibits States from claiming Title IV-E federal financial participation (FFP) for "costs of social services provided to the child, the child's

family or foster family *which provide counseling or treatment to ameliorate or remedy personal problems, behaviors or home conditions*" (45 CFR, Chapter XIII, Part 1356.60(c)(3)) (emphasis added). States have more discretion under Title IV-B, but because its primary purpose is not to provide medical assistance, rehabilitative services are not "intrinsic to" it either. Moreover, IV-B is a capped program that does not envision providing and is not able to provide all necessary services.

It is essential that the systems work together, rather than one stepping completely out of the picture, as 441.45 permits Medicaid to do in certain, vital circumstances. The section also completely defeats the Substance Abuse and Mental Health Services Administration's (SAMHSA) diligent work to promote a system of care that provides a coordinated network of community-based services and supports that are organized to meet the challenges of children and youth with serious mental health needs and their families. As such, SCACHFS strongly urges 441.45(b) to be wholly dropped.

441.45(b)(1)(i) and (ii), Therapeutic Foster Care and Packaged Services Furnished by Foster Care and Child Care Institutions: SCACHFS wishes to specifically address the exclusion of therapeutic foster care services except for "medically necessary rehabilitative services for an eligible child that are clearly distinct from packaged therapeutic foster care services and that are provided by qualified Medicaid providers" (441.45(b)(1)(i)) and similar packaged services furnished by foster care or child care institutions (445.45(b)(1)(ii)) from the definition of Medicaid rehabilitative services. As the Surgeon General indicated in his 1999 report on mental health, with care provided in private homes with specially trained foster parents, therapeutic foster care is considered "the least restrictive form of out-of-home therapeutic placement for children with severe emotional disorders." It provides evidence-based care for children who otherwise would be placed in more institutional and costly settings—settings which can also reap emotional tolls on children and their families. The Surgeon General recommended therapeutic foster care as a community-based avenue forward for children's health and it also seems very in line with the report issued by the President's New Freedom Commission on Mental Health.

Unfortunately, the proposed language, while not explicitly prohibiting therapeutic foster care, whittles away at its core so much that access will surely be restricted, if not completely shut off. As a result, because there is a continuum of care in foster care, children who cannot be maintained be in regular foster care due to serious emotional or other health issues will be forced into more restrictive and more costly settings.

Only therapeutic foster care services that are "clearly distinct from packaged therapeutic foster care services" could be billed as rehabilitative services, but it is unclear what is meant by "clearly distinct." SCACHFS strongly advocates that states be afforded the discretion to define therapeutic foster care as a single service and pay through a case, daily, or appropriate mechanism. Packaged services allow the necessary amount of time and attention to be spent on children suffering from intense mental issues. The alternative imposes the significant administrative burden of relegating activities into somewhat arbitrary time blocks, which ultimately takes time away from the child and reduces services' effectiveness and the child's progress.

441.45(b)(5), Institution of Mental Disease: Summarily excluding services provided to residents of an institution for mental disease (IMD) who are under the age of 65, including residents of community residential treatment facilities more than 16 beds would most likely drive costs up and force children into more restrictive environments. This goes against the best interests of the child and again, conflicts with the President's New Freedom Commission on Mental Health's reports urging more community-based care. This subsection should be stricken. Alternatively, before changes go into effect, an appropriate and reasonable transition period must be provided for impacted parties.

CONCLUSION

On behalf of SCACHFS, its members, and the children and families we serve, we thank you for the opportunity to comment on this proposed rule. We hope that as we move forward with this process, we will work together to keep children's best interest at the forefront. Only then can we ensure that children and their physical and mental health needs are made a national priority.

Sincerely,

Timothy D. McCarty
Director of Operations Support
South Carolina Association of Children's Homes
And Family Services
133 Powell Drive
Lexington, SC 29072
Phone: 803-996-5437
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Email: scachfs-tim@sc.rr.com
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DISABILITY LAW PROJECT

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RUTLAND

OFFICES:

ST. JOHNSBURY
SPRINGFIELD

October 10, 2007

Centers for Medicare & Medicaid Services
Dept. of Health and Human Services
Attention: CMS-2261-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: File Code CMS-2261-P
Notice of Proposed Rule
Medicaid Coverage: Coverage for Rehabilitative Services

Dear Sir or Madam:

Enclosed please find a second original plus two copies of the comments of the Disability Law Project and Vermont Protection and Advocacy on this regulation. The comments were originally sent out with only one copy in error.

Sincerely,

Lila Richardson
Staff Attorney
Disability Law Project

DISABILITY LAW PROJECT

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SPRINGFIELD

October 10, 2007

Centers for Medicare & Medicaid Services
Dept. of Health and Human Services
Attention: CMS-2261-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: File Code CMS-2261-P
Notice of Proposed Rule
Medicaid Coverage: Coverage for Rehabilitative Services

Dear Sir or Madam:

The Disability Law Project is a special project of Vermont Legal Aid and provides legal advocacy for Vermonters with disabilities in legal matters related to their disabilities. Vermont Protection and Advocacy is the designated Protection and Advocacy system for the state of Vermont. A significant part of the Disability Law Project's practice relates to advocacy for children, both in seeking access to needed health care and in education matters. We submit these comments in response to the Notice of Proposed Rule entitled "Medicaid Program: Coverage for Rehabilitative Services," published in the Federal Register on August 13, 2007.

OVERVIEW

The proposed regulation appears to ignore the EPSDT mandate that children under the age of 21 are entitled to all Medicaid services necessary to correct or ameliorate a physical or mental condition, regardless of whether those services are defined in the state plan or covered for adults. 42 U.S.C. § 1396d(r)(5). The regulation needs to be amended to reflect the EPSDT provision. Furthermore, in Section 1.A of the preamble, it is noted that Medicaid has been used to fund services that are included under the IDEA. Such coverage is permissible and appropriate. The Medicaid statute specifically provides that the Secretary cannot prohibit or restrict coverage of Medicaid services simply because the services are included in an individualized education plan for IDEA services. 42 U.S.C. § 1396b(c).

PROVISIONS OF THE PROPOSED RULE

Proposed §440.130(d)(vi) Definition of Restorative Services

The preamble and proposed regulation emphasize that rehabilitation services must reduce disability and restore function in order to be reimbursable under Medicaid. Yet the proposed regulation acknowledges both that maintaining a functional level may be necessary to achieve a rehabilitation goal and that an individual does not have to have actually performed the function in the past. Moreover, the discussion of the written plan in the preamble states that "[i]f it is determined that there has been no measurable reduction of disability and restoration of functional level, any new plan would need to pursue a different rehabilitation strategy..." 72 Fed. Reg. at 45204 (Preamble at II.C.)

The emphasis on change in status and on achievement of specific goals may lead states to deny coverage for medically necessary rehabilitative services because such services do not lead to immediate results. Further, states and providers may interpret the proposed regulation as prohibiting coverage for services necessary for retention of improved functioning as well as maintaining the highest possible functional level.

Recommendation

We concur with the recommendations of the Bazelon Center for Mental Health Law that the regulation should clarify that a child need not demonstrate that he or she was once capable of performing a specific task in the past if it were not possible or age-appropriate for the child to have done so. In addition, that the definition of when services may be furnished to maintain functioning be revised to include as an acceptable goal of a rehabilitation plan, the retaining of functioning level for individuals who can be expected to otherwise deteriorate.

Proposed § 440.130(d)(5) Settings

Proposed §440.130(d)(5) states that rehabilitative services may be provided in a facility, home, or other setting. In the preamble, it is stated that states "have the authority to determine in which settings a particular service may be provided." 72 Fed. Reg. at 45205 (Preamble, II.E.) This statement is in conflict with the statutory definition of rehabilitative services as "rehabilitation services, including any medical or remedial services (provided in a facility, a home, or other setting) recommended by a physician or other licensed practitioner of the healing arts." States do not have the authority to pick and choose among appropriate settings for services. Services constitute rehabilitative services, regardless of the setting in which they are provided.

Recommendations

Clarify that rehabilitation services should be covered in any setting permitted by state law.

We concur with the Bazelon Center for Mental Health Law and recommend that the other settings listed in the preamble (schools, community mental health centers, and substance abuse treatment centers) be added to § 440.130(d).

Proposed § 441.45(b)(1): Non-covered Services

The proposed rule denies Medicaid coverage for covered services to covered individuals if such

services are furnished through another program, including when they are an "intrinsic element" of that program. There is little clarity in the regulation on how this provision would be applied as the regulation provides no guidance on how to determine whether a service is an "intrinsic element" of another program.

However, it is noted in Section 1.A of the preamble that Medicaid has been used to fund services that are included under the Individuals with Disabilities Education Act (IDEA). The "intrinsic element" exclusion appears to be in conflict with the statutory and regulatory provisions regarding Medicaid coverage of related services and third party payment. The Medicaid statute specifically provides that the Secretary cannot prohibit or restrict coverage of Medicaid services simply because they are included in an individualized plan for IDEA services. 42 U.S.C. § 1396b(c). Moreover, the Medicaid statute requires that State and local agencies administering the state Medicaid plan "take all reasonable measures to ascertain the legal liability of third parties..." 42 U.S.C. § 1396a(a)(25)(A). Even if a third party is liable, when EPSDT services are at issue, as they most certainly would be in cases involving services for school age children, the Medicaid agency is supposed to pay a claim for services, then pursue reimbursement from the liable third party. 42 U.S.C. §1396a(a)(25)(E); 42 C.F.R. § 433.139(b)(3)(i)(2007). The result of the proposed rule will be that Medicaid eligible individuals will be denied covered services, both by Medicaid, due to the "intrinsic element" exclusion, and by the other program, due to lack of resources, with the net effect that covered individuals will be denied medically necessary Medicaid Services.

Recommendation

We concur with the recommendation of the Bazelon Center for Mental Health Law that § 441.45(b)should be omitted because it conflicts with the EPSDT requirements and other parts of the Medicaid statute.

In the alternative:

Omit the intrinsic element test.

Section 441.45(b)(1)(iv) should be amended to clarify that Medicaid coverage should not be denied merely because a service is provided in an individual education plan.

The responsibilities for states regarding third party payers, and the third party payers' own responsibilities, should be recognized and clarified in § 441.45(b)(1), and reference made to 42 C.F.R. § 433.139 (2007).

Thank you for the opportunity to comment on the proposed regulation.

Sincerely,

Nancy Breiden, Director
Disability Law Project

Ed Paquin, Executive Director
Vermont Protection and Advocacy

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MINNESOTA DISABILITY LAW CENTER

DULUTH • GRAND RAPIDS • MINNEAPOLIS • MANKATO • MOORHEAD • WILLMAR

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www.mndlc.org

October 10, 2007

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-2261-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: File Core CMS-2261-P, Proposed Rule, Medicaid Program; Coverage for Rehabilitative Services

To Whom This May Concern:

Thank you for the opportunity to comment on the proposed regulation governing coverage of rehabilitative services under the Medicaid Act.

The Minnesota Disability Law Center (MDLC) is concerned about the effect of the following proposed provisions on individuals who are receiving or would be eligible to receive services under the rehabilitation option:

<u>Preamble to the Regulations</u>

The requirement that services not be a "custodial case benefit for individuals with chronic conditions but should result in a change in status," or in other words, produce improvement, is problematic for persons with mental illness who may need a course of treatment to establish a functional skill. In order to assure the skill can be performed, a period of service to integrate the skill into one's life may be needed. The specific skill level may not improve during this time, but regular performance across environments is needed to assure the new skill is used when needed. Limiting the rehabilitation option to working on goals which improve functioning in a specific area is too limited.

<u>Qualified providers of rehabilitation services</u>

The proposed definition of qualified providers in § 440.130(d)(1)(iii) will adversely affect individuals who may currently have providers who do not fit into other mandatory or optional

categories of service under Part 440. For example, Minnesota uses the rehabilitation option to provide behavioral health and chemical health services by providers who do not fit into Part 440 categories of service. The state does so because physicians, psychiatrists, and psychologists are often not available to provide these services, and because their level of education, skill, and licensure is not necessary for the services being provided. By requiring that rehabilitation providers "meet any applicable provider qualifications under Federal law that would be applicable to the same service when it is furnished under other Medicaid benefit categories," we are concerned that CMS staff will take the view that all behavioral health services, for example, must be provided by vendors who are otherwise qualified under sections of Part 440.

Limitations on rehabilitation services

Conflict with EPSDT

(1) The limitations on rehabilitation services and the "intrinsic element" test in the proposed § 441.45(b) are problematic because the terms "intrinsic element" and "program" are not defined. This will cause confusion for state Medicaid officials and providers and could cause erroneous denials of coverage for services. More importantly, the limitations are based on a faulty premise. According to the examples of "programs" listed, these service exclusions will predominantly, if not exclusively, apply to services for children under age 21. Thus, these children will all be eligible for EPSDT, under which a service should be covered if it is necessary to correct or ameliorate a physical or mental condition, even if it could be covered under another program. The proposed regulation does not acknowledge the coverage of these services under EPSDT with sufficient clarity.

Conflict with IDEA

(2) The limitations could also conflict with statutory and regulatory provisions regarding Medicaid coverage of related services under the IDEA and third party payment. Medicaid has been used to fund services that are included under the IDEA. 72 Fed. Reg. at 45202. Such coverage is permissible and appropriate as the Medicaid statute specifically provides that the Secretary cannot prohibit or restrict coverage of Medicaid services simply because the services are included in an individualized education plan for IDEA services. 42 U.S.C. § 1396b(c). Also, the Medicaid statute requires that state and local agencies administering the state Medicaid plan "will take all reasonable measures to ascertain the legal liability of third parties ..." 42 U.S.C. § 1396a(a)(25)(A). Even if a third party is liable, when EPSDT services are at issue, the Medicaid agency is supposed to pay a claim for services, then pursue reimbursement from the liable third party. 42 U.S.C. § 1396a(a)(25)(E); 42 C.F.R. § 433.139(b)(3)(i) (2007). Thus, when a service is the responsibility of a third party, the other program is still a third party payer.

Habilitation and rehabilitation services

The proposed regulations make it explicit that habilitation services are not coverable as rehabilitation services because they are designed to help individuals acquire new functional abilities rather than to restore function. 42 C.F.R. § 441.45(b)(2). As habilitation services are

only covered under two narrow circumstances, the discussion and regulation regarding habilitation is problematic for several reasons.

First, it seems to be based on the premise that individuals with mental retardation or similar conditions would never have a need for rehabilitation services. For example, child with mental retardation may not have developed speech or other communication skills. By limiting rehabilitation services to those that restore function, those born without speech skills would never be able to access speech services under the rehabilitation option. This is overly broad and will lead to automatic exclusion of services for this population when they may be appropriate.

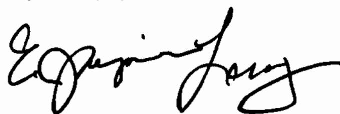
Second, neither the regulations nor preamble acknowledge the different nature of some "related conditions," which include epilepsy, autism, and cerebral palsy. 42 C.F.R. § 435.1010 (2007). These diagnoses can cause loss of function that needs to be restored, thus, those individuals would need and could benefit from rehabilitation services.

Third, the proposed rules do not provide guidance for coverage of services for individuals with dual diagnoses of mental retardation/related conditions and mental illness. The proposed regulations acknowledge that physical impairments and mental health and/or substance related disorders can be appropriately treated with rehabilitation services. However, there is no explanation of how states may cover services for those with dual diagnoses and how they may justify doing so when claiming FFP. This is likely to lead to denial of medically necessary covered services for a population that already faces significant barriers to care.

The result of this discussion would be especially problematic for Minnesota's individuals with developmental disabilities. The two circumstances in which habilitation services are covered are when they are provided in an intermediate care facility for persons with mental retardation (ICF/MR), or when covered as a home and community-based service under section 1915(c), (d), or (i). Minnesota has very few ICFs/MR and has a lengthy waiting list for individuals with mental retardation or a related condition who are eligible for a home and community-based waiver. Moreover, the waiver is not an entitlement. Thus, it would be especially difficult for Minnesota individuals with mental retardation or a related condition to obtain coverage for needed rehabilitative services to improve functioning in key areas such as speech and mobility.

Thank you for the opportunity to comment on this proposed rule. It is our belief that the areas mentioned above should require extra consideration and clarification. We would be willing to participate in further discussion of this regulation.

Very truly yours,



E. Jaynie Leung
Attorney at Law

EJL:cas
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Sheppard Pratt

A not-for-profit behavioral health system

Office of the President and Chief Executive Officer

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October 10, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2261-P, Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-2261-P; PUBLIC COMMENT REGARDING PROPOSED AMENDMENT TO 42 CFR PARTS 440 AND 441: Medicaid Program- Coverage for Rehabilitative Services

To Whom It May Concern:

Sheppard Pratt Health System is a 156-year-old, not-for-profit organization in Maryland that provides comprehensive hospital and community-based mental health services to over 45,000 individuals each year, approximately 10,000 of whom are Medicaid recipients. We oppose the draft regulation amendments because we believe they could be interpreted to conflict with the recovery model and evidence-based practices in the mental health field, and they could thwart some of the recommendations of the President's New Freedom Commission on Mental Health. Furthermore, the implementation of the proposed regulation changes could have serious adverse clinical effects on countless Medicaid recipients, causing an increase in more expensive and more restrictive institutional care – with the overall costs to taxpayers being much greater than the short-term savings hoped to be gained with the regulation changes.

We propose several specific modifications to the draft regulation amendments which we believe would correct the problems, minimize the consequences, and achieve the greatest cost savings. Our comments and proposed changes are articulated in the context of the New Freedom Commission's Final Report which the CMS discussion also cites.

The Commission Report views federal funding agencies and reimbursement regulations to be part of the nation's mental health service delivery system that needs to be transformed. (*Final Report*, 1). We believe that our suggested changes will achieve the *accountability* that CMS seeks while at the same time assuring the *flexibility* that individuals with serious mental illness need – both of which the Commission noted as being critical aspects of effective public mental healthcare financing. (*Id.*at 23).

I. <u>Section 440.130 (d)(1)(vi) and Section 440.130 (d)(3)(xiv)</u>

A. **Problems.** The current language defining "restorative services" and the requirement that the reevaluation of the rehabilitation plan demonstrate a "measurable reduction of disability and restoration of functional ability" can be interpreted to prohibit reimbursement for long-term rehabilitation services for adults with serious mental illness that are provided toward the goals of living in the community without long-term or intermittent hospitalization or of managing symptoms to avoid deterioration or hospitalization. These can be important recovery-oriented goals for individuals who choose them, and for many people, avoiding or reducing hospitalizations is substantial progress in and of itself.

Unlike some other chronic illnesses, serious mental illness is often characterized by a cyclic nature that encompasses periods of gains in functioning followed by periods in which functioning decreases or remains static. It is critical that rehabilitation continues during all phases of the illness in order to keep the individual stable in the community until such time that he or she can once again show progress toward goals. Furthermore, what may look like maintenance of functioning to the untrained eye may actually be subtle but critical internalization of the recovery process. It would be a grave mistake to deny these individuals Medicaid-funded rehabilitation services simply because they fail to show linear progress.

The regulation also contradicts the New Freedom Commission's transformation principle of facilitating recovery – which it defines as "the process in which people are able to *live, work,* learn, and participate fully in their communities. (*Id.* at 5). With this definition, the regulation should unambiguously support a rehabilitation goal of living in the community without long-term or intermittent institutionalization or of reducing symptoms to avoid deterioration or hospitalization. The regulation appears to support a goal of *working* in the community, but not one of *living* in the community.

Several Sheppard Pratt consumers of services with schizophrenia and bipolar disorder exemplify this dynamic. William's psychosis and thought disorganization caused him to spend eight years in a state psychiatric hospital prior to receiving psychiatric rehabilitation services. Dorothy's intense paranoia and auditory hallucinations resulted in over 20 hospitalizations and five years of persistent homelessness. John's almost lethal combination of mania, visual hallucinations, and drug abuse spiraled him into a revolving door between institutionalization, homelessness, and incarceration. While they each ended up in different places in their recovery, the initial journey was similar, with each receiving psychiatric rehabilitation services for over ten years without any apparent progress. In fact, growth was occurring, but it was subtle and slow and it needed to be viewed in light of the potential hospitalizations that were prevented as opposed to the other goals that were not achieved.

It took ten years for William to get to the point that he could identify basic personal care needs such as a haircut and to retain a part-time job with intensive support and an employer willing to try compensatory strategies. He continues to live in the community but only because of rehabilitation services and only with growth so modest that it appears to be more maintenance than progress. The slow struggle with Dorothy was to gradually build trust in order to penetrate the paranoia and persuade her to reject homelessness and accept medication. After a decade of rehabilitation and several years of Dorothy's apparent stability which included employment, Sheppard Pratt yielded to managed care pressure to reduce rehabilitation services, and Dorothy was lost again, falling back into an escalating paranoia that was never able to be pierced. Conversely, John ended up appearing to be one of our most successful consumers – gaining a college degree, renting his own apartment, maintaining a full-time job as a substance abuse counselor, and then graduating entirely from our services. But this was only after a decade of rehabilitation with no apparent growth. Then, several years after rehabilitation services were terminated, during what appeared to be steady, linear progress, he committed suicide, evidently having begun to hear voices again – a warning sign that would have been recognized with regular rehabilitation services but which went undetected during quarterly psychiatric medication checks.

It is important to emphasize that during the first decade of rehabilitation services for these individuals, when each was asked the consumer-centered question of what he or she wanted most in life, they all said they wanted to live in an apartment in the community without the pain of their symptoms and without the restrictiveness of institutional care. Of course, they also expressed a desire to have a job at some point and to gain more education – but those were not their priorities. As a skilled rehabilitation provider, we continued to urge them toward these more aggressive goals because we knew that

evidence-based practices such as Supported Employment could be effective not only in securing a job, but also in achieving the stability they sought. However, the fundamental principle of recovery focuses on consumer choice and empowerment, and one of the most critical factors of success of many of the EBPs is supporting individuals in pursuing their personal goals, however modest. Therefore, for such individuals, while the goals of employment and education may be appropriate, the goal of living in the community without intermittent hospitalizations would also be reasonable – and extremely cost-effective for taxpayers if achieved.

B. Solution. To resolve these problems, we propose that CMS add language that it has used in other program transmittals in which it clarified how to apply the requirement of treatment improvement to individuals with serious mental illness. In two different Medicare program transmittals, CMS used this definition:

> "Reasonable Expectation of Improvement – Services must be for the purpose of diagnostic study or reasonably be expected to improve the patient's condition. The treatment must, at a minimum, be designed to reduce or control the patient's psychiatric symptoms so as to prevent relapse or hospitalization, and improve or maintain the patient's level of functioning. It is not necessary that a course of therapy has as its goal restoration of the patient to the level of functioning exhibited prior to the onset of the illness, although this may be appropriate for some patients. *For many other psychiatric patients, particularly those with long-term, chronic conditions, control of symptoms and maintenance of a functional level to avoid further deterioration or hospitalization is an acceptable expectation of improvement. "Improvement" in this context is measured by comparing the effect of continuing treatment versus discontinuing it. Where there is a reasonable expectation that if treatment services were withdrawn the patient's condition would deteriorate, relapse further, or require hospitalization, this criterion is met.*" (emphasis added). Medicare Hospital Manual, Chapter II, Section 230.5 Hospital Outpatient Psychiatric Services; Medicare Intermediary Manual, Part 3, Chapter II, Section 3112.7 Outpatient Hospital Psychiatric Services.

Adding several sentences to two parts of the proposed regulation would provide the necessary clarification.

1. Section 440.130 (d)(1)(vi) (Definition of "Restorative services").

We propose adding to the end of this section the following sentence borrowed from the CMS Medicare transmittals:

"Examples of acceptable rehabilitation goals in these instances for some individuals, such as those with serious mental illness, could include: living in the community without long-term or intermittent hospitalization; or reduction or control of symptoms to avoid further deterioration or hospitalization."

2. Section 440.130 (d)(3) (xiv) (Requirement of "Measurable Reduction of Disability").

We propose adding to the end of this section the following two sentences borrowed from the CMS Medicare transmittals:

"For some individuals such as those with serious mental illness, 'reduction of disability and restoration of functional level' may be measured by comparing the effect of continuing rehabilitation versus discontinuing it. Where there is a reasonable expectation that if rehabilitation services had been

withdrawn the individual's condition would have deteriorated, relapsed further, or required hospitalization, this criterion would be met."

II. Section 441.45 (b) (1) and 441.45 (b) (3)

A. Problems. We agree that FFP should not cover foster care, child welfare, education, child care, vocational and prevocational training, housing, parole and probation, juvenile justice or public guardianship services. However, when the regulation prohibits FFP for rehabilitation services that are "intrinsic elements" of these non-medical programs, CMS is making a mistake in not differentiating between: *blending of services* – which is positive because it can facilitate integration, increase transferability of skill development in natural settings, and promote a key principle of evidence-based practices; and *blending of funding* – which can be negative because it can lead to cost shifting and reimbursement of non-covered services. As a result, the regulation could be interpreted to perpetuate the obstacle of system fragmentation identified by the New Freedom Commission. In addition, it could be in conflict with the Commission's promise that states will have the "flexibility to combine federal, state and local resources in creative, innovative, and more efficient ways" and Commission's suggestion that states should not need to rely on waivers to achieve this important flexibility. (*Id.* at 8, 22).

In addition, the proposed regulation amendment could have a chilling effect on the implementation of the Commission's strong recommendation to support the advancement and utilization of evidence-based practices and best practices. (*Id.* at 12). For example, the regulation could be interpreted to prohibit FFP for mental health rehabilitation services provided as part of a Supported Employment program even though SAMHSA endorses this service protocol as an effective, evidence-based mental health practice.

Finally, the regulation's unqualified prohibition in 441.45 (b)(3) of FFP for "vocational and prevocational services" creates potential confusion about what types of employment support are successful for individuals with serious mental illness. It could also perpetuate the common misunderstanding that most employment barriers for these individuals involve cognitive limitations relative to performing the job task when in fact the barriers more often include disability-related symptoms and associated functional deficits. Using another Sheppard Pratt consumer as an example, Supported Employment staff spends most of their time helping Lee to develop interpersonal skills necessary to deal with supervisors and peers to prevent conflicts. He needs very little support in learning how to perform the tasks of his job which include washing, drying, and stacking dishes. His employment barrier is that he keeps getting fired because of angry outbursts on the job. Similarly, Jason's Supported Employment staff help him to develop strategies to manage his depression and fear in order to avoid excessive tardiness and absences – which are the reasons he keeps losing jobs.

In the discussion about this section, CMS cites as an example of a covered rehabilitation service teaching an individual to cook in order to restore living skills. The comment identifies as an example of a non-covered vocational service teaching an individual to cook as part of training to be a chef. Sheppard Pratt consumer Steve is an example of a third alternative which needs to be clarified in the regulation: Supported Employment staff assist him in securing and maintaining a job as a cook by helping him to manage his paranoia and auditory hallucinations that prevent him from interacting appropriately with co-workers and customers and assisting him in managing his compulsive behaviors that drive him to excessive hand-washing that reduces his productivity.

B. Solution. Instead of discouraging the effective blending of services in Supported Employment and other similar programs, the regulation should support FFP for rehabilitation services

provided as part of these programs as long as states can distinguish Medicaid funding for the rehabilitation services as being separate from non-Medicaid funding for non-covered services. Similarly, instead of potentially thwarting the implementation of Supported Employment services with an unqualified exclusion of vocational and prevocational services, the regulation should clarify that services geared to supporting employment by reducing disability-related symptoms and deficits that create employment barriers are covered rehabilitation services – whereas services that train the individual to perform job tasks are not. Adding several sentences to two different sections of the regulation would resolve both problems.

1. Section 441.45 (b) (1)

We propose adding the following after the first sentence:

"Services would not be considered to be intrinsic elements of these non-medical programs if they are medically necessary rehabilitation services for an eligible individual that are clearly distinct from the non-covered program services and that are provided by qualified Medicaid providers. One way to demonstrate this distinction is to clearly and reasonably distinguish the funding stream for the Medicaid rehabilitation services as being identifiably separate from that of the non-covered services."

2. Section 441.45 (b)(3)

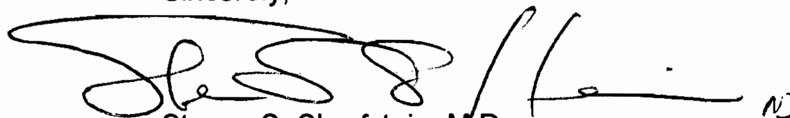
We propose adding the following clause after the phrase "vocational and prevocational services:"

"...that are not focused on reducing disability-related symptoms or deficits and not provided by a qualified Medicaid provider."

III. Conclusion

Sheppard Pratt understands the limitations of federal funding and the constraints of regulation, and appreciates CMS' desire to increase accountability in the Medicaid reimbursement system in order to save money. As Maryland's largest provider of mental health treatment and rehabilitation services to Medicaid beneficiaries, we support all effective ways to protect the supply and longevity of this funding source. However, while we share CMS' concerns, we point instead to the New Freedom Commission's recommended strategies for resolving those concerns. Simply put, a transformed mental health system will save money in the end for all funding sources, including Medicaid. Increasing accountability at the cost of decreasing flexibility will end up wasting money – and lives. We believe that the Commission's comprehensive vision addresses both the quality of life of American citizens and the financial integrity of limited government resources. Our proposed changes to the regulation amendment represent concrete ways to implement the Commission's recommendation to improve both the accountability and flexibility of public financing for mental health services as an important part of the broader system's rehabilitation and transformation. Thank you for considering our comments.

Sincerely,



Steven S. Sharfstein, M.D.
President and Chief Executive Officer

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Center for Medicare and Medicaid Services
US Department of Health and Human Services
Attention CMS-2261-P
PO Box 8018
Baltimore, MD 21244-8018

October 5, 2007

To Whom It May Concern,

I am writing to express my opposition to the regulations in file code CMS-2261-P. I am a physical therapist at Brunswick Center Day-Habilitation. The change that CMS has proposed could eliminate day habilitation services. I know first hand how important day habilitation services are to the population that suffers from mental retardation and developmental disabilities.

A day at Brunswick Center is filled with educational activities, physical therapy, speech therapy, occupational therapy, behavior services, meaningful work, and outings. The socialization of the center allows the consumers to grow cognitively. The therapy promotes the current level of function. Physical therapy has been shown to positively influence overall health, wellness, and fitness by providing services that impact physical fitness which in turn lowers the risk of physical impairments in the future. Adults with mental retardation and developmental disabilities are living longer than they ever have before, and along with it they are displaying many aging disabilities like dementia. Dementia combined with mental retardation is very challenging, and it takes trained professionals to help family members adjust to the changing needs.

After snow days, the consumers are so excited to come back to program because they have sat at home in front of the TV all day long. At program, our consumers receive quite an array of stimulation and activities. By sitting home all day, the inactivity will lead to many medical and cognitive issues that will be more expensive to our community in the long run. The reality of these proposed regulations are that you are sentencing our consumers to a house-bound life.

We have come a long way in society to understanding and providing for the unique needs for adults with special needs in our communities. The changes proposed appear to discriminate against adults with mental retardation. It may sound good on paper, but many consumers have families that can not stimulate the consumer for the whole day or in fact even transport their loved one. Please re-think these regulations and the dramatic impact it will have on the clients that I serve.

Sincerely,

Katherine Hodge MSPT

Katherine Hodge MSPT

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Habilitation Model Comments on Rehab Option NPRM

October 9, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-2261-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: File Code CMS-2261-P

To Whom It may Concern:

We are writing to comment on the notice of proposed rulemaking (NPRM) with respect to Medicaid coverage of rehabilitative services that was published in the Federal Register on August 13, 2007. These comments are being submitted on behalf of Road to Responsibility, Inc. of Marshfield, Mass., provider of a day program that our son and brother, Richard McDonald, attends.

We are commenting on the negative impact of the proposed rule on people like Richard, with intellectual and other developmental disabilities, and their access to habilitation services.

We strongly oppose the provisions related to excluded federal financial participation (FFP) for habilitation services. We urge you to withdraw this proposed rule.

The proposed rule would severely harm people with intellectual and other developmental disabilities in two major ways: it eliminates longstanding programs and it imposes a discriminatory and arbitrary exclusion from receiving many rehabilitation services.

We agree that state programs operated under the rehabilitation and clinic option should set high standards for delivering active treatment and for innovating to develop programs for people with intellectual and other developmental disabilities that maximize their ability to attain, maintain and retain their maximum ability to function.

We feel that for Richard, with his limited communication skills, having a nurse on duty in his day program made a life or death difference for him. He vomited blood caused by a bleeding ulcer, and his nurse recognized an immediate and critical need for him to receive emergency care. We have also witnessed the enhancement of the quality of Richard's day program through the services of Occupational and Speech Therapy evaluations and treatment options. We trust that all of these services will continue for Richard as long as they are needed.

Sincerely,

Ivan Mcdonald
Guardian for Richard McDonald

Nancy Adinolfi
Guardian for Richard McDonald

86

Lorraine Small
11 Winthrop Street,
North Easton, MA 02356

October 8, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS–2261–P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: File Code CMS–2261–P

To Whom It May Concern:

I am writing to comment on the notice of proposed rulemaking (NPRM) with respect to Medicaid coverage of rehabilitative services that was published in the *Federal Register* on August 13, 2007. These comments are being submitted on behalf of **Road to Responsibility.**

I am the parent of a 46 year-old, non-verbal, retarded daughter, Michelle A. Small.

Michelle has been receiving services through Road to Responsibility for many, many years, and has made tremendous progress under their auspices. Her life has improved dramatically and she thoroughly enjoys the time she spends in her RTR Day-Habilitation program.

In separate communications, Road to Responsibility will express support for more comprehensive comments to the NPRM. Here, I am commenting exclusively on the impact of the proposed rule on my daughter who has intellectual and developmental disabilities and access to habilitation services.

I strongly oppose the provisions related to excluded federal financial participation (FFP) for habilitation services and urge you to withdraw this proposed rule.

The proposed rule would severely harm my daughter and other people with intellectual and other developmental disabilities in two major ways: it eliminates longstanding programs for providing day habilitation services to people with developmental disabilities, and it imposes a discriminatory and arbitrary exclusion from receiving many rehabilitation services for people with mental retardation and related conditions.

<u>Elimination of FFP for habilitation services provided under the rehab and clinic options</u>:
I believe that this proposed restriction contradicts the intent of the Congress to protect access to day habilitation services for people with developmental disabilities when it enacted the Section 6411(g) of the Omnibus Budget Reconciliation Act of 1989, P.L. 101-239. This section reads:

(g) DAY HABILITATION AND RELATED SERVICES-

(1) PROHIBITION OF DISALLOWANCE PENDING ISSUANCE OF REGULATIONS- Except as specifically permitted under paragraph (3), the Secretary of Health and Human Services may not--

(A) withhold, suspend, disallow, or deny Federal financial participation under section 1903(a) of the Social Security Act for day habilitation and related services under paragraph (9) or (13) of section 1905(a) of such Act on behalf of persons with mental retardation or with related conditions pursuant to a provision of its State plan as approved on or before June 30, 1989, or

(B) withdraw Federal approval of any such State plan provision.

(2) REQUIREMENTS FOR REGULATION- A final regulation described in this paragraph is a regulation, promulgated after a notice of proposed rule-making and a period of at least 60 days for public comment, that--

(A) specifies the types of day habilitation and related services that a State may cover under paragraph (9) or (13) of section 1905(a) of the Social Security Act on behalf of persons with mental retardation or with related conditions, and

(B) any requirements respecting such coverage.

(3) PROSPECTIVE APPLICATION OF REGULATION- If the Secretary promulgates a final regulation described in paragraph (2) and the Secretary determines that a State plan under title XIX of the Social Security Act does not comply with such regulation, the Secretary shall notify the State of the determination and its basis, and such determination shall not apply to day habilitation and related services furnished before the first day of the first calendar quarter beginning after the date of the notice to the State.

In enacting this provision of law, the Congress was clearly intending to protect access to day habilitation programs for people with mental retardation and related conditions. The proposed rule does not specify which day habilitation services that a state may cover as required by section 6411(g). We believe the blanket prohibition on habilitation services under paragraphs (9) and (13) of section 1905(a) of the Social Security Act exceeds the regulatory authority granted by the Congress.

I also oppose the prohibition of habilitation services on policy grounds. I believe the proposed rule represents a missed opportunity for the Secretary to specify the types of services that may be provided in a way that ensures that individuals receive the highest quality habilitative and rehabilitative services according to current standards of treatment. The preamble of the proposed rule states that the rehab option is not a "custodial" benefit. I agree with the Secretary that state programs operated under the rehab and clinic options should set high standards for delivering active treatment and for innovating to develop programs for people with intellectual and other developmental disabilities that maximizes their ability to attain, maintain, and retain their maximum ability to function, consistent with the original conception of rehabilitation, as found in section 1901 of the Social Security Act.

The preamble to the proposed rule also states that the Secretary intends "to work with those states that have habilitation programs under the clinic services or rehabilitative services benefits

under their state plans to transition to appropriate Medicaid coverage authorities, such as section 1915(c) waivers or the Home and Community-Based Services State plan option under section 1915(i)." I take issue with the assertion that these are more appropriate coverage authorities. In particular, waiver programs operate as discretionary alternatives to their core Medicaid programs, which operate under their state plan. I believe that states should have the flexibility to continue operating habilitation programs under the longstanding state plan options. Further, section 1915(c) waivers and the section 1915(i) are not equivalent to the rehab or clinic options. Section 1915(c) waiver programs require individuals to meet a nursing facility level of care requirement, something which is not required for rehab or clinic option services. Further, the 1915(c) and 1915(i) coverage authorities have different financial eligibility standards. Most significantly, these coverage authorities do not extend an enforceable entitlement to services. Indeed, the disability community opposed aspects of section 1915(i) in the Deficit Reduction Act that permit enrollment caps and that do not extend an entitlement to services. Nonetheless, this option was enacted to give states added flexibility and was not intended to supplant the rehab and clinic options by requiring states to shift to more restrictive coverage authorities. It should also be observed that the 1915(c) waiver programs are notable for their long and large waiting lists. In 2004, more than 206,000 people were on Medicaid waiting lists for community services, an increase of roughly 50,000 people in just two years. In some cases, average wait times to receive waiver services are more than two years (Kaiser Commission on Medicaid and the Uninsured, 2006).

I strongly recommend that the proposed exclusion of FFP for habilitative services under the clinic and rehab options not be implemented.

<u>Discriminatory and arbitrary exclusion from receiving many rehabilitation services for people with mental retardation and related conditions</u> : I strongly oppose the proposed rule's definition of habilitation services [see section 441.45(b)(2)] as including "services provided to individuals with mental retardation and related conditions." This population exclusion violates a fundamental principle of Medicaid, that medical assistance provided to one Medicaid beneficiary shall not be less in amount, duration, and scope than the medical assistance made available to any other Medicaid beneficiary [see section 1902(a)(10(B) of the Social Security Act]. The proposed rule also states that, "Most physical impairment, and mental health and/or substance related disorders, are not included in the scope of related services, so rehabilitative services may be appropriately provided." Nonetheless, this policy would, at a minimum, create uncertainty that states can receive FFP for medically necessary rehab option services for people with intellectual and other disabilities. Additionally, it exposes a false premise that persons with intellectual disabilities have achieved no prior capacity to function for which a rehabilitative service would be appropriately furnished under the rehab option. I urge the Secretary to rescind this constraint on rehab option services that is so blatantly stigmatizing and discriminatory to people with intellectual and other developmental disabilities.

Sincerely yours,

Lorraine Small

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STATE OF CALIFORNIA - HEALTH AND HUMAN SERVICES AGENCY ARNOLD SCHWARZENEGGER, *Governor*

DEPARTMENT OF ALCOHOL AND DRUG PROGRAMS
1700 K STREET
SACRAMENTO, CA 95811-4037
TDD (916) 445-1942
(916) 327-4178

October 10, 2007

Submitted Electronically

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2261-P
P.O. Box 8018
Baltimore, MD 21244-8018

PROPOSED FEDERAL REGULATIONS ON MEDICAID PROGRAM COVERAGE OR REHABILITATIVE SERVICES

The proposed regulations as published in the August 13, 2007 Federal Register section 440.130 would require significant and sudden changes in the substance abuse treatment service system. Although the California Medicaid plan for substance abuse services already requires documentation from a licensed physician of medical necessity for services and updated treatment plans (or rehabilitation service) more frequently than once per year, some of the proposed changes are deleterious to persons suffering from substance dependence.

The proposed Regulation 440.130(d)(3)(xiv) appears to require measurable reduction in disability and restoration of functional level on an annual basis. If measurable results are not achieved, a new strategy is required in the treatment plan. This change ignores scientific evidence that substance abuse is a chronic, relapsing illness characterized by observable changes in brain chemistry, according to the federal Substance Abuse and Mental Health Services Agency, the American Society of Addiction Medicine, and other prominent organizations. Acute care is not sufficient to effectively treat substance dependence and the proposed regulations would deny continued Medicaid funding for all patients who achieve the "best possible functional level" and wish to maintain their hard-earned health improvements through continued services. Denying effective ongoing treatment is likely to result in costs to other health care services.

The proposed Regulations 440.130(d)(3)(v) and 440.130(d)(3)(xiii) requires the service plan to be developed and reevaluated with the active participation of the individual and the individual's family, the individual's authorized decision maker, and/or the person of the individual's choosing. Requiring the participation of another individual would conflict with federal confidentiality regulations for alcohol and other drug services (42 CFR Part 2). Inclusion of another person in the development of an individual's treatment plan may be permissive under 42 CFR if consent is given by the individual. As the proposed regulation is written, this can cause conflict for all states. The proposed regulation does not contain a provision for individuals to waive other individual's involvement.

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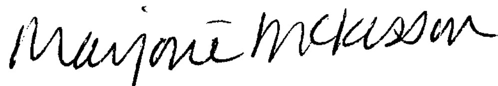
For energy saving tips, visit the Flex Your Power website at
http://www.fypower.org

Substance abuse services are often not distinguished from mental health services, yet many fundamental differences exist. One area where federal statute and regulations considers the two service systems together is within the limit on the number of beds in an institute for mental disease. If this exclusion no longer applied to persons with a primary diagnosis of substance dependence, significant cost efficiencies to state and the federal government could be realized in the delivery of Medicaid substance abuse services.

No provision is made in the regulations for transition to the new requirements. Given the significance of some of the proposed changes, a thoughtful, "no-harm" transition is necessary to protect the health of beneficiaries impacted by the changes.

For these reasons, the California Department of Alcohol and Drug Programs disagrees with some of the proposed changes and would be very concerned with the resulting reduction in services to Medicaid-eligible patients. If you should have any concerns regarding these comments please contact me at (916) 327-4178 or mmckisson@adp.ca.gov.

Sincerely,



Marjorie McKisson
Assistant Deputy Director
Program Services Division -Treatment

cc: Mr. Irvin White, Deputy Director
California Department of Health Care Services

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October 10, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-2261-P,
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-2261-P; PUBLIC COMMENT REGARDING PROPOSED AMENDMENT TO 42 CFR PARTS 440 AND 441: Medicaid Program- Coverage for Rehabilitative Services

TO WHOM IT MAY CONCERN:

Way Station is a 30 year-old not-for-profit organization in Maryland that provides comprehensive community-based mental health services to over 7,000 individuals each year, approximately 4,000 of whom are Medicaid recipients. We thank you for the opportunity to give input, and we submit the following comments which we believe will achieve the *accountability* that CMS seeks while at the same time assuring the *flexibility* that individuals with serious mental illness need – both of which the New Freedom Commission noted as being critical aspects of effective public mental healthcare financing. (*Final Report*, at 23). Attached to this letter is a red-lined version of the regulation and preamble, showing our proposed modifications in the yellow highlighted sections.

I. Section 440.130 (d) (1)(vi) and Section 440.130 (d) (3) (xiv)

We are concerned that the proposed language defining "restorative services" and the rehabilitation plan requirement for reevaluation of "measurable reduction of disability and restoration of functional ability" could be misinterpreted to prohibit coverage for long-term rehabilitation services for adults with serious mental illness that are provided toward goals of living in the community without intermittent hospitalization or of reducing symptoms to avoid hospitalization. While such individuals may choose the type of goals that involve positive outcomes such as employment or formal education, others may choose the type that involve reducing symptoms and avoiding negative outcomes such as hospitalization. The New Freedom Commission views both types of goals as being recovery-oriented as both are included in the Commission's definition of "recovery." (*Id.* at 5) Furthermore, for many individuals with serious mental illness and histories of multiple hospitalizations, the latter type of goal can be just as ambitious as the former, and avoiding hospitalization can be substantial progress in and of itself.

To provide the necessary clarification, we propose that CMS add language that it has used in other program transmittals in which it clarified how to apply the requirement of treatment improvement to individuals with serious mental illness. In two different Medicare program transmittals, CMS used this definition:

PO Box 3826 / Frederick, Maryland 21705-3826 / 301-662-0099 / Toll Free 888-549-0629 / Fax 301-694-9932
9030 Route 108, Suite A / Columbia, Maryland 21045 / 410—740-8262 / Toll Free 877-381-5482 / Fax 410-740-8237
25 East North Avenue, Hagerstown, MD 21740 / 301-733-6063 / Fax 301-733-6220

www.waystationinc.org

"Reasonable Expectation of Improvement – Services must be for the purpose of diagnostic study or reasonably be expected to improve the patient's condition. The treatment must, at a minimum, be designed to reduce or control the patient's psychiatric symptoms so as to prevent relapse or hospitalization, and improve or maintain the patient's level of functioning. It is not necessary that a course of therapy has as its goal restoration of the patient to the level of functioning exhibited prior to the onset of the illness, although this may be appropriate for some patients. *For many other psychiatric patients, particularly those with long-term, chronic conditions, control of symptoms and maintenance of a functional level to avoid further deterioration or hospitalization is an acceptable expectation of improvement. "Improvement" in this context is measured by comparing the effect of continuing treatment versus discontinuing it. Where there is a reasonable expectation that if treatment services were withdrawn the patient's condition would deteriorate, relapse further, or require hospitalization, this criterion is met.*" (emphasis added) Medicare Hospital Manual, Chapter II, Section 230.5 Hospital Outpatient Psychiatric Services; Medicare Intermediary Manual, Part 3, Chapter II, Section 3112.7 Outpatient Hospital Psychiatric Services.

Our proposed highlighted changes in the attached red-lined version incorporate this CMS language.

II. Section 441.45 (b) (1) and 441.45 (b) (3)

We agree that FFP should not cover foster care, child welfare, education, child care, vocational and prevocational training, housing, parole and probation, juvenile justice or public guardianship services. However, when the regulation prohibits FFP for rehabilitation services that are "intrinsic elements" of these non-medical programs, we are concerned that this could be misinterpreted as prohibiting the positive blending of Medicaid-covered and non-covered services even though such blending can yield important clinical benefits such as facilitating integration, increasing the transferability of skill development in natural settings, and promoting a key principle of evidence-based practices. In addition, the regulation could be misinterpreted to prohibit FFP for mental health rehabilitation services provided as part of a Supported Employment program even though SAMHSA endorses this service protocol as an effective, evidence-based mental health practice. Finally, the regulation's prohibition in 441.45 (b)(3) of FFP for "vocational and prevocational services" could be misinterpreted to prohibit coverage for rehabilitation services that are focused on reducing disability-related symptoms or deficits which create employment barriers. Those types of services are quite different from services which train the individual to perform a job task, but the language does not clarify that important distinction.

The modification we have proposed in the attached red-lined version states that distinguishing funding streams is one concrete way of demonstrating how Medicaid rehabilitation services are not "intrinsic elements" of non-covered programs. As such, services can be blended (which is critical to *flexibility*) as long as funding is "braided" (which is important for *accountability*). In addition, our language clarifies the distinction between vocational services that train individuals to perform job tasks versus rehabilitation services that reduce symptoms which create employment barriers.

III. **440.130 (d) (3)**

The more minor suggestions included in the attached red-lined version relate to clarifying potential confusion around the requirement in (3) (xi) to list "anticipated providers of services" and allowing providers to document reasons if an individual refuses to sign the plan.

In conclusion, we hope that our proposed changes to the regulation represent concrete ways to implement the Commission's recommendation to improve both the accountability and the flexibility of public financing for mental health services as an important part of the broader system's rehabilitation and transformation. We thank

you for considering our comments, and offer to assist in any way in providing additional information or answering any follow-up questions.

Sincerely,

Scott Rose
President/CEO

SUMMARY: EPA proposes to approve the State Implementation Plan (SIP) revision submitted by the Commonwealth of Virginia for the purpose of establishing a variance for the International Paper, Franklin Paper Mill facility located in Franklin, Virginia. The variance provides regulatory relief from compliance with state regulations governing new source review for the implementation of the International Paper, Franklin Paper Mill innovation project. In lieu of compliance with these regulatory requirements, the variance requires the facility to comply with site-wide emission caps. In the Final Rules section of this **Federal Register**, EPA is approving the Commonwealth's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

DATES: Comments must be received in writing by September 12, 2007.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA- R03-OAR-2006-0060 by one of the following methods:

A. http://www.regulations.gov. Follow the on-line instructions for submitting comments.

B. E-mail: cam pbell.dave@epa.gov.

C. *Mail:* EPA-R03-OAR-2006-0060, David Campbell, Chief, Permits and Technical Assessment Branch, Mailcode 3AP11, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information. *Instructions:* Direct your comments to Docket ID No. EPA-R03-OAR-2006- 0060. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at http:// www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business

Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through http:// www.regulations.gov or e-mail. The http://www.regulations.gov Web site is an anonymous access system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through http:// www.regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the http://www.regulations.gov *index.* Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in http:// www.regulations.gov or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Virginia Department of Environmental Quality, 629 East Main Street, Richmond, Virginia, 23219.

FOR FURTHER INFORMATION CONTACT: Sharon McCauley, (215) 814-3376, or by e-mail at *mccauley.sharon@epa.gov.*

SUPPLEMENTARY INFORMATION: For further information, please see the information provided in the direct final action, with the same title, that is located in the Rules and Regulations section of this **Federal Register** publication. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions

of the rule that are not subject of an adverse comment.

Dated: July 31, 2007.

William T. Wisniewski,

Acting Regional Administrator, Region II. [FR Doc. E7-15585 Filed 8-10-07; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 440 and 441

[CMS 2261 -P] RIN 0938-A081

Medicaid Program; Coverage for Rehabilitative Services

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the definition of Medicaid rehabilitative services in order to provide for important beneficiary protections such as a person-centered written rehabilitation plan and maintenance of case records. The proposed rule would also ensure the fiscal integrity of claimed Medicaid expenditures by clarifying the service definition and providing that Medicaid rehabilitative services must be coordinated with but do not include services furnished by other programs that are focused on social or educational development goals and available as part of other services or programs. These services and programs include, but

are not limited to, foster care, child welfare, education, child care, prevocational and vocational services, housing, parole and probation, juvenile justice, public guardianship, and any other non-Medicaid services from Federal, State, or local programs.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on October 12, 2007.

ADDRESSES: In commenting, please refer to file code CMS–2261–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–2261– P, P.O. Box 8018, Baltimore, MD 21244– 8018.

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–2261–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– 3685 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: Maria Reed, (410) 786–2255 or Shawn Terrell, (410) 786–0672.

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–2261–P 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 (for example, names, addresses, social security numbers, and medical diagnoses) or confidential business information (including proprietary 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

A. Overview

Section 1905(a)(13) of the Social Security Act (the Act) includes rehabilitative services as an optional Medicaid State plan benefit. Current Medicaid regulations at 42 CFR 440.130(d) provide a broad definition of rehabilitative services. Rehabilitative services are defined as "any medical or remedial services recommended by a physician or other licensed practitioner of the healing arts, within the scope of his or her practice under State law, for maximum reduction of physical or mental disability and restoration of a recipient to his best possible functional level." The broad general language in this regulatory definition has afforded States considerable flexibility under their State plans to meet the needs of their State's Medicaid population.

Over the years the scope of services States have provided under the rehabilitation benefit has expanded from physical rehabilitative services to also include mental health and substance abuse treatment rehabilitative services. For example, services currently provided by States under the rehabilitative benefit include services aimed at improving physical disabilities, including physical, occupational, and speech therapies; mental health services, such as individual and group therapy, psychosocial therapy services; and services for substance-related disorders (for example, substance use disorders and substance induced disorders). These Medicaid services may be delivered through various models of care and in a variety of settings.

The broad language of the current

statutory and regulatory definition has, however, had some unintended consequences. It has also led to some confusion over whether otherwise applicable statutory or regulatory provider standards would apply under the rehabilitative services benefit.

As the number of States providing rehabilitative services has increased, some States have viewed the rehabilitation benefit as a ''catch-all'' category to cover services included in other Federal, State and local programs. For example, it appears some States have used Medicaid to fund services that are included in the provision of foster care and in the Individuals with Disabilities Education Improvement Act (IDEA). Our audit reviews have recently revealed that Medicaid funds have also been used to pay for behavioral treatment services in ''wilderness camps,'' juvenile detention, and similar facilities where youth are involuntarily confined. These facilities are under the domain of the juvenile justice or youth systems in the State, rather than Medicaid, and there is no assurance that the claimed services reflect an independent evaluation of individual rehabilitative needs.

This proposed regulation is designed to clarify the broad general language of the current regulation to ensure that rehabilitative services are provided in a coordinated manner that is in the best interest of the individuals, are limited to rehabilitative purposes and are furnished by qualified providers. This proposed regulation would rectify the improper reliance on the Medicaid rehabilitation benefit for services furnished by other programs that are focused on social or educational development goals in programs other than Medicaid.

This proposed regulation would provide guidance to ensure that services claimed under the optional Medicaid rehabilitative benefit are in fact rehabilitative out-patient services, are furnished by qualified providers, are provided to Medicaid eligible individuals according to a goal-oriented rehabilitation plan, and are not for services that are included in programs with a focus other than that of Medicaid.

B. Habilitation Services

Section 6411(g) of the Omnibus Budget Reconciliation Act of 1989 (OBRA 89) prohibits us from taking adverse action against States with approved habilitation provisions pending the issuance of a regulation that ''specifies types of day habilitation services that a State may cover under paragraphs (9) (clinic services) or (13) (rehabilitative services) of section 1905(a) of the Act on behalf of persons with mental retardation or with related conditions.'' We believe that issuance of a final rule based on this proposed rule will satisfy this condition. We intend to work with those States that have habilitation programs under the clinic services or rehabilitative services benefits in their State plans to transition to appropriate Medicaid coverage authorities, such as section 1915(c) waivers or the Home and Community-Based Services State plan option under section 1915 (i) of the Deficit Reduction Act (DRA) of 2005 (Pub. L. 107–171), enacted on February 8, 2006.

II. Provisions of the Proposed Rule

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

A. Definitions

In 440.130(d)(1), we propose to define the terms used in this rule, as listed below:

- Recommended by a physician or other licensed practitioner of the healing arts.
- Other licensed practitioner of the healing arts.
- Qualified providers of rehabilitative services.
- Under the direction of.
- Written rehabilitation plan.
- Restorative services.
- Medical services.
- Remedial services.

In § 440.130(d)(1)(iii), we would define ''qualified providers of rehabilitative services'' to require that individuals providing rehabilitative services meet the provider qualification requirements applicable to the same service when it is furnished under other benefit categories. Further, the provider qualifications must be set forth in the Medicaid State plan. These qualifications may include education, work experience, training, credentialing, supervision and licensing, that are applied uniformly. Provider qualifications must be reasonable given the nature of the service provided and the population being served. We require uniform application of these qualifications to ensure the individual free choice of qualified providers, consistent with section 1902(a)(23) of the Act.

Under this proposed definition, if specific provider qualifications are set forth elsewhere in subpart A of part 440, those provider qualifications take precedence when those services are provided under the rehabilitation option. Thus, if a State chooses to provide the various therapies discussed at § 440.110 (physical therapy, occupational therapy, speech, language and hearing services) under § 440.130(d), the requirements of § 440.110 applicable to those services would apply. For example, speech therapy is addressed in regulation at § 440.110(c) with specific provider requirements for speech pathologists and audiologists that must be met. If a State offers speech therapy as a rehabilitative service, the specific provider requirements at § 440.110(c) must be met. It should be noted that the definition of Occupational Therapy in § 440.110 is not correct insofar as the following—Occupational Therapists must be certified through the National Board of Certification for Occupational Therapy, not the American Occupational Therapy Association.

We are proposing a definition of the term ''under the direction of'' because it is a key issue in the provision of therapy services through the rehabilitative services benefit. Therapy services may be furnished by or ''under the direction of'' a qualified provider under the provisions of § 440.110. We are proposing to clarify that the term means that the therapist providing direction is supervising the individual's care which, at a minimum, includes seeing the individual initially, prescribing the type of care to be provided, reviewing the need for continued services throughout treatment, assuming professional responsibility for services provided, and ensuring that all services are medically necessary. The term ''under the direction of'' requires each of these elements; in particular, professional responsibility requires face-to-face contact by the therapist at least at the beginning of treatment and periodically thereafter. Note that this definition applies specifically to providers of physical therapy, occupational therapy, and services for individuals with speech, hearing

and language disorders. This language is not meant to exclude appropriate supervision arrangements for other rehabilitative services.

B. Scope of Services

Consistent with the provision of section 1905(a)(13) of the Act, we have retained the current definition of rehabilitative services in § 440.130(d)(2) as including "medical or remedial services recommended by a physician or other licensed practitioner of the healing arts, within the scope of his practice under State law, for maximum reduction of physical or mental disability and restoration of a recipient to his best possible functional level." We would, however, clarify that rehabilitative services do not include room and board in an institution, consistent with the longstanding CMS interpretation that section 1905(a) of the Act has specifically identified circumstances in which Medicaid would pay for coverage of room and board in an inpatient setting. This interpretation was upheld in *Texas* v. *U.S. Dep't Health and Human Servs.*, 61 F.3d 438 (5th Cir. 1995).

C. Written Rehabilitation Plan

We propose to add a new requirement, at § 440.130(d)(3), that covered rehabilitative services for each individual must be identified under a written rehabilitation plan. This rehabilitation plan would ensure that the services are designed and coordinated to lead to the goals set forth in statute and regulation (maximum reduction of physical or mental disability and restoration to the best possible functional level). It would ensure transparency of coverage and medical necessity determinations, so that the beneficiary, and family or other responsible individuals, would have a clear understanding of the services that are being made available to the beneficiary. In all situations, the ultimate goal is to reduce the duration and intensity of medical care to the least intrusive level possible which sustains health. The Medicaid goal is to deliver and pay for the clinically-appropriate, Medicaid-covered services that would contribute to the treatment goal. It is our expectation that, for persons with mental illnesses and substance-related disorders, the rehabilitation plan would include recovery goals. The rehabilitation plan would establish a basis for evaluating the effectiveness of the care offered in meeting the stated goals. It would provide for a process to involve the beneficiary, and family or other responsible individuals, in the overall management of rehabilitative care. The rehabilitation plan would also document that the services have been determined to be rehabilitative services consistent with the regulatory definition, and will have a timeline, based on the individual's assessed needs and anticipated progress, for reevaluation of the plan, not longer than one year. It is our expectation that the reevaluation of the plan would involve the beneficiary, family, or other responsible individuals and would include a review of whether the goals set forth in the plan are being met and whether each of the services described in the plan has contributed to meeting the stated goals. If it is determined that there has been no measurable reduction of disability and restoration of functional level, any new plan would need to pursue a different rehabilitation strategy including revision of the rehabilitative goals, services and/or methods. It is important to note that this benefit is not a custodial care benefit for individuals with chronic conditions but should result in a change in status. **However, it is also important to note that for some individuals such as those with serious mental illness, "reduction of disability and restoration of functional level" may be measured by comparing the effect of continuing rehabilitation versus discontinuing it. Where there is a reasonable expectation that if rehabilitation services had been withdrawn the individual's condition would have deteriorated, relapsed further, or required hospitalization, this criterion would be met.** The rehabilitation plan should identify the rehabilitation objectives that would be achieved under the plan in terms of measurable reductions in a diagnosed physical or mental disability and in terms of restored functional abilities. We recognize, however, that rehabilitation goals are often contingent on the individual's maintenance of a current level of functioning. In these instances, services that provide assistance in maintaining functioning may be considered rehabilitative only when necessary to help an individual achieve a rehabilitation goal as defined in the rehabilitation plan. **Acceptable rehabilitation goals in these instances could include avoidance of negative outcomes such as hospitalization or achievement of positive outcomes such as community participation.** Services provided primarily in order to maintain a level of functioning in the absence of a rehabilitation goal are not rehabilitation services.

It is our further expectation that the rehabilitation plan be reasonable and based on the individual's diagnosed condition(s) and on the standards of practice for provisions of rehabilitative services to an individual with the individual's condition(s). The rehabilitation plan is not intended to limit or restrict the State's ability to require prior authorization for services. The proposed requirements state that the written rehabilitation plan must:

- Be based on a comprehensive assessment of an individual's rehabilitation needs including diagnoses and presence of a functional impairment in daily living;
- Be developed by qualified provider(s) working within the State scope of practice acts with input from the individual, individual's family, the individual's authorized health care decision maker and/or persons of the individual's choosing;
- Ensure the active participation of the individual, individual's family, the individual's authorized health care decision maker and/or persons of the individual's choosing in the development, review and modification of these goals and services;
- Specify the individual's rehabilitation goals to be achieved, including recovery goals for persons with mental health and/or substance related disorders;
- Specify the physical impairment, mental health and/or substance related disorder that is being addressed;
- Identify the medical and remedial services intended to reduce the identified physical impairment, mental health and/or substance related disorder, **and identify the individuals or agencies responsible for providing**

these services:

- Identify the methods that would be used to deliver services;
- Specify the anticipated outcomes;
- Indicate the frequency, amount and duration of the services;
- Be signed by the individual responsible for developing the rehabilitation plan, or if the individuals refuses to sign the plan, document the reason(s);
- ~~Indicate the anticipated provider(s) of the service(s) and the extent to which the services may be available from alternate provider(s) of the same service;~~
- Specify a timeline for reevaluation of the plan, based on the individual's assessed needs and anticipated progress, but not longer than one year;
- Document that the individual or representative participated in the development of the plan, signed the plan, and received a copy of the rehabilitation plan; and
- Document that the services have been determined to be rehabilitative services consistent with the regulatory definition.

We believe that a written rehabilitation plan would ensure that services are provided within the scope of the rehabilitative services and would increase the likelihood that an individual's disability would be reduced and functional level restored. In order to determine whether a specific service is a covered rehabilitative benefit, it is helpful to scrutinize the purpose of the service as defined in the care plan.

For example, an activity that may appear to be a recreational activity may be rehabilitative if it is furnished with a focus on medical or remedial outcomes to address a particular impairment and functional loss. Such an activity, if provided by a Medicaid qualified provider, could address a physical or mental impairment that would help to increase motor skills in an individual who has suffered a stroke, or help to restore social functioning and personal interaction skills for a person with a mental illness.

We are proposing to require in § 440.130(d)(3)(iii) that the written rehabilitation plan include the active participation of the individual (or the individual's authorized health care decision maker) in the development, review, and reevaluation of the rehabilitation goals and services. We recommend the use of a person-centered planning process. Since the rehabilitation plan identifies recovery-oriented goals, the individual must be at the center of the planning process.

D. Impairments to be Addressed

We propose in § 440.130(d)(4) that rehabilitative services include services provided to an eligible individual to address the individual's physical needs, mental health needs, and/or substance-related disorder treatment needs. Because rehabilitative services are an optional service for adults, a State has flexibility to determine whether rehabilitative services would be limited to certain rehabilitative services (for example, only physical rehabilitative services) or will include rehabilitative treatment for mental health or substance-related disorders as well.

Provision of rehabilitative services to individuals with mental health or substance-related disorders is consistent with the recommendations of the New Freedom Commission on Mental Health. The Commission challenged States, among others, to expand access to quality mental health care and noted that States are at the very center of mental health system transformation. Thus, while States are not required to provide rehabilitative services for treatment of mental health and substance-related disorders, they are encouraged to do so. The Commission noted in its report that, ''[m]ore individuals would recover from even the most serious mental illnesses and emotional disturbances if they had earlier access in their communities to treatment and supports that are evidence-based and tailored to their needs.''

Under existing provisions at § 440.230(a), States are required to provide in the State plan a detailed description of the services to be provided. In reviewing a State plan amendment that proposes rehabilitative services, we would consider whether the proposed services are consistent with the requirements in § 440.130(d) and section 1905(a)(13) of the Act. We would also consider whether the proposed scope of rehabilitative services is ''sufficient in amount, duration and scope to reasonably achieve its purpose'' as required at § 440.230(b). For that analysis, we will review whether any assistive devices, supplies, and equipment necessary to the provision of those services are covered either under the rehabilitative services benefit or elsewhere under the plan.

E. Settings

In §440.130(d)(5), consistent with the provisions of section 1905(a)(13) of the Act, we propose that rehabilitative services may be provided in a facility, home, or other setting. For example, rehabilitative services may be furnished in freestanding outpatient clinics and to supplement services otherwise available as an integral part of the services of facilities such as schools, community mental health centers, or substance abuse treatment centers. Other settings may include the office of qualified independent practitioners, mobile crisis vehicles, and appropriate community settings. The State has the authority to determine in which settings a particular service may be provided. While services may be provided in a variety of settings, the rehabilitative services benefit is not an inpatient benefit. Rehabilitative services do not include room and board in an institutional, community or home setting.

F. Requirements and Limitations for Rehabilitative Services

1. Requirements for Rehabilitative Services

In § 441.45(a), we set forth the assurances required in a State plan amendment that provides for rehabilitative services in this proposed rule. In § 441.45(b) we set forth the expenditures for which Federal financial participation (FFP) would not be available.

As with most Medicaid services, rehabilitative services are subject to the requirements of section 1902(a) of the Act. These include statewideness at section 1902(a)(1) of the Act, comparability at section 1902(a)(10)(B), and freedom of choice of qualified providers at section 1902(a)(23) of the Act. Accordingly, at § 441.45(a)(1), we propose to require that States comport with the listed

requirements.

At § 441.45(a)(2), we propose to require that the State ensure that rehabilitative services claimed for Medicaid payment are only those provided for the maximum reduction of physical or mental disability and restoration of the individual to the best possible functional level.

In § 441.45(a)(3) and (a)(4), we propose to require that providers of the rehabilitative services maintain case records that contain a copy of the rehabilitation plan. We also propose to require that the provider document the following for all individuals receiving rehabilitative services:

- The name of the individual;
- The date of the rehabilitative service or services provided;
- The nature, content, and units of rehabilitative services provided; and
- The progress made toward functional improvement and attainment of the individual's goals.

We believe this information is necessary to establish an audit trail for rehabilitative services provided, and to establish whether or not the services have achieved the maximum reduction of physical or mental disability, and to restore the individual to his or her best possible functional level.

A State that opts to provide rehabilitative services must do so by amending its State plan in accordance with proposed § 441.45(a)(5). The amendment must (1) describe the rehabilitative services proposed to be furnished, (2) specify the provider type and provider qualifications that are reasonably related to each of the rehabilitative services, and (3) specify the methodology under which rehabilitation providers would be paid.

2. Limitations for Rehabilitative Services

In § 441.45(b)(1) through (b)(8) we set forth limitations on coverage of rehabilitative services in this proposed rule.

We propose in § 441.45(b)(1) that coverage of rehabilitative services would not include services that are furnished through a non-medical program as either a benefit or administrative activity, including programs other than Medicaid, such as foster care, child welfare, education, child care, vocational and prevocational training, housing, parole and probation, juvenile justice, or public guardianship. We also propose in § 441.45(b)(1) that coverage of rehabilitative services would not include services that are intrinsic elements of programs other than Medicaid.

It should be noted however, that enrollment in these non-medical programs does not affect eligibility for Title XIX services. Rehabilitation services may be covered by Medicaid if they are not the responsibility of other programs and if all applicable requirements of the Medicaid program are met. <u>One way to demonstrate that Medicaid rehabilitation services are not intrinsic elements of non-covered programs is to clearly and reasonably distinguish the funding stream for the Medicaid rehabilitation services as being identifiably separate from that of the non-covered services.</u> Medicaid rehabilitative services must be coordinated with, but do not include, services furnished by other programs that are focused on social or educational development goals and are available as part of other services or programs. Further, Medicaid rehabilitation services must be available for all participants based on an identified medical need and otherwise would have been provided to the individual outside of the foster care, juvenile justice, parole and probation systems and other non-Medicaid systems. Individuals must have free choice of providers and all willing and qualified providers must be permitted to enroll in Medicaid.

For instance, therapeutic foster care is a model of care, not a medically necessary service defined under Title XIX of the Act. States have used it as an umbrella to package an array of services, some of which may be medically necessary services, some of which are not. In order for a service to be reimbursable by Medicaid, states must specifically define all of the services that are to be provided, provider qualifications, and payment methodology. It is important to note that provider qualifications for those who furnish care to children in foster care must be the same as provider qualifications for those who furnish the same care to children not in foster care. Examples of therapeutic foster care components that would not be Medicaid coverable services include provider recruitment, foster parent training and other such services that are the responsibility of the foster care system.

In § 441.45(b)(2), we propose to exclude FFP for expenditures for habilitation services including those provided to individuals with mental retardation or "related conditions" as defined in the State Medicaid Manual § 4398. Physical impairments and mental health and/or substance related disorder are not considered "related conditions" and are therefore medical conditions for which rehabilitation services may be appropriately provided. As a matter of general usage in the medical community, there is a distinction between the terms "habilitation" and "rehabilitation." Rehabilitation refers to measures used to restore individuals to their best functional levels. The emphasis in covering rehabilitation services is the restoration of a functional ability. Individuals receiving rehabilitation services must have had the capability to perform an activity in the past rather than to actually have performed the activity. For example, a person may not have needed to drive a car in the past, but may have had the capability to do so prior to having the disability.

Habilitation typically refers to services that are for the purpose of helping persons acquire new functional abilities. Current Medicaid policy explicitly covers habilitation services in two ways: (1) When provided in an intermediate care facility for persons with mental retardation (ICF/MR); or (2) when covered under sections 1915(c), (d), or (i) of the Act as a home and community-based service. Habilitation services may also be provided under some 1905(a) service authorities such as Physician services defined at 42 CFR 440.50, Therapy services defined at 42 CFR 440.110 (such as, Physical Therapy, Occupational Therapy, and Speech/Language/Audiology Therapy), and Medical or other remedial care provided by licensed practitioners, defined at 42 CFR 440.60. Habilitative services can also be provided under the 1915(i) State Plan Home and Community Based Services pursuant to the Deficit Reduction Act of 2005. In the late 1980s, the Congress responded to State concerns about disallowances for habilitation services provided under the State's rehabilitative

services benefit by passing section 6411(g) of the OBRA 89. This provision prohibited us from taking adverse actions against States with approved habilitation provisions pending the issuance of a regulation that ''specifies types of day habilitation services that a State may cover under paragraphs (9) [clinic services] or (13) [rehabilitative services] of section 1905(a) of the Act on behalf of persons with mental retardation or with related conditions.'' Accordingly, this regulation would specify that all such habilitation services would not be covered under sections 1905(a)(9) or 1905(a)(13) of the Act. If this regulation is issued in final form, the protections provided to certain States by section 6411(g) of OBRA 89 for day habilitation services will no longer be in force. We intend to provide for a delayed compliance date so that States will have a transition period of the lesser of 2 years or 1 year after the close of the first regular session of the State legislature that begins after this regulation becomes final before we will take enforcement action. This transition period will permit States an opportunity to transfer coverage of habilitation services from the rehabilitation option into another appropriate Medicaid authority. We are available to States as needed for technical assistance during this transition period.

In § 441.45(b)(3), we propose to provide that rehabilitative services would not include recreational and social activities that are not specifically focused on the improvement of physical or mental health impairment and achievement of a specific rehabilitative goal specified in the rehabilitation plan, and provided by a Medicaid qualified provider recognized under State law. We would also specify in this provision that rehabilitative services would not include personal care services; transportation; vocational and prevocational services that are not specifically focused on reducing disability-related symptoms or deficits and that are not provided by a qualified Medicaid provider; or patient education not related to the improvement of physical or mental health impairment and achievement of a specific rehabilitative goal specified in the rehabilitation plan. The first two of these services may be otherwise covered under the State plan. But these services are not primarily focused on rehabilitation, and thus do not meet the definition of medical or remedial services for rehabilitative purposes that would be contained in § 440.130(d)(1).

It is possible that some recreational or social activities are reimbursable as rehabilitative services if they are provided for the purpose allowed under the benefit and meet all the requirements governing rehabilitative services. For example, in one instance the activity of throwing a ball to an individual and having her/him throw it back, may be a recreational activity. In another instance, the activity may be part of a program of physical therapy that is provided by, or under the direction of, a qualified therapist for the purpose of restoring motor skills and balance in an individual who has suffered a stroke. Likewise, for an individual suffering from mental illness, what may appear to be a social activity may in fact be addressing the rehabilitation goal of social skills development as identified in the rehabilitation plan. The service would need to be specifically related to an identified rehabilitative goal as documented in the rehabilitation plan with specific time-limited treatment goals and outcomes. The rehabilitative service would further need to be provided by a qualified provider, be documented in the case record, and meet all requirements of this proposed regulation.

When personal care services are provided during the course of the provision of a rehabilitative service, they are an incidental activity and separate payment may not be made for the performance of the incidental activity. For example, an individual recovering from the effects of a stroke may receive occupational therapy services from a qualified occupational therapy provider under the rehabilitation option to regain the capacity to feed himself or herself. If during the course of those services the individual's clothing becomes soiled and the therapist assists the individual with changing his or her clothing, no separate payment may be made for assisting the individual with dressing under the rehabilitation option. However, FFP may be available for optional State plan personal care services under § 440.167 if provided by an enrolled, qualified personal care services provider.

Similarly, transportation is not within the scope of the definition of rehabilitative services proposed by this regulation since the transportation service itself does not result in the maximum reduction of a physical or mental disability and restoration of the individual to the best possible functional level. However, transportation is a Medicaid covered service and may be billed separately as a medical assistance service under § 440.170, if provided by an enrolled, qualified provider, or may be provided under the Medicaid program as an administrative activity necessary for the proper and efficient administration of the State's Medicaid program.

Generally, vocational services are those that teach specific skills required by an individual to perform tasks associated with performing a job. Prevocational services address underlying habilitative goals that are associated with performing compensated work. To the extent that the primary purpose of these services is to help individuals acquire a specific job skill, and are not provided for the purpose of reducing disability and restoring a person to a previous functional level, they would not be construed as covered rehabilitative services. For example, teaching an individual to cook a meal to train for a job as a chef would not be covered, whereas, teaching an individual to cook in order to re-establish the use of her or his hands or to restore living skills may be coverable. Furthermore, rehabilitative services in support of an individual employed as a chef may be coverable if those services teach the individual how to manage disability-related symptoms or deficits that create employment barriers such as paranoia that causes conflicts with co-workers or depression that causes absences or tardiness. While it may be possible for Medicaid to cover prevocational services when provided under the section 1915(c) of the Act, home and community based services waiver programs, funding for vocational services rests with other, non-Medicaid Federal and State funding sources.

Similarly, the purpose of patient education is one important

determinant to whether the activity is a rehabilitative activity covered under § 440.130(d). While taking classes in an academic setting may increase an individual's integration into the community and enable the individual to learn social skills, the primary purpose of this activity is academic enhancement.

Thus, patient education in an academic setting is not covered under the Medicaid rehabilitation option. On the other hand, some patient education directed towards a specific rehabilitative therapy service may be provided for the purpose of equipping the individual with specific skills that will decrease disability and restore the individual to a previous functioning level. For example, an individual with a mental disorder that manifests with behavioral difficulties may need anger management training to restore his or her ability to interact appropriately with others. These services may be covered under the rehabilitation option if all of the requirements of this regulation are met.

In § 441.45(b)(4), we propose to exclude payment for services, including services that are rehabilitative services that are provided to inmates living in the secure custody of law enforcement and residing in a public institution. An individual is considered to be living in secure custody if serving time for a criminal offense in, or confined involuntarily to, State or Federal prisons, local jails, detention facilities, or other penal facilities. A facility is a public institution when it is under the responsibility of a governmental unit or over which a governmental unit exercises administrative control. Rehabilitative services could be reimbursed on behalf of Medicaid-eligible individuals paroled, on probation, on home release, in foster care, in a group home, or other community placement, that are not part of the public institution system, when the services are identified due to a medical condition targeted under the State's Plan, are not used in the administration of other non-medical programs.

We also propose to exclude payment for services that are provided to residents of an institution for mental disease (IMD), including residents of a community residential treatment facility of over 16 beds, that is primarily engaged in providing diagnosis, treatment, or care of persons with mental illness, and that does not meet the requirements at § 440.160. It appears that in the past, certain States may have provided services under the rehabilitation option to these individuals. Our proposed exclusion of FFP for rehabilitative services provided to these populations is consistent with the statutory requirements in paragraphs (A) and (B) following section 1905(a)(28) of the Act. The statute indicates that "except as otherwise provided in paragraph (16), such term [medical assistance] does not include—

(A)Any such payments with respect to care or services for any individual who is an inmate of a public institution; or

(B)any such payments with respect to care or services for any individual who has not attained 65 years and who is a patient in an IMD." Section 1905(a)(16) of the Act defines as "medical assistance" "* * * inpatient psychiatric hospital services for individuals under age 21 * * *". The Secretary has defined the term "inpatient psychiatric hospital services for individuals under age 21" in regulations at § 440.160 to include "a psychiatric facility which is accredited by the Joint Commission on Accreditation of Healthcare Organizations, the Council on Accreditation of Services for Families and Children, the Commission on Accreditation of Rehabilitation Facilities, or by any other accrediting organization, with comparable standards, that is recognized by the State." Thus, the term "inpatient psychiatric hospital services for individuals under age 21" includes services furnished in accredited children's psychiatric residential treatment facilities that are not hospitals. The rehabilitative services that are provided by the psychiatric hospital or accredited psychiatric residential treatment facility (PRTF) providing inpatient psychiatric services for individuals under age 21 to its residents would be reimbursed under the benefit for inpatient psychiatric services for individuals under age 21 (often referred to as the "psych under 21" benefit), rather than under the rehabilitative services benefit.

In § 441.45(b)(6), we propose to exclude expenditures for room and board from payment under the rehabilitative services option. While rehabilitative services may be furnished in a residential setting that is not an IMD, the benefit provided by section 1905(a)(13) of the Act is primarily intended for community based services. Thus, when rehabilitative services are provided in a residential setting, such as in a residential substance abuse treatment facility of less than 17 beds, delivered by qualified providers, only the costs of the specific rehabilitative services will be covered.

In § 441.45(b)(7), we propose to preclude payment for services furnished for the rehabilitation of an individual who is not Medicaid eligible. This provision reinforces basic program requirements found in section 1905(a) of the Act that require medical assistance to be furnished only to eligible individuals. An "eligible individual" is a person who is eligible for Medicaid and requires rehabilitative services as defined in the Medicaid State plan at the time the services are furnished. The provision of rehabilitative services to non-Medicaid eligible individuals cannot be covered if it relates directly to the non-eligible individual's care and treatment. However, effective rehabilitation of eligible individuals may require some contact with non-eligible individuals. For instance, in developing the rehabilitation plan for a child with a mental illness, it may be appropriate to include the child's parents, who are not eligible for Medicaid, in the process. In addition, counseling sessions for the treatment of the child might include the parents and other non-eligible family members. In all cases, in order for a service to be a Medicaid coverable service, it must be provided to, or directed exclusively toward, the treatment of the Medicaid eligible individual.

Thus, contacts with family members for the purpose of treating the Medicaid eligible individual may be covered by Medicaid. If these other family members or other individuals also are Medicaid eligible and in need of the services covered under the State's rehabilitation plan, Medicaid could pay for the services furnished to them.

In § 441.45(b)(8), we propose that FFP would only be available for claims for services provided to a specific individual that are documented in an individual's case record.

We will work with States to

implement this rule in a timely fashion using existing monitoring and compliance authority.

III. Collection of Information Requirements

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

Section 440.130 Diagnostic, Screening, Preventative, and Rehabilitative Services

This section outlines the scope of service for rehabilitative services provided by States. The services discussed in this section must be provided under a written rehabilitation plan as defined in § 440.130(d)(1)(v). Specifically, § 440.130(d)(3) states that the written rehabilitation plan must meet the following requirements:

(i) Be based on a comprehensive assessment of an individual's rehabilitation needs including diagnoses and presence of a functional impairment in daily living.

(ii) Be developed by a qualified provider(s) working within the State scope of practice act with input from the individual, individual's family, the individual's authorized health care decision maker and/or persons of the individual's choosing.

(iii) Ensure the active participation of the individual, individual's family, the individual's authorized health care decision maker and/or persons of the individual's choosing in the development, review, and modification of these goals and services.

(iv) Specify the individual's rehabilitation goals to be achieved including recovery goals for persons with mental illnesses or substance related disorders.

(v) Specify the physical impairment, mental health and/or substance related disorder that is being addressed.

(vi) Identify the medical and remedial services intended to reduce the identified physical impairment, mental health and/or substance related disorder.

(vii) Identify the methods that will be used to deliver services.

(viii) Specify the anticipated outcomes.

(ix) Indicate the frequency and duration of the services.

(x) Be signed by the individual responsible for developing the rehabilitation plan.

(xi) Indicate the anticipated provider(s) of the service(s) and the extent to which the services may be available from alternate provider(s) of the same service.

(xii) Specify a timeline for reevaluation of the plan, based on the individual's assessed needs and anticipated progress, but not longer than one year.

(xiii) Be reevaluated with the involvement of the beneficiary, family or other responsible individuals.

(xiv) Be reevaluated including a review of whether the goals set forth in the plan are being met and whether each of the services described in the plan has contributed to meeting the stated goals. If it is determined that there has been no measurable reduction of disability and restoration of functional level, any new plan would need to pursue a different rehabilitation strategy including revision of the rehabilitative goals, services and/or methods.

(xv) Document that the individual or representative participated in the development of the plan, signed the plan, and received a copy of the rehabilitation plan.

(xvi) Document that the services have been determined to be rehabilitative services consistent with the regulatory definition.

The burden associated with the requirements in this section is the time and effort put forth by the provider to gather the information and develop a specific written rehabilitation plan. While these requirements are subject to the PRA, we believe they meet the exemption requirements for the PRA found at 5 CFR 1320.3(b)(2), and as such, the burden associated with these requirements is exempt.

Section 441.45 Rehabilitative Services

Section 441.45(a)(3) requires that providers maintain case records that contain a copy of the rehabilitation plan for all individuals.

The burden associated with these requirements is the time and effort put forth by the provider to maintain the case records. While these requirements are subject to the PRA, we believe they meet the exemption requirements for the PRA found at 5 CFR 1320.3(b)(2), and as such, the burden associated with these requirements is exempt.

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

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group, Attn: Melissa Musotto [CMS–2261–P], Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244– 1850; and

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–1321–P], katherine_astrich@omb.eop.gov. Fax (202) 395–6974.

IV. 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.

V. Regulatory Impact

Analysis *A. Overall Impact*

We have examined the impacts 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 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) 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 is a major rule because of the size of the anticipated reduction in Federal financial participation that is estimated to have an economically significant effect of more than $100 million in each of the Federal fiscal years 2008 through 2012.

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. The Secretary certifies that this major rule would not have a direct impact on providers of rehabilitative services that furnish services pursuant to section 1905(a)(13) of the Act. The rule would directly affect states and we do not know nor can we predict the manner in which states would adjust or respond to the provisions of this rule. CMS is unable to determine the percentage of providers of rehabilitative services that are considered small businesses according to the Small Business Administration's size standards with total revenues of $6.5 million to $31.5 million or less in any 1 year. Individuals and States are not included in the definition of a small entity. 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 (proposed documents) 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 Medicaid payment regulations and has fewer than 100 beds. The Secretary certifies that this major rule would not have a direct impact on small rural hospitals. The rule would directly affect states and we do not know nor can we predict the manner in which states would adjust or respond to the provisions of this rule.

Section 202 of the Unfunded Mandates Reform Act (UMRA) 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. Since this rule would not mandate spending in any 1 year of $120 million or more, the requirements of the UMRA are not applicable.

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 rule would not impose any costs on State or local governments, preempt State law, or otherwise have Federalism implications, the requirements of E.O. 13132 are not applicable.

B. Anticipated Effects

FFP will be available for rehabilitative services for treatment of physical, mental health, or substance-related disorder rehabilitation treatment if the State elects to provide those services through the approved State plan. Individuals retain the right to select among qualified providers of rehabilitative services. However, because FFP will be excluded for rehabilitative services that are included in other Federal, State and local programs, it is estimated that Federal Medicaid spending on rehabilitative services would be reduced by approximately $180 million in FY 2008 and would be reduced by $2.2 billion between FY 2008 and FY 2012. This reduction in spending is expected to occur because FFP for rehabilitative services would no longer be paid to inappropriate other third parties or other Federal, State, or local programs.

The estimated impact on Federal Medicaid spending was calculated starting with an estimate of rehabilitative service spending that may be subject to this rule. This estimate was developed after consulting with several experts, as data for rehabilitative services, particularly as it would apply to this rule, is limited. Given this estimate, the actuaries discounted this amount to account for four factors: (1) The ability of CMS to effectively identify the rehabilitative services spending that would be subject to this proposal; (2) the effectiveness of CMS's efforts to implement this rule and the potential that some identified rehabilitative services spending may still be permissible under the rule; (3) the change in States' plans that may regain some of the lost Federal funding; and (4) the length of time for CMS to fully implement the rule and review all States' plans.

The actual impact to the Federal Medicaid program may be different than the estimate to the extent that the estimate of the amount of rehabilitative services spending subject to this rule is different than the actual amount and to the extent that the effectiveness of the rule is greater than or less than assumed. Because a comprehensive review of these rehabilitative services had not been conducted at the time of this estimate and because we do not routinely collect data on spending for rehabilitative services, particularly as it relates to this rule, there is a significantly wide range of possible impacts.

Thus, we are unable to determine what fiscal impact the publication of this rule would have on consumers, individual industries, Federal, State, or local government agencies or geographic regions under Executive Order 12866. We invite public comment on the potential impact of the rule.

C. Alternatives Considered

This proposed rule would amend

the definition of rehabilitative services to provide for important individual protections and to clarify that Medicaid rehabilitative services must be coordinated with but do not include services furnished by other programs that are focused on social or educational development goals and available as part of other services or programs. We believe this proposed rule is the best approach to clarifying the covered rehabilitative services, and also because all stakeholders will have the opportunity to comment on the proposed rule. These comments will then be considered before the final document is published.

In considering regulatory options, we considered requiring States to license all providers as an alternative to only requiring that providers to be qualified as defined by the State. However we believe that giving States the flexibility to determine how providers are credentialed allows for necessary flexibility to States to consider a wide range of provider types necessary to cover a variety of rehabilitation services. We believe this flexibility will result in decreases in administrative and service costs.

We also considered restricting the rule to only include participant protections but not explicitly prohibiting FFP for services that are intrinsic elements of other non-Medicaid programs. Had we not prohibited FFP for services that are intrinsic elements of other programs, States would continue to provide non-Medicaid services to participants, the result would have been a less efficient use of Medicaid funding because increased Medicaid spending would not result in any increase in services to beneficiaries. Instead, increased Medicaid funding would have simply replaced other sources of funding.

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 savings associated with the provisions of this proposed rule. This table provides our best estimate of the savings to the Federal Government as a result of the changes presented in this proposed rule that Federal Medicaid spending on rehabilitative services would be reduced by approximately $180 million in FY 2008 and would be reduced by $2.24 billion between FY 2008 and FY 2012. All savings are classified as transfers from the Federal Government to State Government. These transfers represent a reduction in the federal share of Medicaid spending once the rule goes into effect, as it would limit States from claiming Medicaid reimbursement for rehabilitation services that could be covered through other programs.

ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED SAVINGS, FROM FY 2008 TO FY 2012
[In millions]

Category	Primary estimates	Year dollar	Units discount rate	Period covered
Federal Annualized Monetized ($millions/year)	**443.4**	**2008**	7%	2008–2012
	441.6	**2008**	3%	2008–2012
	448	**2008**	0%	2008–2012
From Whom to Whom?	**Federal Government to State Government**			

Column 1: Category—Contains the description of the different impacts of the rule; it could include monetized, quantitative but not monetized, or qualitative but not quantitative or monetized impacts; it also may contain unit of measurement (such as, dollars). In this case, the only impact is the Federal annualized monetized impact of the rule.

Column 2: Primary Estimate—Contains the quantitative or qualitative impact of the rule for the respective category of impact. Monetized amounts are generally shown in real dollar terms. In this case, the federalized annualized monetized primary estimate represents the equivalent amount that, if paid (saved) each year over the period covered, would result in the same net present value of the stream of costs (savings) estimated over the period covered.

Column 3: Year Dollar—Contains the year to which dollars are normalized; that is, the first year that dollars are discounted in the estimate.

Column 4: Unit Discount Rate—Contains the discount rate or rates used to estimate the annualized monetized impacts. In this case, three rates are used: 7 percent; 3 percent; 0 percent.

Column 5: Period Covered—Contains the years for which the estimate was made.

Rows: The rows contain the estimates associated with each specific impact and each discount rate used.

"From Whom to Whom?"—In the case of a transfer (as opposed to a change in aggregate social welfare as described in the OMB Circular), this section describes the parties involved in the transfer of costs. In this case, costs previously paid for by the Federal Government would be transferred to the State Governments. The table may also contain minimum and maximum estimates and sources cited. In this case, there is only a primary estimate and there are no additional sources for the estimate.

Estimated Savings—The following table shows the discounted costs (savings) for each discount rate and for each year over the period covered. "Total" represents the net present value of the impact in the year the rule takes effect. These numbers represent the anticipated annual reduction in Federal Medicaid spending under this rule.

ESTIMATED SAVINGS, FROM FY 2008 TO FY 2012
[In millions]

Discount rate (percent)	2008	2009	2010	2011	2012	Total
0	180	360	520	570	610	2,288
3	175	339	476	506	526	2,069
7	168	314	424	435	435	1,822

E. Conclusion

For these reasons, we are not preparing analyses for either the RFA or section 110 2(b) of the Act because a comprehensive review of these rehabilitative services had not been conducted at the time of this estimate and because we do not routinely collect data on spending for rehabilitative services. Accordingly, there is a significantly wide range of possible impacts due to this rule. As indicated in the Estimated Savings table above, we project an estimated savings of $180 million in FY 2008, $360 million in FY 2009, $520 million in FY 2010, $570 million in FY 2011, and $610 million in FY 2012. This reflects a total estimated savings of $2.240 billion dollars for FY 2008 through FY 2012. We invite public comment on the potential impact of this rule.

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

List of Subjects

42 CFR Part 440

Grant programs—health, Medicaid.

42 CFR Part 441

Family planning, Grant programs— health, Infants and children, Medicaid, Penalties, Prescription drugs, 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 440—SERVICES: GENERAL PROVISIONS

1. The authority citation for part 440 continues to read as follows:

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

2. Section 440.130 is amended by revising paragraph (d) to read as follows:

§ 440.130 Diagnostic, screening, preventative, and rehabilitative services.

* * * * *

(d) *Rehabilitative Services—(1) Definitions.* For purposes of this subpart, the following definitions apply:

(i) *Recommended by a physician or other licensed practitioner of the healing arts* means that a physician or other licensed practitioner of the healing arts, based on a comprehensive assessment of the individual, has—

(A) Determined that receipt of rehabilitative services would result in reduction of the individual's physical or mental disability and restoration to the best possible functional level of the individual; and

(B) Recommended the rehabilitative services to achieve specific individualized goals.

(ii) *Other licensed practitioner of the healing arts* means any health practitioner or practitioner of the healing arts who is licensed in the State to diagnose and treat individuals with the physical or mental disability or functional limitations at issue, and operating within the scope of practice defined in State law.

(iii) *Qualified providers of rehabilitative services* means individuals who meet any applicable provider qualifications under Federal law that would be applicable to the same service when it is furnished under other Medicaid benefit categories, qualifications under applicable State scope of practice laws, and any additional qualifications set forth in the Medicaid State plan. These qualifications may include minimum age requirements, education, work experience, training, credentialing, supervision and licensing requirements that are applied uniformly. Provider qualifications must be documented in the State plan and be reasonable given the nature of the service provided and the population served. Individuals must have free choice of providers and all willing and qualified providers must be permitted to enroll in Medicaid.

(iv) *Under the direction of* means that for physical therapy, occupational therapy, and services for individuals with speech, hearing and language disorders (see § 440.110, ''Inpatient hospital services, other than services in an institution for mental diseases'') the Medicaid qualified therapist providing direction is a licensed practitioner of the healing arts qualified under State law to diagnose and treat individuals with the disability or functional limitations at issue, is working within the scope of practice defined in State law and is supervising each individual's care. The supervision must include, at a minimum, face-to-face contact with the individual initially and periodically as needed, prescribing the services to be provided, and reviewing the need for continued services throughout the course of treatment. The qualified therapist must also assume professional responsibility for the services provided and ensure that the services are medically necessary. Therapists must spend as much time as necessary directly supervising services to ensure beneficiaries are receiving services in a safe and efficient manner in accordance with accepted standards of practice. Moreover, documentation must be kept supporting the supervision of services and ongoing involvement

in the treatment. Note that this definition applies specifically to providers of physical therapy, occupational therapy, and services for individuals with speech, hearing and language disorders. This language is not meant to exclude appropriate supervision arrangements for other rehabilitative services.

(v) *Rehabilitation plan* means a written plan that specifies the physical impairment, mental health and/or substance related disorder to be addressed, the individualized rehabilitation goals and the medical and remedial services to achieve those goals. The plan is developed by a qualified provider(s) working within the State scope of practice act, with input from the individual, individual's family, the individual's authorized decision maker and/or of the individual's choosing and also ensures the active participation of the individual, individual's family, individual's authorized decision maker and/or of the individual's choosing in the development, review, and modification of the goals and services. The plan must document that the services have been determined to be rehabilitative services consistent with the regulatory definition. The plan must have a timeline, based on the individual's assessed needs and anticipated progress, for reevaluation of the plan, not longer than one year. The plan must be reasonable and based on the individual's condition(s) and on general standards of practice for provision of rehabilitative services to an individual with the individual's condition(s).

(vi) *Restorative services* means services that are provided to an individual who has had a functional loss and has a specific rehabilitative goal toward regaining that function. The emphasis in covering rehabilitation services is on the ability to perform a function rather than to actually have performed the function in the past. For example, a person may not have needed to take public transportation in the past, but may have had the ability to do so prior to having the disability. Rehabilitation goals are often contingent on the individual's maintenance of a current level of functioning. In these instances services that provide assistance in maintaining functioning may be considered rehabilitative only when necessary to help an individual achieve a rehabilitation goal defined in the rehabilitation plan. <u>Acceptable rehabilitation goals in these instances could include avoidance of negative outcomes such as hospitalization or achievement of positive outcomes such as community participation.</u> Services provided primarily in order to maintain a level of functioning in the absence of a rehabilitation goal are not within the scope of rehabilitation services.

(vii) *Medical services* means services specified in the rehabilitation plan that are required for the diagnosis, treatment, or care of a physical or mental disorder and are recommended by a physician or other licensed practitioner of the healing arts within the scope of his or her practice under State law. Medical services may include physical therapy, occupational therapy, speech therapy, and mental health and substance-related disorder rehabilitative services.

(viii) *Remedial services* means services that are intended to correct a physical or mental disorder and are necessary to achieve a specific rehabilitative goal specified in the individual's rehabilitation plan.

(2) *Scope of services.* Except as otherwise provided under this subpart, rehabilitative services include medical or remedial services recommended by a physician or other licensed practitioner of the healing arts, within the scope of his practice under State law, for maximum reduction of physical or mental disability and restoration of a individual to the best possible functional level. Rehabilitative services may include assistive devices, medical equipment and supplies, not otherwise covered under the plan, which are determined necessary to the achievement of the individual's rehabilitation goals. Rehabilitative services do not include room and board in an institution or community setting.

(3) *Written rehabilitation plan.* The written rehabilitation plan shall be reasonable and based on the individual's condition(s) and on the standards of practice for provision of rehabilitative services to an individual with the individual's condition(s). In addition, the written rehabilitation plan must meet the following requirements:

(i) Be based on a comprehensive assessment of an individual's rehabilitation needs including diagnoses and presence of a functional impairment in daily living.

(ii) Be developed by a qualified provider(s) working within the State scope of practice act with input from the individual, individual's family, the individual's authorized health care decision maker and/or persons of the individual's choosing.

(iii) Follow guidance obtained through the active participation of the individual, and/or persons of the individual's choosing (which may include the individual's family and the individual's authorized health care decision maker), in the development, review, and modification of plan goals and services.

(iv) Specify the individual's rehabilitation goals to be achieved, including recovery goals for persons with mental health and/or substance related disorders.

(v) Specify the physical impairment, mental health and/or substance related disorder that is being addressed.

(vi) Identify the medical and remedial services intended to reduce the identified physical impairment, mental health and/or substance related disorder, **<u>and identify the individuals or agencies responsible for providing these services.</u>**

(vii) Identify the methods that will be used to deliver services.

(viii) Specify the anticipated outcomes.

(ix) Indicate the frequency, amount and duration of the

services.

(x) Be signed by the individual responsible for developing the rehabilitation plan, and if the individual refuses to sign the plan, document the reason(s).

(xi) ~~Indicate the anticipated provider(s) of the service(s) and the extent to which the services may be available from alternate provider(s) of the same service~~.

(xii) Specify a timeline for reevaluation of the plan, based on the individual's assessed needs and anticipated progress, but not longer than one year.

(xiii) Be reevaluated with the involvement of the individual, family or other responsible individuals.

(xiv) Be reevaluated including a review of whether the goals set forth in the plan are being met and whether each of the services described in the plan has contributed to meeting the stated goals. If it is determined that there has been no measurable reduction of disability and restoration of functional level, any new plan would need to pursue a different rehabilitation strategy including revision of the rehabilitative goals, services and/or methods. For some individuals such as those with serious mental illness, "reduction of disability and restoration of functional level" may be measured by comparing the effect of continuing rehabilitation versus discontinuing it. Where there is a reasonable expectation that if the rehabilitation services had been withdrawn the individual's condition would have deteriorated, relapsed further, or required hospitalization, this criterion would be met.

(xiv) Document that the individual or representative participated in the development of the plan, signed the plan, and received a copy of the rehabilitation plan.

(xv) Document that the services have been determined to be rehabilitative services consistent with the regulatory definition.

(xvi) Include the individual's relevant history, current medical findings, contraindications and identify the individual's care coordination needs, if any, as needed to achieve the rehabilitation goals.

(4) *Impairments to be addressed.* For purposes of this section, rehabilitative services include services provided to the Medicaid eligible individual to address the individual's physical impairments, mental health impairments, and/or substance-related disorder treatment needs.

(5) *Settings.* Rehabilitative services may be provided in a facility, home, or other setting.

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

1. The authority citation for part 441 continues to read as follows:

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

Subpart A—General Provisions

2. A new § 441.45 is added to subpart A to read as follows:

§441.45 Rehabilitative services.

(a) If a State covers rehabilitative services, as defined in § 440.130(d) of this chapter, the State must meet the following requirements:

(1) Ensure that services are provided in accordance with § 431.50, § 431.51, § 440.230, and § 440.240 of this chapter.

(2) Ensure that rehabilitative services are limited to services furnished for the maximum reduction of physical or mental disability and restoration of the individual to their best possible functional level.

(3) Require that providers maintain case records that contain a copy of the rehabilitation plan for all individuals.

(4) For all individuals receiving rehabilitative services, require that providers maintain case records that include the following:

(i) A copy of the rehabilitative plan.

(ii) The name of the individual.

(iii) The date of the rehabilitative services provided.

(iv) The nature, content, and units of the rehabilitative services.

(v) The progress made toward functional improvement and attainment of the individual's goals as identified in the rehabilitation plan and case record.

(5) Ensure the State plan for rehabilitative services includes the following requirements:

(i) Describes the rehabilitative services furnished.

(ii) Specifies provider qualifications that are reasonably related to the rehabilitative services proposed to be furnished.

(iii) Specifies the methodology under which rehabilitation providers are paid.

(b) Rehabilitation does not include, and FFP is not available in expenditures for, services defined in § 440.130(d) of this chapter if the following conditions exist:

(1) The services are furnished through a non-medical program as either a benefit or administrative activity, including services that are intrinsic elements of programs other than Medicaid, such as foster care, child welfare, education, child care, vocational and prevocational training, housing, parole and probation, juvenile justice, or public guardianship. Services would not be considered to be intrinsic elements of these non-medical programs if they are medically necessary rehabilitation services for an eligible individual that are clearly distinct from the non-covered program services and that are provided by qualified Medicaid providers. One way to demonstrate this distinction is to clearly and reasonably distinguish the funding stream for the Medicaid rehabilitation services as being identifiably separate from that of the non-covered services. Examples of services that are intrinsic elements of other programs and that would not be paid under Medicaid include, but are not limited to, the following:

(i) Therapeutic foster care services furnished by foster care providers to children, except for

medically necessary rehabilitation services for an eligible child that are clearly distinct from packaged therapeutic foster care services and that are provided by qualified Medicaid providers.

(ii) Packaged services furnished by foster care or child care institutions for a foster child except for medically necessary rehabilitation services for an eligible child that are clearly distinct from packaged therapeutic foster care services and that are provided by qualified Medicaid providers.

(iii) Adoption services, family preservation, and family reunification services furnished by public or private social services agencies.

(iv) Routine supervision and non-medical support services provided by teacher aides in school settings (sometimes referred to as "classroom aides" and "recess aides").

(2) Habilitation services, including services for which FFP was formerly permitted under the Omnibus Budget Reconciliation Act of 1989. Habilitation services include "services provided to individuals" with mental retardation or related conditions. (Most physical impairments, and mental health and/or substance related disorders, are not included in the scope of related conditions, so rehabilitation services may be appropriately provided.)

(3) Recreational or social activities that are not focused on rehabilitation and not provided by a Medicaid qualified provider; personal care services; transportation; vocational and prevocational services **that are not focused on reducing disability-related symptoms or deficits and not provided by a qualified Medicaid provider**; or patient education not related to reduction of physical or mental disability and the restoration of an individual to his or her best possible functional level.

(4) Services that are provided to inmates living in the secure custody of law enforcement and residing in a public institution. An individual is considered to be living in secure custody if serving time for a criminal offence in, or confined involuntarily to, public institutions such as State or Federal prisons, local jails, detention facilities, or other penal facilities. A facility is a public institution when it is under the responsibility of a governmental unit; or over which a governmental unit exercises administrative control. Rehabilitative services could be reimbursed on behalf of Medicaid-eligible individuals paroled, on probation, on home release, in foster care, in a group home, or other community placement, that are not part of the public institution system, when the services are identified due to a medical condition targeted under the State's Plan, are not used in the administration of other non-medical programs.

(5) Services provided to residents of an institution for mental disease (IMD) who are under the age of 65, including residents of community residential treatment facilities with more than 16 beds that do not meet the requirements at § 440.160 of this chapter.

(6)Room and board.

(7) Services furnished for the treatment of an individual who is not Medicaid eligible.

(8) Services that are not provided to a specific individual as documented in an individual's case record.

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

Dated: March 22, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: July 12, 2007.

Michael O. Leavitt,

Secretary.

[FR Doc. 07–3925 Filed 8–8–07; 4:00 pm] BILLING CODE 4120-01-P

October 10, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-2261-P,
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-2261-P; PUBLIC COMMENT REGARDING PROPOSED AMENDMENT TO 42 CFR PARTS 440 AND 441: Medicaid Program- Coverage for Rehabilitative Services

TO WHOM IT MAY CONCERN:

Way Station is a 30 year-old not-for-profit organization in Maryland that provides comprehensive community-based mental health services to over 7,000 individuals each year, approximately 4,000 of whom are Medicaid recipients. We thank you for the opportunity to give input, and we submit the following comments which we believe will achieve the *accountability* that CMS seeks while at the same time assuring the *flexibility* that individuals with serious mental illness need – both of which the New Freedom Commission noted as being critical aspects of effective public mental healthcare financing. (*Final Report*, at 23). Attached to this letter is a red-lined version of the regulation and preamble, showing our proposed modifications in the yellow highlighted sections.

I. <u>Section 440.130 (d) (1)(vi) and Section 440.130 (d) (3) (xiv)</u>

We are concerned that the proposed language defining "restorative services" and the rehabilitation plan requirement for reevaluation of "measurable reduction of disability and restoration of functional ability" could be misinterpreted to prohibit coverage for long-term rehabilitation services for adults with serious mental illness that are provided toward goals of living in the community without intermittent hospitalization or of reducing symptoms to avoid hospitalization. While such individuals may choose the type of goals that involve positive outcomes such as employment or formal education, others may choose the type that involve reducing symptoms and avoiding negative outcomes such as hospitalization. The New Freedom Commission views both types of goals as being recovery-oriented as both are included in the Commission's definition of "recovery." (*Id.* at 5) Furthermore, for many individuals with serious mental illness and histories of multiple hospitalizations, the latter type of goal can be just as ambitious as the former, and avoiding hospitalization can be substantial progress in and of itself.

To provide the necessary clarification, we propose that CMS add language that it has used in other program transmittals in which it clarified how to apply the requirement of treatment improvement to individuals with serious mental illness. In two different Medicare program transmittals, CMS used this definition:

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9030 Route 108, Suite A / Columbia, Maryland 21045 / 410—740-8262 / Toll Free 877-381-5482 / Fax 410-740-8237
25 East North Avenue, Hagerstown, MD 21740 / 301-733-6063 / Fax 301-733-6220

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"Reasonable Expectation of Improvement – Services must be for the purpose of diagnostic study or reasonably be expected to improve the patient's condition. The treatment must, at a minimum, be designed to reduce or control the patient's psychiatric symptoms so as to prevent relapse or hospitalization, and improve or maintain the patient's level of functioning. It is not necessary that a course of therapy has as its goal restoration of the patient to the level of functioning exhibited prior to the onset of the illness, although this may be appropriate for some patients. *For many other psychiatric patients, particularly those with long-term, chronic conditions, control of symptoms and maintenance of a functional level to avoid further deterioration or hospitalization is an acceptable expectation of improvement. "Improvement" in this context is measured by comparing the effect of continuing treatment versus discontinuing it. Where there is a reasonable expectation that if treatment services were withdrawn the patient's condition would deteriorate, relapse further, or require hospitalization, this criterion is met.*" (emphasis added) Medicare Hospital Manual, Chapter II, Section 230.5 Hospital Outpatient Psychiatric Services; Medicare Intermediary Manual, Part 3, Chapter II, Section 3112.7 Outpatient Hospital Psychiatric Services.

Our proposed highlighted changes in the attached red-lined version incorporate this CMS language.

II. **Section 441.45 (b) (1) and 441.45 (b) (3)**

We agree that FFP should not cover foster care, child welfare, education, child care, vocational and prevocational training, housing, parole and probation, juvenile justice or public guardianship services. However, when the regulation prohibits FFP for rehabilitation services that are "intrinsic elements" of these non-medical programs, we are concerned that this could be misinterpreted as prohibiting the positive blending of Medicaid-covered and non-covered services even though such blending can yield important clinical benefits such as facilitating integration, increasing the transferability of skill development in natural settings, and promoting a key principle of evidence-based practices. In addition, the regulation could be misinterpreted to prohibit FFP for mental health rehabilitation services provided as part of a Supported Employment program even though SAMHSA endorses this service protocol as an effective, evidence-based mental health practice. Finally, the regulation's prohibition in 441.45 (b)(3) of FFP for "vocational and prevocational services" could be misinterpreted to prohibit coverage for rehabilitation services that are focused on reducing disability-related symptoms or deficits which create employment barriers. Those types of services are quite different from services which train the individual to perform a job task, but the language does not clarify that important distinction.

The modification we have proposed in the attached red-lined version states that distinguishing funding streams is one concrete way of demonstrating how Medicaid rehabilitation services are not "intrinsic elements" of non-covered programs. As such, services can be blended (which is critical to *flexibility*) as long as funding is "braided" (which is important for *accountability*). In addition, our language clarifies the distinction between vocational services that train individuals to perform job tasks versus rehabilitation services that reduce symptoms which create employment barriers.

III. **440.130 (d) (3)**

The more minor suggestions included in the attached red-lined version relate to clarifying potential confusion around the requirement in (3) (xi) to list "anticipated providers of services" and allowing providers to document reasons if an individual refuses to sign the plan.

In conclusion, we hope that our proposed changes to the regulation represent concrete ways to implement the Commission's recommendation to improve both the accountability and the flexibility of public financing for mental health services as an important part of the broader system's rehabilitation and transformation. We thank

you for considering our comments, and offer to assist in any way in providing additional information or answering any follow-up questions.

Sincerely,

Scott Rose
President/CEO

SUMMARY: EPA proposes to approve the State Implementation Plan (SIP) revision submitted by the Commonwealth of Virginia for the purpose of establishing a variance for the International Paper, Franklin Paper Mill facility located in Franklin, Virginia. The variance provides regulatory relief from compliance with state regulations governing new source review for the implementation of the International Paper, Franklin Paper Mill innovation project. In lieu of compliance with these regulatory requirements, the variance requires the facility to comply with site-wide emission caps. In the Final Rules section of this **Federal Register**, EPA is approving the Commonwealth's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

DATES: Comments must be received in writing by September 12, 2007.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA- R03-OAR-2006-0060 by one of the following methods:

A. *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.

B. E-mail: cam pbell.dave@epa.gov.

C. *Mail:* EPA-R03-OAR-2006-0060, David Campbell, Chief, Permits and Technical Assessment Branch, Mailcode 3AP11, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information. *Instructions:* Direct your comments to Docket ID No. EPA-R03-OAR-2006- 0060. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *http:// www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http:// www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an anonymous access system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http:// www.regulations.gov,* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the *http://www.regulations.gov index.* Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *http:// www.regulations.gov* or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Virginia Department of Environmental Quality, 629 East Main Street, Richmond, Virginia, 23219.

FOR FURTHER INFORMATION CONTACT: Sharon McCauley, (215) 814-3376, or by e-mail at *mccauley.sharon@epa.gov.*

SUPPLEMENTARY INFORMATION: For further information, please see the information provided in the direct final action, with the same title, that is located in the Rules and Regulations section of this **Federal Register** publication. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions

of the rule that are not subject of an adverse comment.

Dated: July 31, 2007.

William T. Wisniewski,

Acting Regional Administrator, Region II. [FR Doc. E7-15585 Filed 8-10-07; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 440 and 441

[CMS 2261 -P] RIN 0938-A081

Medicaid Program; Coverage for Rehabilitative Services

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the definition of Medicaid rehabilitative services in order to provide for important beneficiary protections such as a person-centered written rehabilitation plan and maintenance of case records. The proposed rule would also ensure the fiscal integrity of claimed Medicaid expenditures by clarifying the service definition and providing that Medicaid rehabilitative services must be coordinated with but do not include services furnished by other programs that are focused on social or educational development goals and available as part of other services or programs. These services and programs include, but

are not limited to, foster care, child welfare, education, child care, prevocational and vocational services, housing, parole and probation, juvenile justice, public guardianship, and any other non-Medicaid services from Federal, State, or local programs.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on October 12, 2007.

ADDRESSES: In commenting, please refer to file code CMS-2261-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-2261- P, P.O. Box 8018, Baltimore, MD 21244- 8018.

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-2261-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- 3685 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: Maria Reed, (410) 786-2255 or Shawn Terrell, (410) 786-0672.

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-2261-P 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 (for example, names, addresses, social security numbers, and medical diagnoses) or confidential business information (including proprietary 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

A. Overview

Section 1905(a)(13) of the Social Security Act (the Act) includes rehabilitative services as an optional Medicaid State plan benefit. Current Medicaid regulations at 42 CFR 440.130(d) provide a broad definition of rehabilitative services. Rehabilitative services are defined as "any medical or remedial services recommended by a physician or other licensed practitioner of the healing arts, within the scope of his or her practice under State law, for maximum reduction of physical or mental disability and restoration of a recipient to his best possible functional level." The broad general language in this regulatory definition has afforded States considerable flexibility under their State plans to meet the needs of their State's Medicaid population.

Over the years the scope of services States have provided under the rehabilitation benefit has expanded from physical rehabilitative services to also include mental health and substance abuse treatment rehabilitative services. For example, services currently provided by States under the rehabilitative benefit include services aimed at improving physical disabilities, including physical, occupational, and speech therapies; mental health services, such as individual and group therapy, psychosocial therapy services; and services for substance-related disorders (for example, substance use disorders and substance induced disorders). These Medicaid services may be delivered through various models of care and in a variety of settings.

The broad language of the current

statutory and regulatory definition has, however, had some unintended consequences. It has also led to some confusion over whether otherwise applicable statutory or regulatory provider standards would apply under the rehabilitative services benefit.

As the number of States providing rehabilitative services has increased, some States have viewed the rehabilitation benefit as a ''catch-all'' category to cover services included in other Federal, State and local programs. For example, it appears some States have used Medicaid to fund services that are included in the provision of foster care and in the Individuals with Disabilities Education Improvement Act (IDEA). Our audit reviews have recently revealed that Medicaid funds have also been used to pay for behavioral treatment services in ''wilderness camps,'' juvenile detention, and similar facilities where youth are involuntarily confined. These facilities are under the domain of the juvenile justice or youth systems in the State, rather than Medicaid, and there is no assurance that the claimed services reflect an independent evaluation of individual rehabilitative needs.

This proposed regulation is designed to clarify the broad general language of the current regulation to ensure that rehabilitative services are provided in a coordinated manner that is in the best interest of the individuals, are limited to rehabilitative purposes and are furnished by qualified providers. This proposed regulation would rectify the improper reliance on the Medicaid rehabilitation benefit for services furnished by other programs that are focused on social or educational development goals in programs other than Medicaid.

This proposed regulation would provide guidance to ensure that services claimed under the optional Medicaid rehabilitative benefit are in fact rehabilitative out-patient services, are furnished by qualified providers, are provided to Medicaid eligible individuals according to a goal-oriented rehabilitation plan, and are not for services that are included in programs with a focus other than that of Medicaid.

B. Habilitation Services

Section 6411(g) of the Omnibus Budget Reconciliation Act of 1989 (OBRA 89) prohibits us from taking adverse action against States with approved habilitation provisions pending the issuance of a regulation that ''specifies types of day habilitation services that a State may cover under paragraphs (9) (clinic services) or (13) (rehabilitative services) of section 1905(a) of the Act on behalf of persons with mental retardation or with related conditions.'' We believe that issuance of a final rule based on this proposed rule will satisfy this condition. We intend to work with those States that have habilitation programs under the clinic services or rehabilitative services benefits in their State plans to transition to appropriate Medicaid coverage authorities, such as section 1915(c) waivers or the Home and Community-Based Services State plan option under section 1915 (i) of the Deficit Reduction Act (DRA) of 2005 (Pub. L. 107–171), enacted on February 8, 2006.

II. Provisions of the Proposed Rule

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

A. Definitions

In 440.130(d)(1), we propose to define the terms used in this rule, as listed below:

- Recommended by a physician or other licensed practitioner of the healing arts.
- Other licensed practitioner of the healing arts.
- Qualified providers of rehabilitative services.
- Under the direction of.
- Written rehabilitation plan.
- Restorative services.
- Medical services.
- Remedial services.

In § 440.130(d)(1)(iii), we would define ''qualified providers of rehabilitative services'' to require that individuals providing rehabilitative services meet the provider qualification requirements applicable to the same service when it is furnished under other benefit categories. Further, the provider qualifications must be set forth in the Medicaid State plan. These qualifications may include education, work experience, training, credentialing, supervision and licensing, that are applied uniformly. Provider qualifications must be reasonable given the nature of the service provided and the population being served. We require uniform application of these qualifications to ensure the individual free choice of qualified providers, consistent with section 1902(a)(23) of the Act.

Under this proposed definition, if specific provider qualifications are set forth elsewhere in subpart A of part 440, those provider qualifications take precedence when those services are provided under the rehabilitation option. Thus, if a State chooses to provide the various therapies discussed at § 440.110 (physical therapy, occupational therapy, speech, language and hearing services) under § 440.130(d), the requirements of § 440.110 applicable to those services would apply. For example, speech therapy is addressed in regulation at § 440.110(c) with specific provider requirements for speech pathologists and audiologists that must be met. If a State offers speech therapy as a rehabilitative service, the specific provider requirements at § 440.110(c) must be met. It should be noted that the definition of Occupational Therapy in § 440.110 is not correct insofar as the following—Occupational Therapists must be certified through the National Board of Certification for Occupational Therapy, not the American Occupational Therapy Association.

We are proposing a definition of the term ''under the direction of'' because it is a key issue in the provision of therapy services through the rehabilitative services benefit. Therapy services may be furnished by or ''under the direction of'' a qualified provider under the provisions of § 440.110. We are proposing to clarify that the term means that the therapist providing direction is supervising the individual's care which, at a minimum, includes seeing the individual initially, prescribing the type of care to be provided, reviewing the need for continued services throughout treatment, assuming professional responsibility for services provided, and ensuring that all services are medically necessary. The term ''under the direction of'' requires each of these elements; in particular, professional responsibility requires face-to-face contact by the therapist at least at the beginning of treatment and periodically thereafter. Note that this definition applies specifically to providers of physical therapy, occupational therapy, and services for individuals with speech, hearing

and language disorders. This language is not meant to exclude appropriate supervision arrangements for other rehabilitative services.

B. Scope of Services

Consistent with the provision of section 1905(a)(13) of the Act, we have retained the current definition of rehabilitative services in § 440.130(d)(2) as including "medical or remedial services recommended by a physician or other licensed practitioner of the healing arts, within the scope of his practice under State law, for maximum reduction of physical or mental disability and restoration of a recipient to his best possible functional level." We would, however, clarify that rehabilitative services do not include room and board in an institution, consistent with the longstanding CMS interpretation that section 1905(a) of the Act has specifically identified circumstances in which Medicaid would pay for coverage of room and board in an inpatient setting. This interpretation was upheld in *Texas* v. *U.S. Dep't Health and Human Servs.*, 61 F.3d 438 (5th Cir. 1995).

C. Written Rehabilitation Plan

We propose to add a new requirement, at § 440.130(d)(3), that covered rehabilitative services for each individual must be identified under a written rehabilitation plan. This rehabilitation plan would ensure that the services are designed and coordinated to lead to the goals set forth in statute and regulation (maximum reduction of physical or mental disability and restoration to the best possible functional level). It would ensure transparency of coverage and medical necessity determinations, so that the beneficiary, and family or other responsible individuals, would have a clear understanding of the services that are being made available to the beneficiary. In all situations, the ultimate goal is to reduce the duration and intensity of medical care to the least intrusive level possible which sustains health. The Medicaid goal is to deliver and pay for the clinically-appropriate, Medicaid-covered services that would contribute to the treatment goal. It is our expectation that, for persons with mental illnesses and substance-related disorders, the rehabilitation plan would include recovery goals. The rehabilitation plan would establish a basis for evaluating the effectiveness of the care offered in meeting the stated goals. It would provide for a process to involve the beneficiary, and family or other responsible individuals, in the overall management of rehabilitative care. The rehabilitation plan would also document that the services have been determined to be rehabilitative services consistent with the regulatory definition, and will have a timeline, based on the individual's assessed needs and anticipated progress, for reevaluation of the plan, not longer than one year. It is our expectation that the reevaluation of the plan would involve the beneficiary, family, or other responsible individuals and would include a review of whether the goals set forth in the plan are being met and whether each of the services described in the plan has contributed to meeting the stated goals. If it is determined that there has been no measurable reduction of disability and restoration of functional level, any new plan would need to pursue a different rehabilitation strategy including revision of the rehabilitative goals, services and/or methods. It is important to note that this benefit is not a custodial care benefit for individuals with chronic conditions but should result in a change in status. **However, it is also important to note that for some individuals such as those with serious mental illness, "reduction of disability and restoration of functional level" may be measured by comparing the effect of continuing rehabilitation versus discontinuing it. Where there is a reasonable expectation that if rehabilitation services had been withdrawn the individual's condition would have deteriorated, relapsed further, or required hospitalization, this criterion would be met.** The rehabilitation plan should identify the rehabilitation objectives that would be achieved under the plan in terms of measurable reductions in a diagnosed physical or mental disability and in terms of restored functional abilities. We recognize, however, that rehabilitation goals are often contingent on the individual's maintenance of a current level of functioning. In these instances, services that provide assistance in maintaining functioning may be considered rehabilitative only when necessary to help an individual achieve a rehabilitation goal as defined in the rehabilitation plan. **Acceptable rehabilitation goals in these instances could include avoidance of negative outcomes such as hospitalization or achievement of positive outcomes such as community participation.** Services provided primarily in order to maintain a level of functioning in the absence of a rehabilitation goal are not rehabilitation services.

It is our further expectation that the rehabilitation plan be reasonable and based on the individual's diagnosed condition(s) and on the standards of practice for provisions of rehabilitative services to an individual with the individual's condition(s). The rehabilitation plan is not intended to limit or restrict the State's ability to require prior authorization for services. The proposed requirements state that the written rehabilitation plan must:

- Be based on a comprehensive assessment of an individual's rehabilitation needs including diagnoses and presence of a functional impairment in daily living;
- Be developed by qualified provider(s) working within the State scope of practice acts with input from the individual, individual's family, the individual's authorized health care decision maker and/or persons of the individual's choosing;
- Ensure the active participation of the individual, individual's family, the individual's authorized health care decision maker and/or persons of the individual's choosing in the development, review and modification of these goals and services;
- Specify the individual's rehabilitation goals to be achieved, including recovery goals for persons with mental health and/or substance related disorders;
- Specify the physical impairment, mental health and/or substance related disorder that is being addressed;
- Identify the medical and remedial services intended to reduce the identified physical impairment, mental health and/or substance related disorder, **and identify the individuals or agencies responsible for providing**

these services:

- Identify the methods that would be used to deliver services;
- Specify the anticipated outcomes;
- Indicate the frequency, amount and duration of the services;
- Be signed by the individual responsible for developing the rehabilitation plan, or if the individuals refuses to sign the plan, document the reason(s);
- ~~Indicate the anticipated provider(s) of the service(s) and the extent to which the services may be available from alternate provider(s) of the same service;~~
- Specify a timeline for reevaluation of the plan, based on the individual's assessed needs and anticipated progress, but not longer than one year;
- Document that the individual or representative participated in the development of the plan, signed the plan, and received a copy of the rehabilitation plan; and
- Document that the services have been determined to be rehabilitative services consistent with the regulatory definition.

We believe that a written rehabilitation plan would ensure that services are provided within the scope of the rehabilitative services and would increase the likelihood that an individual's disability would be reduced and functional level restored. In order to determine whether a specific service is a covered rehabilitative benefit, it is helpful to scrutinize the purpose of the service as defined in the care plan.

For example, an activity that may appear to be a recreational activity may be rehabilitative if it is furnished with a focus on medical or remedial outcomes to address a particular impairment and functional loss. Such an activity, if provided by a Medicaid qualified provider, could address a physical or mental impairment that would help to increase motor skills in an individual who has suffered a stroke, or help to restore social functioning and personal interaction skills for a person with a mental illness.

We are proposing to require in § 440.130(d)(3)(iii) that the written rehabilitation plan include the active participation of the individual (or the individual's authorized health care decision maker) in the development, review, and reevaluation of the rehabilitation goals and services. We recommend the use of a person-centered planning process. Since the rehabilitation plan identifies recovery-oriented goals, the individual must be at the center of the planning process.

D. Impairments to be Addressed

We propose in § 440.130(d)(4) that rehabilitative services include services provided to an eligible individual to address the individual's physical needs, mental health needs, and/or substance-related disorder treatment needs. Because rehabilitative services are an optional service for adults, a State has flexibility to determine whether rehabilitative services would be limited to certain rehabilitative services (for example, only physical rehabilitative services) or will include rehabilitative treatment for mental health or substance-related disorders as well.

Provision of rehabilitative services to individuals with mental health or substance-related disorders is consistent with the recommendations of the New Freedom Commission on Mental Health. The Commission challenged States, among others, to expand access to quality mental health care and noted that States are at the very center of mental health system transformation. Thus, while States are not required to provide rehabilitative services for treatment of mental health and substance-related disorders, they are encouraged to do so. The Commission noted in its report that, "[m]ore individuals would recover from even the most serious mental illnesses and emotional disturbances if they had earlier access in their communities to treatment and supports that are evidence-based and tailored to their needs."

Under existing provisions at § 440.230(a), States are required to provide in the State plan a detailed description of the services to be provided. In reviewing a State plan amendment that proposes rehabilitative services, we would consider whether the proposed services are consistent with the requirements in § 440.130(d) and section 1905(a)(13) of the Act. We would also consider whether the proposed scope of rehabilitative services
is "sufficient in amount, duration and scope to reasonably achieve its purpose" as required at § 440.230(b). For that analysis, we will review whether any assistive devices, supplies, and equipment necessary to the provision of those services are covered either under the rehabilitative services benefit or elsewhere under the plan.

E. Settings

In §440.130(d)(5), consistent with the provisions of section 1905(a)(13) of the Act, we propose that rehabilitative services may be provided in a facility, home, or other setting. For example, rehabilitative services may be furnished in freestanding outpatient clinics and to supplement services otherwise available as an integral part of the services of facilities such as schools, community mental health centers, or substance abuse treatment centers. Other settings may include the office of qualified independent practitioners, mobile crisis vehicles, and appropriate community settings. The State has the authority to determine in which settings a particular service may be provided. While services may be provided in a variety of settings, the rehabilitative services benefit is not an inpatient benefit. Rehabilitative services do not include room and board in an institutional, community or home setting.

F. Requirements and Limitations for Rehabilitative Services

1. Requirements for Rehabilitative Services

In § 441.45(a), we set forth the assurances required in a State plan amendment that provides for rehabilitative services in this proposed rule. In § 441.45(b) we set forth the expenditures for which Federal financial participation (FFP) would not be available.

As with most Medicaid services, rehabilitative services are subject to the requirements of section 1902(a) of the Act. These include statewideness at section 1902(a)(1) of the Act, comparability at section 1902(a)(10)(B), and freedom of choice of qualified providers at section 1902(a)(23) of the Act. Accordingly, at § 441.45(a)(1), we propose to require that States comport with the listed

requirements.

At § 441.45(a)(2), we propose to require that the State ensure that rehabilitative services claimed for Medicaid payment are only those provided for the maximum reduction of physical or mental disability and restoration of the individual to the best possible functional level.

In § 441.45(a)(3) and (a)(4), we propose to require that providers of the rehabilitative services maintain case records that contain a copy of the rehabilitation plan. We also propose to require that the provider document the following for all individuals receiving rehabilitative services:

- The name of the individual;
- The date of the rehabilitative service or services provided;
- The nature, content, and units of rehabilitative services provided; and
- The progress made toward functional improvement and attainment of the individual's goals.

We believe this information is necessary to establish an audit trail for rehabilitative services provided, and to establish whether or not the services have achieved the maximum reduction of physical or mental disability, and to restore the individual to his or her best possible functional level.

A State that opts to provide rehabilitative services must do so by amending its State plan in accordance with proposed § 441.45(a)(5). The amendment must (1) describe the rehabilitative services proposed to be furnished, (2) specify the provider type and provider qualifications that are reasonably related to each of the rehabilitative services, and (3) specify the methodology under which rehabilitation providers would be paid.

2. Limitations for Rehabilitative Services

In § 441.45(b)(1) through (b)(8) we set forth limitations on coverage of rehabilitative services in this proposed rule.

We propose in § 441.45(b)(1) that coverage of rehabilitative services would not include services that are furnished through a non-medical program as either a benefit or administrative activity, including programs other than Medicaid, such as foster care, child welfare, education, child care, vocational and prevocational training, housing, parole and probation, juvenile justice, or public guardianship. We also propose in § 441.45(b)(1) that coverage of rehabilitative services would not include services that are intrinsic elements of programs other than Medicaid.

It should be noted however, that enrollment in these non-medical programs does not affect eligibility for Title XIX services. Rehabilitation services may be covered by Medicaid if they are not the responsibility of other programs and if all applicable requirements of the Medicaid program are met. <u>One way to demonstrate that Medicaid rehabilitation services are not intrinsic elements of non-covered programs is to clearly and reasonably distinguish the funding stream for the Medicaid rehabilitation services as being identifiably separate from that of the non-covered services.</u> Medicaid rehabilitative services must be coordinated with, but do not include, services furnished by other programs that are focused on social or educational development goals and are available as part of other services or programs. Further, Medicaid rehabilitation services must be available for all participants based on an identified medical need and otherwise would have been provided to the individual outside of the foster care, juvenile justice, parole and probation systems and other non-Medicaid systems. Individuals must have free choice of providers and all willing and qualified providers must be permitted to enroll in Medicaid.

For instance, therapeutic foster care is a model of care, not a medically necessary service defined under Title XIX of the Act. States have used it as an umbrella to package an array of services, some of which may be medically necessary services, some of which are not. In order for a service to be reimbursable by Medicaid, states must specifically define all of the services that are to be provided, provider qualifications, and payment methodology. It is important to note that provider qualifications for those who furnish care to children in foster care must be the same as provider qualifications for those who furnish the same care to children not in foster care. Examples of therapeutic foster care components that would not be Medicaid coverable services include provider recruitment, foster parent training and other such services that are the responsibility of the foster care system.

In § 441.45(b)(2), we propose to exclude FFP for expenditures for habilitation services including those provided to individuals with mental retardation or ''related conditions'' as defined in the State Medicaid Manual § 4398. Physical impairments and mental health and/or substance related disorder are not considered ''related conditions'' and are therefore medical conditions for which rehabilitation services may be appropriately provided. As a matter of general usage in the medical community, there is a distinction between the terms ''habilitation'' and ''rehabilitation.'' Rehabilitation refers to measures used to restore individuals to their best functional levels. The emphasis in covering rehabilitation services is the restoration of a functional ability. Individuals receiving rehabilitation services must have had the capability to perform an activity in the past rather than to actually have performed the activity. For example, a person may not have needed to drive a car in the past, but may have had the capability to do so prior to having the disability.

Habilitation typically refers to services that are for the purpose of helping persons acquire new functional abilities. Current Medicaid policy explicitly covers habilitation services in two ways: (1) When provided in an intermediate care facility for persons with mental retardation (ICF/MR); or (2) when covered under sections 1915(c), (d), or (i) of the Act as a home and community-based service. Habilitation services may also be provided under some 1905(a) service authorities such as Physician services defined at 42 CFR 440.50, Therapy services defined at 42 CFR 440.110 (such as, Physical Therapy, Occupational Therapy, and Speech/ Language/Audiology Therapy), and Medical or other remedial care provided by licensed practitioners, defined at 42 CFR 440.60. Habilitative services can also be provided under the 1915(i) State Plan Home and Community Based Services pursuant to the Deficit Reduction Act of 2005. In the late 1980s, the Congress responded to State concerns about disallowances for habilitation services provided under the State's rehabilitative

services benefit by passing section 6411(g) of the OBRA 89. This provision prohibited us from taking adverse actions against States with approved habilitation provisions pending the issuance of a regulation that ''specifies types of day habilitation services that a State may cover under paragraphs (9) [clinic services] or (13) [rehabilitative services] of section 1905(a) of the Act on behalf of persons with mental retardation or with related conditions.'' Accordingly, this regulation would specify that all such habilitation services would not be covered under sections 1905(a)(9) or 1905(a)(13) of the Act. If this regulation is issued in final form, the protections provided to certain States by section 6411(g) of OBRA 89 for day habilitation services will no longer be in force. We intend to provide for a delayed compliance date so that States will have a transition period of the lesser of 2 years or 1 year after the close of the first regular session of the State legislature that begins after this regulation becomes final before we will take enforcement action. This transition period will permit States an opportunity to transfer coverage of habilitation services from the rehabilitation option into another appropriate Medicaid authority. We are available to States as needed for technical assistance during this transition period.

In § 441.45(b)(3), we propose to provide that rehabilitative services would not include recreational and social activities that are not specifically focused on the improvement of physical or mental health impairment and achievement of a specific rehabilitative goal specified in the rehabilitation plan, and provided by a Medicaid qualified provider recognized under State law. We would also specify in this provision that rehabilitative services would not include personal care services; transportation; vocational and prevocational services that are not specifically focused on reducing disability-related symptoms or deficits and that are not provided by a qualified Medicaid provider; or patient education not related to the improvement of physical or mental health impairment and achievement of a specific rehabilitative goal specified in the rehabilitation plan. The first two of these services may be otherwise covered under the State plan. But these services are not primarily focused on rehabilitation, and thus do not meet the definition of medical or remedial services for rehabilitative purposes that would be contained in § 440.130(d)(1).

It is possible that some recreational or social activities are reimbursable as rehabilitative services if they are provided for the purpose allowed under the benefit and meet all the requirements governing rehabilitative services. For example, in one instance the activity of throwing a ball to an individual and having her/him throw it back, may be a recreational activity. In another instance, the activity may be part of a program of physical therapy that is provided by, or under the direction of, a qualified therapist for the purpose of restoring motor skills and balance in an individual who has suffered a stroke. Likewise, for an individual suffering from mental illness, what may appear to be a social activity may in fact be addressing the rehabilitation goal of social skills development as identified in the rehabilitation plan. The service would need to be specifically related to an identified rehabilitative goal as documented in the rehabilitation plan with specific time-limited treatment goals and outcomes. The rehabilitative service would further need to be provided by a qualified provider, be documented in the case record, and meet all requirements of this proposed regulation.

When personal care services are provided during the course of the provision of a rehabilitative service, they are an incidental activity and separate payment may not be made for the performance of the incidental activity. For example, an individual recovering from the effects of a stroke may receive occupational therapy services from a qualified occupational therapy provider under the rehabilitation option to regain the capacity to feed himself or herself. If during the course of those services the individual's clothing becomes soiled and the therapist assists the individual with changing his or her clothing, no separate payment may be made for assisting the individual with dressing under the rehabilitation option. However, FFP may be available for optional State plan personal care services under § 440.167 if provided by an enrolled, qualified personal care services provider.

Similarly, transportation is not within the scope of the definition of rehabilitative services proposed by this regulation since the transportation service itself does not result in the maximum reduction of a physical or mental disability and restoration of the individual to the best possible functional level. However, transportation is a Medicaid covered service and may be billed separately as a medical assistance service under § 440.170, if provided by an enrolled, qualified provider, or may be provided under the Medicaid program as an administrative activity necessary for the proper and efficient administration of the State's Medicaid program.

Generally, vocational services are those that teach specific skills required by an individual to perform tasks associated with performing a job. Prevocational services address underlying habilitative goals that are associated with performing compensated work. To the extent that the primary purpose of these services is to help individuals acquire a specific job skill, and are not provided for the purpose of reducing disability and restoring a person to a previous functional level, they would not be construed as covered rehabilitative services. For example, teaching an individual to cook a meal to train for a job as a chef would not be covered, whereas, teaching an individual to cook in order to re-establish the use of her or his hands or to restore living skills may be coverable. Furthermore, rehabilitative services in support of an individual employed as a chef may be coverable if those services teach the individual how to manage disability-related symptoms or deficits that create employment barriers such as paranoia that causes conflicts with co-workers or depression that causes absences or tardiness. While it may be possible for Medicaid to cover prevocational services when provided under the section 1915(c) of the Act, home and community based services waiver programs, funding for vocational services rests with other, non-Medicaid Federal and State funding sources.

Similarly, the purpose of patient education is one important

determinant to whether the activity is a rehabilitative activity covered under § 440.130(d). While taking classes in an academic setting may increase an individual's integration into the community and enable the individual to learn social skills, the primary purpose of this activity is academic enhancement.

Thus, patient education in an academic setting is not covered under the Medicaid rehabilitation option. On the other hand, some patient education directed towards a specific rehabilitative therapy service may be provided for the purpose of equipping the individual with specific skills that will decrease disability and restore the individual to a previous functioning level. For example, an individual with a mental disorder that manifests with behavioral difficulties may need anger management training to restore his or her ability to interact appropriately with others. These services may be covered under the rehabilitation option if all of the requirements of this regulation are met.

In § 441.45(b)(4), we propose to exclude payment for services, including services that are rehabilitative services that are provided to inmates living in the secure custody of law enforcement and residing in a public institution. An individual is considered to be living in secure custody if serving time for a criminal offense in, or confined involuntarily to, State or Federal prisons, local jails, detention facilities, or other penal facilities. A facility is a public institution when it is under the responsibility of a governmental unit or over which a governmental unit exercises administrative control. Rehabilitative services could be reimbursed on behalf of Medicaid-eligible individuals paroled, on probation, on home release, in foster care, in a group home, or other community placement, that are not part of the public institution system, when the services are identified due to a medical condition targeted under the State's Plan, are not used in the administration of other non-medical programs.

We also propose to exclude payment for services that are provided to residents of an institution for mental disease (IMD), including residents of a community residential treatment facility of over 16 beds, that is primarily engaged in providing diagnosis, treatment, or care of persons with mental illness, and that does not meet the requirements at § 440.160. It appears that in the past, certain States may have provided services under the rehabilitation option to these individuals. Our proposed exclusion of FFP for rehabilitative services provided to these populations is consistent with the statutory requirements in paragraphs (A) and (B) following section 1905(a)(28) of the Act. The statute indicates that "except as otherwise provided in paragraph (16), such term [medical assistance] does not include—

(A)Any such payments with respect to care or services for any individual who is an inmate of a public institution; or
(B)any such payments with respect to care or services for any individual who has not attained 65 years and who is a patient in an IMD." Section 1905(a)(16) of the Act defines as "medical assistance" "* * * inpatient psychiatric hospital services for individuals under age 21 * * *". The Secretary has defined the term "inpatient psychiatric hospital services for individuals under age 21" in regulations at § 440.160 to include "a psychiatric facility which is accredited by the Joint Commission on Accreditation of Healthcare Organizations, the Council on Accreditation of Services for Families and Children, the Commission on Accreditation of Rehabilitation Facilities, or by any other accrediting organization, with comparable standards, that is recognized by the State." Thus, the term "inpatient psychiatric hospital services for individuals under age 21" includes services furnished in accredited children's psychiatric residential treatment facilities that are not hospitals. The rehabilitative services that are provided by the psychiatric hospital or accredited psychiatric residential treatment facility (PRTF) providing inpatient psychiatric services for individuals under age 21 to its residents would be reimbursed under the benefit for inpatient psychiatric services for individuals under age 21 (often referred to as the "psych under 21" benefit), rather than under the rehabilitative services benefit.

In § 441.45(b)(6), we propose to exclude expenditures for room and board from payment under the rehabilitative services option. While rehabilitative services may be furnished in a residential setting that is not an IMD, the benefit provided by section 1905(a)(13) of the Act is primarily intended for community based services. Thus, when rehabilitative services are provided in a residential setting, such as in a residential substance abuse treatment facility of less than 17 beds, delivered by qualified providers, only the costs of the specific rehabilitative services will be covered.

In § 441.45(b)(7), we propose to preclude payment for services furnished for the rehabilitation of an individual who is not Medicaid eligible. This provision reinforces basic program requirements found in section 1905(a) of the Act that require medical assistance to be furnished only to eligible individuals. An "eligible individual" is a person who is eligible for Medicaid and requires rehabilitative services as defined in the Medicaid State plan at the time the services are furnished. The provision of rehabilitative services to non-Medicaid eligible individuals cannot be covered if it relates directly to the non-eligible individual's care and treatment. However, effective rehabilitation of eligible individuals may require some contact with non-eligible individuals. For instance, in developing the rehabilitation plan for a child with a mental illness, it may be appropriate to include the child's parents, who are not eligible for Medicaid, in the process. In addition, counseling sessions for the treatment of the child might include the parents and other non-eligible family members. In all cases, in order for a service to be a Medicaid coverable service, it must be provided to, or directed exclusively toward, the treatment of the Medicaid eligible individual.

Thus, contacts with family members for the purpose of treating the Medicaid eligible individual may be covered by Medicaid. If these other family members or other individuals also are Medicaid eligible and in need of the services covered under the State's rehabilitation plan, Medicaid could pay for the services furnished to them.

In § 441.45(b)(8), we propose that FFP would only be available for claims for services provided to a specific individual that are documented in an individual's case record.

We will work with States to

implement this rule in a timely fashion using existing monitoring and compliance authority.

III. Collection of Information Requirements

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

Section 440.130 Diagnostic, Screening, Preventative, and Rehabilitative Services

This section outlines the scope of service for rehabilitative services provided by States. The services discussed in this section must be provided under a written rehabilitation plan as defined in § 440.130(d)(1)(v). Specifically, § 440.130(d)(3) states that the written rehabilitation plan must meet the following requirements:

(i) Be based on a comprehensive assessment of an individual's rehabilitation needs including diagnoses and presence of a functional impairment in daily living.

(ii) Be developed by a qualified provider(s) working within the State scope of practice act with input from the individual, individual's family, the individual's authorized health care decision maker and/or persons of the individual's choosing.

(iii) Ensure the active participation of the individual, individual's family, the individual's authorized health care decision maker and/or persons of the individual's choosing in the development, review, and modification of these goals and services.

(iv) Specify the individual's rehabilitation goals to be achieved including recovery goals for persons with mental illnesses or substance related disorders.

(v) Specify the physical impairment, mental health and/or substance related disorder that is being addressed.

(vi) Identify the medical and remedial services intended to reduce the identified physical impairment, mental health and/or substance related disorder.

(vii) Identify the methods that will be used to deliver services.

(viii) Specify the anticipated outcomes.

(ix) Indicate the frequency and duration of the services.

(x) Be signed by the individual responsible for developing the rehabilitation plan.

(xi) Indicate the anticipated provider(s) of the service(s) and the extent to which the services may be available from alternate provider(s) of the same service.

(xii) Specify a timeline for reevaluation of the plan, based on the individual's assessed needs and anticipated progress, but not longer than one year.

(xiii) Be reevaluated with the involvement of the beneficiary, family or other responsible individuals.

(xiv) Be reevaluated including a review of whether the goals set forth in the plan are being met and whether each of the services described in the plan has contributed to meeting the stated goals. If it is determined that there has been no measurable reduction of disability and restoration of functional level, any new plan would need to pursue a different rehabilitation strategy including revision of the rehabilitative goals, services and/or methods.

(xv) Document that the individual or representative participated in the development of the plan, signed the plan, and received a copy of the rehabilitation plan.

(xvi) Document that the services have been determined to be rehabilitative services consistent with the regulatory definition.

The burden associated with the requirements in this section is the time and effort put forth by the provider to gather the information and develop a specific written rehabilitation plan. While these requirements are subject to the PRA, we believe they meet the exemption requirements for the PRA found at 5 CFR 1320.3(b)(2), and as such, the burden associated with these requirements is exempt.

Section 441.45 Rehabilitative Services

Section 441.45(a)(3) requires that providers maintain case records that contain a copy of the rehabilitation plan for all individuals.

The burden associated with these requirements is the time and effort put forth by the provider to maintain the case records. While these requirements are subject to the PRA, we believe they meet the exemption requirements for the PRA found at 5 CFR 1320.3(b)(2), and as such, the burden associated with these requirements is exempt.

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

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group, Attn: Melissa Musotto [CMS–2261–P], Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244– 1850; and

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–1321–P], *katherine_astrich@omb.eop.gov*. Fax (202) 395–6974.

IV. 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.

V. Regulatory Impact

Analysis *A. Overall Impact*

We have examined the impacts 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 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) 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 is a major rule because of the size of the anticipated reduction in Federal financial participation that is estimated to have an economically significant effect of more than $100 million in each of the Federal fiscal years 2008 through 2012.

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. The Secretary certifies that this major rule would not have a direct impact on providers of rehabilitative services that furnish services pursuant to section 1905(a)(13) of the Act. The rule would directly affect states and we do not know nor can we predict the manner in which states would adjust or respond to the provisions of this rule. CMS is unable to determine the

percentage of providers of rehabilitative services that are considered small businesses according to the Small Business Administration's size standards with total revenues of $6.5 million to $31.5 million or less in any 1 year. Individuals and States are not included in the definition of a small entity. 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 (proposed documents) 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 Medicaid payment regulations and has fewer than 100 beds. The Secretary certifies that this major rule would not have a direct impact on small rural hospitals. The rule would directly affect states and we do not know nor can we predict the manner in which states would adjust or respond to the provisions of this rule.

Section 202 of the Unfunded Mandates Reform Act (UMRA) 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. Since this rule would not mandate spending in any 1 year of $120 million or more, the requirements of the UMRA are not applicable.

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 rule would not impose any costs on State or local governments, preempt State law, or otherwise have Federalism implications, the requirements of E.O. 13132 are not applicable.

B. Anticipated Effects

FFP will be available for rehabilitative services for treatment of physical, mental health, or substance-related disorder rehabilitation treatment if the State elects to provide those services through the approved State plan. Individuals retain the right to select among qualified providers of rehabilitative services. However, because FFP will be excluded for rehabilitative services that are included in other Federal, State and local programs, it is estimated that Federal Medicaid spending on rehabilitative services would be reduced by approximately $180 million in FY 2008 and would be reduced by $2.2 billion between FY 2008 and FY 2012. This reduction in spending is expected to occur because FFP for rehabilitative services would no longer be paid to inappropriate other third parties or other Federal, State, or local programs.

The estimated impact on Federal Medicaid spending was calculated starting with an estimate of rehabilitative service spending that may be subject to this rule. This estimate was developed after consulting with several experts, as data for rehabilitative services, particularly as it would apply to this rule, is limited. Given this estimate, the actuaries discounted this amount to account for four factors: (1) The ability of CMS to effectively identify the rehabilitative services spending that would be subject to this proposal; (2) the effectiveness of CMS's efforts to implement this rule and the potential that some identified rehabilitative services spending may still be permissible under the rule; (3) the change in States' plans that may regain some of the lost Federal funding; and (4) the length of time for CMS to fully implement the rule and review all States' plans.

The actual impact to the Federal Medicaid program may be different than the estimate to the extent that the estimate of the amount of rehabilitative services spending subject to this rule is different than the actual amount and to the extent that the effectiveness of the rule is greater than or less than assumed. Because a comprehensive review of these rehabilitative services had not been conducted at the time of this estimate and because we do not routinely collect data on spending for rehabilitative services, particularly as it relates to this rule, there is a significantly wide range of possible impacts.

Thus, we are unable to determine what fiscal impact the publication of this rule would have on consumers, individual industries, Federal, State, or local government agencies or geographic regions under Executive Order 12866. We invite public comment on the potential impact of the rule.

C. Alternatives Considered

This proposed rule would amend

the definition of rehabilitative services to provide for important individual protections and to clarify that Medicaid rehabilitative services must be coordinated with but do not include services furnished by other programs that are focused on social or educational development goals and available as part of other services or programs. We believe this proposed rule is the best approach to clarifying the covered rehabilitative services, and also because all stakeholders will have the opportunity to comment on the proposed rule. These comments will then be considered before the final document is published.

In considering regulatory options, we considered requiring States to license all providers as an alternative to only requiring that providers to be qualified as defined by the State. However we believe that giving States the flexibility to determine how providers are credentialed allows for necessary flexibility to States to consider a wide range of provider types necessary to cover a variety of rehabilitation services. We believe this flexibility will result in decreases in administrative and service costs.

We also considered restricting the rule to only include participant protections but not explicitly prohibiting FFP for services that are intrinsic elements of other non-Medicaid programs. Had we not prohibited FFP for services that are intrinsic elements of other programs, States would continue to provide non-Medicaid services to participants, the result would have been a less efficient use of Medicaid funding because increased Medicaid spending would not result in any increase in services to beneficiaries. Instead, increased Medicaid funding would have simply replaced other sources of funding.

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 savings associated with the provisions of this proposed rule. This table provides our best estimate of the savings to the Federal Government as a result of the changes presented in this proposed rule that Federal Medicaid spending on rehabilitative services would be reduced by approximately $180 million in FY 2008 and would be reduced by $2.24 billion between FY 2008 and FY 2012. All savings are classified as transfers from the Federal Government to State Government. These transfers represent a reduction in the federal share of Medicaid spending once the rule goes into effect, as it would limit States from claiming Medicaid reimbursement for rehabilitation services that could be covered through other programs.

ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED SAVINGS, FROM FY 2008 TO FY 2012
[In millions]

Category	Primary estimates	Year dollar	Units discount rate	Period covered
Federal Annualized Monetized ($millions/year)	443.4	2008	7%	2008–2012
	441.6	2008	3%	2008–2012
	448	2008	0%	2008–2012
From Whom to Whom?	Federal Government to State Government			

Column 1: Category—Contains the description of the different impacts of the rule; it could include monetized, quantitative but not monetized, or qualitative but not quantitative or monetized impacts; it also may contain unit of measurement (such as, dollars). In this case, the only impact is the Federal annualized monetized impact of the rule.

Column 2: Primary Estimate—Contains the quantitative or qualitative impact of the rule for the respective category of impact. Monetized amounts are generally shown in real dollar terms. In this case, the federalized annualized monetized primary estimate represents the equivalent amount that, if paid (saved) each year over the period covered, would result in the same net present value of the stream of costs (savings) estimated over the period covered.

Column 3: Year Dollar—Contains the year to which dollars are normalized; that is, the first year that dollars are discounted in the estimate.

Column 4: Unit Discount Rate—Contains the discount rate or rates used to estimate the annualized monetized impacts. In this case, three rates are used: 7 percent; 3 percent; 0 percent.

Column 5: Period Covered—Contains the years for which the estimate was made.

Rows: The rows contain the estimates associated with each specific impact and each discount rate used.

"From Whom to Whom?"—In the case of a transfer (as opposed to a change in aggregate social welfare as described in the OMB Circular), this section describes the parties involved in the transfer of costs. In this case, costs previously paid for by the Federal Government would be transferred to the State Governments. The table may also contain minimum and maximum estimates and sources cited. In this case, there is only a primary estimate and there are no additional sources for the estimate.

Estimated Savings—The following table shows the discounted costs (savings) for each discount rate and for each year over the period covered. "Total" represents the net present value of the impact in the year the rule takes effect. These numbers represent the anticipated annual reduction in Federal Medicaid spending under this rule.

ESTIMATED SAVINGS, FROM FY 2008 TO FY 2012
[In millions]

Discount rate (percent)	2008	2009	2010	2011	2012	Total
0	180	360	520	570	610	2,288
3	175	339	476	506	526	2,069
7	168	314	424	435	435	1,822

E. Conclusion

For these reasons, we are not preparing analyses for either the RFA or section 110 2(b) of the Act because a comprehensive review of these rehabilitative services had not been conducted at the time of this estimate and because we do not routinely collect data on spending for rehabilitative services. Accordingly, there is a significantly wide range of possible impacts due to this rule. As indicated in the Estimated Savings table above, we project an estimated savings of $180 million in FY 2008, $360 million in FY 2009, $520 million in FY 2010, $570 million in FY 2011, and $610 million in FY 2012. This reflects a total estimated savings of $2.240 billion dollars for FY 2008 through FY 2012. We invite public comment on the potential impact of this rule.

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

List of Subjects

42 CFR Part 440

Grant programs—health, Medicaid.

42 CFR Part 441

Family planning, Grant programs— health, Infants and children, Medicaid, Penalties, Prescription drugs, 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 440—SERVICES: GENERAL PROVISIONS

1. The authority citation for part 440 continues to read as follows:

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

2. Section 440.130 is amended by revising paragraph (d) to read as follows:

§ 440.130 Diagnostic, screening, preventative, and rehabilitative services.

* * * * *

(d) *Rehabilitative Services—(1) Definitions.* For purposes of this subpart, the following definitions apply:

(i) *Recommended by a physician or other licensed practitioner of the healing arts* means that a physician or other licensed practitioner of the healing arts, based on a comprehensive assessment of the individual, has—

(A) Determined that receipt of rehabilitative services would result in reduction of the individual's physical or mental disability and restoration to the best possible functional level of the individual; and

(B) Recommended the rehabilitative services to achieve specific individualized goals.

(ii) *Other licensed practitioner of the healing arts* means any health practitioner or practitioner of the healing arts who is licensed in the State to diagnose and treat individuals with the physical or mental disability or functional limitations at issue, and operating within the scope of practice defined in State law.

(iii) *Qualified providers of rehabilitative services* means individuals who meet any applicable provider qualifications under Federal law that would be applicable to the same service when it is furnished under other Medicaid benefit categories, qualifications under applicable State scope of practice laws, and any additional qualifications set forth in the Medicaid State plan. These qualifications may include minimum age requirements, education, work experience, training, credentialing, supervision and licensing requirements that are applied uniformly. Provider qualifications must be documented in the State plan and be reasonable given the nature of the service provided and the population served. Individuals must have free choice of providers and all willing and qualified providers must be permitted to enroll in Medicaid.

(iv) *Under the direction of* means that for physical therapy, occupational therapy, and services for individuals with speech, hearing and language disorders (see § 440.110, ''Inpatient hospital services, other than services in an institution for mental diseases'') the Medicaid qualified therapist providing direction is a licensed practitioner of the healing arts qualified under State law to diagnose and treat individuals with the disability or functional limitations at issue, is working within the scope of practice defined in State law and is supervising each individual's care. The supervision must include, at a minimum, face-to-face contact with the individual initially and periodically as needed, prescribing the services to be provided, and reviewing the need for continued services throughout the course of treatment. The qualified therapist must also assume professional responsibility for the services provided and ensure that the services are medically necessary. Therapists must spend as much time as necessary directly supervising services to ensure beneficiaries are receiving services in a safe and efficient manner in accordance with accepted standards of practice. Moreover, documentation must be kept supporting the supervision of services and ongoing involvement

in the treatment. Note that this definition applies specifically to providers of physical therapy, occupational therapy, and services for individuals with speech, hearing and language disorders. This language is not meant to exclude appropriate supervision arrangements for other rehabilitative services.

(v) *Rehabilitation plan* means a written plan that specifies the physical impairment, mental health and/or substance related disorder to be addressed, the individualized rehabilitation goals and the medical and remedial services to achieve those goals. The plan is developed by a qualified provider(s) working within the State scope of practice act, with input from the individual, individual's family, the individual's authorized decision maker and/or of the individual's choosing and also ensures the active participation of the individual, individual's family, individual's authorized decision maker and/or of the individual's choosing in the development, review, and modification of the goals and services. The plan must document that the services have been determined to be rehabilitative services consistent with the regulatory definition. The plan must have a timeline, based on the individual's assessed needs and anticipated progress, for reevaluation of the plan, not longer than one year. The plan must be reasonable and based on the individual's condition(s) and on general standards of practice for provision of rehabilitative services to an individual with the individual's condition(s).

(vi) *Restorative services* means services that are provided to an individual who has had a functional loss and has a specific rehabilitative goal toward regaining that function. The emphasis in covering rehabilitation services is on the ability to perform a function rather than to actually have performed the function in the past. For example, a person may not have needed to take public transportation in the past, but may have had the ability to do so prior to having the disability. Rehabilitation goals are often contingent on the individual's maintenance of a current level of functioning. In these instances services that provide assistance in maintaining functioning may be considered rehabilitative only when necessary to help an individual achieve a rehabilitation goal defined in the rehabilitation plan. Acceptable rehabilitation goals in these instances could include avoidance of negative outcomes such as hospitalization or achievement of positive outcomes such as community participation. Services provided primarily in order to maintain a level of functioning in the absence of a rehabilitation goal are not within the scope of rehabilitation services.

(vii) *Medical services* means services specified in the rehabilitation plan that are required for the diagnosis, treatment, or care of a physical or mental disorder and are recommended by a physician or other licensed practitioner of the healing arts within the scope of his or her practice under State law. Medical services may include physical therapy, occupational therapy, speech therapy, and mental health and substance-related disorder rehabilitative services.

(viii) *Remedial services* means services that are intended to correct a physical or mental disorder and are necessary to achieve a specific rehabilitative goal specified in the individual's rehabilitation plan.

(2) *Scope of services.* Except as otherwise provided under this subpart, rehabilitative services include medical or remedial services recommended by a physician or other licensed practitioner of the healing arts, within the scope of his practice under State law, for maximum reduction of physical or mental disability and restoration of a individual to the best possible functional level. Rehabilitative services may include assistive devices, medical equipment and supplies, not otherwise covered under the plan, which are determined necessary to the achievement of the individual's rehabilitation goals. Rehabilitative services do not include room and board in an institution or community setting.

(3) *Written rehabilitation plan.* The written rehabilitation plan shall be reasonable and based on the individual's condition(s) and on the standards of practice for provision of rehabilitative services to an individual with the individual's condition(s). In addition, the written rehabilitation plan must meet the following requirements:

(i)Be based on a comprehensive assessment of an individual's rehabilitation needs including diagnoses and presence of a functional impairment in daily living.

(ii) Be developed by a qualified provider(s) working within the State scope of practice act with input from the individual, individual's family, the individual's authorized health care
decision maker and/or persons of the individual's choosing.

(iii) Follow guidance obtained through the active participation of the individual, and/or persons of the individual's choosing (which may include the individual's family and the individual's authorized health care decision maker), in the development, review, and modification of plan goals and services.

(iv) Specify the individual's rehabilitation goals to be achieved, including recovery goals for persons with mental health and/or substance related disorders.

(v) Specify the physical impairment, mental health and/or substance related disorder that is being addressed.

(vi) Identify the medical and remedial services intended to reduce the identified physical impairment, mental health and/or substance related disorder, and identify the individuals or agencies responsible for providing these services.

(vii)Identify the methods that will be used to deliver services.

(viii) Specify the anticipated outcomes.

(ix) Indicate the frequency, amount and duration of the

services.

(x) Be signed by the individual responsible for developing the rehabilitation plan, and if the individual refuses to sign the plan, document the reason(s).

(xi) ~~Indicate the anticipated provider(s) of the service(s) and the extent to which the services may be available from alternate provider(s) of the same service~~.

(xii) Specify a timeline for reevaluation of the plan, based on the individual's assessed needs and anticipated progress, but not longer than one year.

(xiii) Be reevaluated with the involvement of the individual, family or other responsible individuals.

(xiv) Be reevaluated including a review of whether the goals set forth in the plan are being met and whether each of the services described in the plan has contributed to meeting the stated goals. If it is determined that there has been no measurable reduction of disability and restoration of functional level, any new plan would need to pursue a different rehabilitation strategy including revision of the rehabilitative goals, services and/or methods. For some individuals such as those with serious mental illness, "reduction of disability and restoration of functional level" may be measured by comparing the effect of continuing rehabilitation versus discontinuing it. Where there is a reasonable expectation that if the rehabilitation services had been withdrawn the individual's condition would have deteriorated, relapsed further, or required hospitalization, this criterion would be met.

(xiv) Document that the individual or representative participated in the development of the plan, signed the plan, and received a copy of the rehabilitation plan.

(xv) Document that the services have been determined to be rehabilitative services consistent with the regulatory definition.

(xvi) Include the individual's relevant history, current medical findings, contraindications and identify the individual's care coordination needs, if any, as needed to achieve the rehabilitation goals.

(4) *Impairments to be addressed.* For purposes of this section, rehabilitative services include services provided to the Medicaid eligible individual to address the individual's physical impairments, mental health impairments, and/or substance-related disorder treatment needs.

(5) *Settings.* Rehabilitative services may be provided in a facility, home, or other setting.

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

1. The authority citation for part 441 continues to read as follows:

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

Subpart A—General Provisions

2. A new § 441.45 is added to subpart A to read as follows:

§441.45 Rehabilitative services.

(a) If a State covers rehabilitative services, as defined in § 440.130(d) of this chapter, the State must meet the following requirements:

(1) Ensure that services are provided in accordance with § 431.50, § 431.51, § 440.230, and § 440.240 of this chapter.

(2) Ensure that rehabilitative services are limited to services furnished for the maximum reduction of physical or mental disability and restoration of the individual to their best possible functional level.

(3) Require that providers maintain case records that contain a copy of the rehabilitation plan for all individuals.

(4) For all individuals receiving rehabilitative services, require that providers maintain case records that include the following:

(i) A copy of the rehabilitative plan.

(ii) The name of the individual.

(iii) The date of the rehabilitative services provided.

(iv) The nature, content, and units of the rehabilitative services.

(v) The progress made toward functional improvement and attainment of the individual's goals as identified in the rehabilitation plan and case record.

(5) Ensure the State plan for rehabilitative services includes the following requirements:

(i) Describes the rehabilitative services furnished.

(ii) Specifies provider qualifications that are reasonably related to the rehabilitative services proposed to be furnished.

(iii) Specifies the methodology under which rehabilitation providers are paid.

(b) Rehabilitation does not include, and FFP is not available in expenditures for, services defined in § 440.130(d) of this chapter if the following conditions exist:

(1) The services are furnished through a non-medical program as either a benefit or administrative activity, including services that are intrinsic elements of programs other than Medicaid, such as foster care, child welfare, education, child care, vocational and prevocational training, housing, parole and probation, juvenile justice, or public guardianship. Services would not be considered to be intrinsic elements of these non-medical programs if they are medically necessary rehabilitation services for an eligible individual that are clearly distinct from the non-covered program services and that are provided by qualified Medicaid providers. One way to demonstrate this distinction is to clearly and reasonably distinguish the funding stream for the Medicaid rehabilitation services as being identifiably separate from that of the non-covered services. Examples of services that are intrinsic elements of other programs and that would not be paid under Medicaid include, but are not limited to, the following:

(i) Therapeutic foster care services furnished by foster care providers to children, except for

medically necessary rehabilitation services for an eligible child that are clearly distinct from packaged therapeutic foster care services and that are provided by qualified Medicaid providers.

(ii) Packaged services furnished by foster care or child care institutions for a foster child except for medically necessary rehabilitation services for an eligible child that are clearly distinct from packaged therapeutic foster care services and that are provided by qualified Medicaid providers.

(iii) Adoption services, family preservation, and family reunification services furnished by public or private social services agencies.

(iv) Routine supervision and non-medical support services provided by teacher aides in school settings (sometimes referred to as "classroom aides" and "recess aides").

(2) Habilitation services, including services for which FFP was formerly permitted under the Omnibus Budget Reconciliation Act of 1989. Habilitation services include "services provided to individuals" with mental retardation or related conditions. (Most physical impairments, and mental health and/or substance related disorders, are not included in the scope of related conditions, so rehabilitation services may be appropriately provided.)

(3) Recreational or social activities that are not focused on rehabilitation and not provided by a Medicaid qualified provider; personal care services; transportation; vocational and prevocational services that are not focused on reducing disability-related symptoms or deficits and not provided by a qualified Medicaid provider; or patient education not related to reduction of physical or mental disability and the restoration of an individual to his or her best possible functional level.

(4) Services that are provided to inmates living in the secure custody of law enforcement and residing in a public institution. An individual is considered to be living in secure custody if serving time for a criminal offence in, or confined involuntarily to, public institutions such as State or Federal prisons, local jails, detention facilities, or other penal facilities. A facility is a public institution when it is under the responsibility of a governmental unit; or over which a governmental unit exercises administrative control. Rehabilitative services could be reimbursed on behalf of Medicaid-eligible individuals paroled, on probation, on home release, in foster care, in a group home, or other community placement, that are not part of the public institution system, when the services are identified due to a medical condition targeted under the State's Plan, are not used in the administration of other non-medical programs.

(5) Services provided to residents of an institution for mental disease (IMD) who are under the age of 65, including residents of community residential treatment facilities with more than 16 beds that do not meet the requirements at § 440.160 of this chapter.

(6)Room and board.

(7) Services furnished for the treatment of an individual who is not Medicaid eligible.

(8) Services that are not provided to a specific individual as documented in an individual's case record.

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

Dated: March 22, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: July 12, 2007.

Michael O. Leavitt,

Secretary.

[FR Doc. 07-3925 Filed 8-8-07; 4:00 pm] BILLING CODE 4120-01-P

October 10, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-2261-P,
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-2261-P; PUBLIC COMMENT REGARDING PROPOSED AMENDMENT TO 42 CFR PARTS 440 AND 441: Medicaid Program- Coverage for Rehabilitative Services

TO WHOM IT MAY CONCERN:

Way Station is a 30 year-old not-for-profit organization in Maryland that provides comprehensive community-based mental health services to over 7,000 individuals each year, approximately 4,000 of whom are Medicaid recipients. We thank you for the opportunity to give input, and we submit the following comments which we believe will achieve the *accountability t*hat CMS seeks while at the same time assuring the *flexibility* that individuals with serious mental illness need – both of which the New Freedom Commission noted as being critical aspects of effective public mental healthcare financing. (*Final Report*, at 23). Attached to this letter is a red-lined version of the regulation and preamble, showing our proposed modifications in the yellow highlighted sections.

I. <u>Section 440.130 (d) (1)(vi) and Section 440.130 (d) (3) (xiv)</u>

We are concerned that the proposed language defining "restorative services" and the rehabilitation plan requirement for reevaluation of "measurable reduction of disability and restoration of functional ability" could be misinterpreted to prohibit coverage for long-term rehabilitation services for adults with serious mental illness that are provided toward goals of living in the community without intermittent hospitalization or of reducing symptoms to avoid hospitalization. While such individuals may choose the type of goals that involve positive outcomes such as employment or formal education, others may choose the type that involve reducing symptoms and avoiding negative outcomes such as hospitalization. The New Freedom Commission views both types of goals as being recovery-oriented as both are included in the Commission's definition of "recovery." (*Id.* at 5) Furthermore, for many individuals with serious mental illness and histories of multiple hospitalizations, the latter type of goal can be just as ambitious as the former, and avoiding hospitalization can be substantial progress in and of itself.

To provide the necessary clarification, we propose that CMS add language that it has used in other program transmittals in which it clarified how to apply the requirement of treatment improvement to individuals with serious mental illness. In two different Medicare program transmittals, CMS used this definition:

PO Box 3826 / Frederick, Maryland 21705-3826 / 301-662-0099 / Toll Free 888-549-0629 / Fax 301-694-9932
9030 Route 108, Suite A / Columbia, Maryland 21045 / 410—740-8262 / Toll Free 877-381-5482 / Fax 410-740-8237
25 East North Avenue, Hagerstown, MD 21740 / 301-733-6063 / Fax 301-733-6220

www.waystationinc.org

"Reasonable Expectation of Improvement – Services must be for the purpose of diagnostic study or reasonably be expected to improve the patient's condition. The treatment must, at a minimum, be designed to reduce or control the patient's psychiatric symptoms so as to prevent relapse or hospitalization, and improve or maintain the patient's level of functioning. It is not necessary that a course of therapy has as its goal restoration of the patient to the level of functioning exhibited prior to the onset of the illness, although this may be appropriate for some patients. *For many other psychiatric patients, particularly those with long-term, chronic conditions, control of symptoms and maintenance of a functional level to avoid further deterioration or hospitalization is an acceptable expectation of improvement. "Improvement" in this context is measured by comparing the effect of continuing treatment versus discontinuing it. Where there is a reasonable expectation that if treatment services were withdrawn the patient's condition would deteriorate, relapse further, or require hospitalization, this criterion is met.*" (emphasis added) Medicare Hospital Manual, Chapter II, Section 230.5 Hospital Outpatient Psychiatric Services; Medicare Intermediary Manual, Part 3, Chapter II, Section 3112.7 Outpatient Hospital Psychiatric Services.

Our proposed highlighted changes in the attached red-lined version incorporate this CMS language.

II. Section 441.45 (b) (1) and 441.45 (b) (3)

We agree that FFP should not cover foster care, child welfare, education, child care, vocational and prevocational training, housing, parole and probation, juvenile justice or public guardianship services. However, when the regulation prohibits FFP for rehabilitation services that are "intrinsic elements" of these non-medical programs, we are concerned that this could be misinterpreted as prohibiting the positive blending of Medicaid-covered and non-covered services even though such blending can yield important clinical benefits such as facilitating integration, increasing the transferability of skill development in natural settings, and promoting a key principle of evidence-based practices. In addition, the regulation could be misinterpreted to prohibit FFP for mental health rehabilitation services provided as part of a Supported Employment program even though SAMHSA endorses this service protocol as an effective, evidence-based mental health practice. Finally, the regulation's prohibition in 441.45 (b)(3) of FFP for "vocational and prevocational services" could be misinterpreted to prohibit coverage for rehabilitation services that are focused on reducing disability-related symptoms or deficits which create employment barriers. Those types of services are quite different from services which train the individual to perform a job task, but the language does not clarify that important distinction.

The modification we have proposed in the attached red-lined version states that distinguishing funding streams is one concrete way of demonstrating how Medicaid rehabilitation services are not "intrinsic elements" of non-covered programs. As such, services can be blended (which is critical to *flexibility*) as long as funding is "braided" (which is important for *accountability*). In addition, our language clarifies the distinction between vocational services that train individuals to perform job tasks versus rehabilitation services that reduce symptoms which create employment barriers.

III. **440.130 (d) (3)**

The more minor suggestions included in the attached red-lined version relate to clarifying potential confusion around the requirement in (3) (xi) to list "anticipated providers of services" and allowing providers to document reasons if an individual refuses to sign the plan.

In conclusion, we hope that our proposed changes to the regulation represent concrete ways to implement the Commission's recommendation to improve both the accountability and the flexibility of public financing for mental health services as an important part of the broader system's rehabilitation and transformation. We thank

you for considering our comments, and offer to assist in any way in providing additional information or answering any follow-up questions.

Sincerely,

Scott Rose
President/CEO

SUMMARY: EPA proposes to approve the State Implementation Plan (SIP) revision submitted by the Commonwealth of Virginia for the purpose of establishing a variance for the International Paper, Franklin Paper Mill facility located in Franklin, Virginia. The variance provides regulatory relief from compliance with state regulations governing new source review for the implementation of the International Paper, Franklin Paper Mill innovation project. In lieu of compliance with these regulatory requirements, the variance requires the facility to comply with site-wide emission caps. In the Final Rules section of this **Federal Register**, EPA is approving the Commonwealth's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

DATES: Comments must be received in writing by September 12, 2007.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA- R03-OAR-2006-0060 by one of the following methods:

A. http://www.regulations.gov. Follow the on-line instructions for submitting comments.

B. E-mail: cam pbell.dave@epa.gov.

C. *Mail:* EPA-R03-OAR-2006-0060, David Campbell, Chief, Permits and Technical Assessment Branch, Mailcode 3AP11, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information. *Instructions:* Direct your comments to Docket ID No. EPA-R03-OAR-2006- 0060. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at http:// www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through http:// www.regulations.gov or e-mail. The http://www.regulations.gov Web site is an anonymous access system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through http:// www.regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the http://www.regulations.gov *index.* Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in http:// www.regulations.gov or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Virginia Department of Environmental Quality, 629 East Main Street, Richmond, Virginia, 23219.

FOR FURTHER INFORMATION CONTACT: Sharon McCauley, (215) 814-3376, or by e-mail at *mccauley.sharon@epa.gov.*

SUPPLEMENTARY INFORMATION: For further information, please see the information provided in the direct final action, with the same title, that is located in the Rules and Regulations section of this **Federal Register** publication. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions

of the rule that are not subject of an adverse comment.

Dated: July 31, 2007.

William T. Wisniewski,

Acting Regional Administrator, Region II. [FR Doc. E7-15585 Filed 8-10-07; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 440 and 441

[CMS 2261 -P] RIN 0938-A081

Medicaid Program; Coverage for Rehabilitative Services

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the definition of Medicaid rehabilitative services in order to provide for important beneficiary protections such as a person-centered written rehabilitation plan and maintenance of case records. The proposed rule would also ensure the fiscal integrity of claimed Medicaid expenditures by clarifying the service definition and providing that Medicaid rehabilitative services must be coordinated with but do not include services furnished by other programs that are focused on social or educational development goals and available as part of other services or programs. These services and programs include, but

are not limited to, foster care, child welfare, education, child care, prevocational and vocational services, housing, parole and probation, juvenile justice, public guardianship, and any other non-Medicaid services from Federal, State, or local programs.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on October 12, 2007.

ADDRESSES: In commenting, please refer to file code CMS-2261-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-2261- P, P.O. Box 8018, Baltimore, MD 21244- 8018.

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-2261-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- 3685 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:** Maria Reed, (410) 786-2255 or Shawn Terrell, (410) 786-0672.

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-2261-P 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 (for example, names, addresses, social security numbers, and medical diagnoses) or confidential business information (including proprietary 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

A. Overview

Section 1905(a)(13) of the Social Security Act (the Act) includes rehabilitative services as an optional Medicaid State plan benefit. Current Medicaid regulations at 42 CFR 440.130(d) provide a broad definition of rehabilitative services. Rehabilitative services are defined as "any medical or remedial services recommended by a physician or other licensed practitioner of the healing arts, within the scope of his or her practice under State law, for maximum reduction of physical or mental disability and restoration of a recipient to his best possible functional level." The broad general language in this regulatory definition has afforded States considerable flexibility under their State plans to meet the needs of their State's Medicaid population.

Over the years the scope of services States have provided under the rehabilitation benefit has expanded from physical rehabilitative services to also include mental health and substance abuse treatment rehabilitative services. For example, services currently provided by States under the rehabilitative benefit include services aimed at improving physical disabilities, including physical, occupational, and speech therapies; mental health services, such as individual and group therapy, psychosocial therapy services; and services for substance-related disorders (for example, substance use disorders and substance induced disorders). These Medicaid services may be delivered through various models of care and in a variety of settings.

The broad language of the current

statutory and regulatory definition has, however, had some unintended consequences. It has also led to some confusion over whether otherwise applicable statutory or regulatory provider standards would apply under the rehabilitative services benefit.

As the number of States providing rehabilitative services has increased, some States have viewed the rehabilitation benefit as a "catch-all" category to cover services included in other Federal, State and local programs. For example, it appears some States have used Medicaid to fund services that are included in the provision of foster care and in the Individuals with Disabilities Education Improvement Act (IDEA). Our audit reviews have recently revealed that Medicaid funds have also been used to pay for behavioral treatment services in "wilderness camps," juvenile detention, and similar facilities where youth are involuntarily confined. These facilities are under the domain of the juvenile justice or youth systems in the State, rather than Medicaid, and there is no assurance that the claimed services reflect an independent evaluation of individual rehabilitative needs.

This proposed regulation is designed to clarify the broad general language of the current regulation to ensure that rehabilitative services are provided in a coordinated manner that is in the best interest of the individuals, are limited to rehabilitative purposes and are furnished by qualified providers. This proposed regulation would rectify the improper reliance on the Medicaid rehabilitation benefit for services furnished by other programs that are focused on social or educational development goals in programs other than Medicaid.

This proposed regulation would provide guidance to ensure that services claimed under the optional Medicaid rehabilitative benefit are in fact rehabilitative out-patient services, are furnished by qualified providers, are provided to Medicaid eligible individuals according to a goal-oriented rehabilitation plan, and are not for services that are included in programs with a focus other than that of Medicaid.

B. Habilitation Services

Section 6411(g) of the Omnibus Budget Reconciliation Act of 1989 (OBRA 89) prohibits us from taking adverse action against States with approved habilitation provisions pending the issuance of a regulation that "specifies types of day habilitation services that a State may cover under paragraphs (9) (clinic services) or (13) (rehabilitative services) of section 1905(a) of the Act on behalf of persons with mental retardation or with related conditions." We believe that issuance of a final rule based on this proposed rule will satisfy this condition. We intend to work with those States that have habilitation programs under the clinic services or rehabilitative services benefits in their State plans to transition to appropriate Medicaid coverage authorities, such as section 1915(c) waivers or the Home and Community-Based Services State plan option under section 1915 (i) of the Deficit Reduction Act (DRA) of 2005 (Pub. L. 107–171), enacted on February 8, 2006.

II. Provisions of the Proposed Rule

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

A. Definitions

In 440.130(d)(1), we propose to define the terms used in this rule, as listed below:

- Recommended by a physician or other licensed practitioner of the healing arts.
- Other licensed practitioner of the healing arts.
- Qualified providers of rehabilitative services.
- Under the direction of.
- Written rehabilitation plan.
- Restorative services.
- Medical services.
- Remedial services.

In § 440.130(d)(1)(iii), we would define "qualified providers of rehabilitative services" to require that individuals providing rehabilitative services meet the provider qualification requirements applicable to the same service when it is furnished under other benefit categories. Further, the provider qualifications must be set forth in the Medicaid State plan. These qualifications may include education, work experience, training, credentialing, supervision and licensing, that are applied uniformly. Provider qualifications must be reasonable given the nature of the service provided and the population being served. We require uniform application of these qualifications to ensure the individual free choice of qualified providers, consistent with section 1902(a)(23) of the Act.

Under this proposed definition, if specific provider qualifications are set forth elsewhere in subpart A of part 440, those provider qualifications take precedence when those services are provided under the rehabilitation option. Thus, if a State chooses to provide the various therapies discussed at § 440.110 (physical therapy, occupational therapy, speech, language and hearing services) under § 440.130(d), the requirements of § 440.110 applicable to those services would apply. For example, speech therapy is addressed in regulation at § 440.110(c) with specific provider requirements for speech pathologists and audiologists that must be met. If a State offers speech therapy as a rehabilitative service, the specific provider requirements at § 440.110(c) must be met. It should be noted that the definition of Occupational Therapy in § 440.110 is not correct insofar as the following—Occupational Therapists must be certified through the National Board of Certification for Occupational Therapy, not the American Occupational Therapy Association.

We are proposing a definition of the term "under the direction of" because it is a key issue in the provision of therapy services through the rehabilitative services benefit. Therapy services may be furnished by or "under the direction of" a qualified provider under the provisions of § 440.110. We are proposing to clarify that the term means that the therapist providing direction is supervising the individual's care which, at a minimum, includes seeing the individual initially, prescribing the type of care to be provided, reviewing the need for continued services throughout treatment, assuming professional responsibility for services provided, and ensuring that all services are medically necessary. The term "under the direction of" requires each of these elements; in particular, professional responsibility requires face-to-face contact by the therapist at least at the beginning of treatment and periodically thereafter. Note that this definition applies specifically to providers of physical therapy, occupational therapy, and services for individuals with speech, hearing

and language disorders. This language is not meant to exclude appropriate supervision arrangements for other rehabilitative services.

B. Scope of Services

Consistent with the provision of section 1905(a)(13) of the Act, we have retained the current definition of rehabilitative services in § 440.130(d)(2) as including "medical or remedial services recommended by a physician or other licensed practitioner of the healing arts, within the scope of his practice under State law, for maximum reduction of physical or mental disability and restoration of a recipient to his best possible functional level.'' We would, however, clarify that rehabilitative services do not include room and board in an institution, consistent with the longstanding CMS interpretation that section 1905(a) of the Act has specifically identified circumstances in which Medicaid would pay for coverage of room and board in an inpatient setting. This interpretation was upheld in *Texas* v. *U.S. Dep't Health and Human Servs.*, 61 F.3d 438 (5th Cir. 1995).

C. Written Rehabilitation Plan

We propose to add a new requirement, at § 440.130(d)(3), that covered rehabilitative services for each individual must be identified under a written rehabilitation plan. This rehabilitation plan would ensure that the services are designed and coordinated to lead to the goals set forth in statute and regulation (maximum reduction of physical or mental disability and restoration to the best possible functional level). It would ensure transparency of coverage and medical necessity determinations, so that the beneficiary, and family or other responsible individuals, would have a clear understanding of the services that are being made available to the beneficiary. In all situations, the ultimate goal is to reduce the duration and intensity of medical care to the least intrusive level possible which sustains health. The Medicaid goal is to deliver and pay for the clinically-appropriate, Medicaid-covered services that would contribute to the treatment goal. It is our expectation that, for persons with mental illnesses and substance-related disorders, the rehabilitation plan would include recovery goals. The rehabilitation plan would establish a basis for evaluating the effectiveness of the care offered in meeting the stated goals. It would provide for a process to involve the beneficiary, and family or other responsible individuals, in the overall management of rehabilitative care. The rehabilitation plan would also document that the services have been determined to be rehabilitative services consistent with the regulatory definition, and will have a timeline, based on the individual's assessed needs and anticipated progress, for reevaluation of the plan, not longer than one year. It is our expectation that the reevaluation of the plan would involve the beneficiary, family, or other responsible individuals and would include a review of whether the goals set forth in the plan are being met and whether each of the services described in the plan has contributed to meeting the stated goals. If it is determined that there has been no measurable reduction of disability and restoration of functional level, any new plan would need to pursue a different rehabilitation strategy including revision of the rehabilitative goals, services and/or methods. It is important to note that this benefit is not a custodial care benefit for individuals with chronic conditions but should result in a change in status. <u>However, it is also important to note that for some individuals such as those with serious mental illness, "reduction of disability and restoration of functional level" may be measured by comparing the effect of continuing rehabilitation versus discontinuing it. Where there is a reasonable expectation that if rehabilitation services had been withdrawn the individual's condition would have deteriorated, relapsed further, or required hospitalization, this criterion would be met.</u> The rehabilitation plan should identify the rehabilitation objectives that would be achieved under the plan in terms of measurable reductions in a diagnosed physical or mental disability and in terms of restored functional abilities. We recognize, however, that rehabilitation goals are often contingent on the individual's maintenance of a current level of functioning. In these instances, services that provide assistance in maintaining functioning may be considered rehabilitative only when necessary to help an individual achieve a rehabilitation goal as defined in the rehabilitation plan. <u>Acceptable rehabilitation goals in these instances could include avoidance of negative outcomes such as hospitalization or achievement of positive outcomes such as community participation.</u> Services provided primarily in order to maintain a level of functioning in the absence of a rehabilitation goal are not rehabilitation services.

It is our further expectation that the rehabilitation plan be reasonable and based on the individual's diagnosed condition(s) and on the standards of practice for provisions of rehabilitative services to an individual with the individual's condition(s). The rehabilitation plan is not intended to limit or restrict the State's ability to require prior authorization for services. The proposed requirements state that the written rehabilitation plan must:

- Be based on a comprehensive assessment of an individual's rehabilitation needs including diagnoses and presence of a functional impairment in daily living;
- Be developed by qualified provider(s) working within the State scope of practice acts with input from the individual, individual's family, the individual's authorized health care decision maker and/or persons of the individual's choosing;
- Ensure the active participation of the individual, individual's family, the individual's authorized health care decision maker and/or persons of the individual's choosing in the development, review and modification of these goals and services;
- Specify the individual's rehabilitation goals to be achieved, including recovery goals for persons with mental health and/or substance related disorders;
- Specify the physical impairment, mental health and/or substance related disorder that is being addressed;
- Identify the medical and remedial services intended to reduce the identified physical impairment, mental health and/or substance related disorder, <u>and identify the individuals or agencies responsible for providing</u>

these services;

- Identify the methods that would be used to deliver services;
- Specify the anticipated outcomes;
- Indicate the frequency, amount and duration of the services;
- Be signed by the individual responsible for developing the rehabilitation plan, **or if the individuals refuses to sign the plan, document the reason(s);**
- ~~Indicate the anticipated provider(s) of the service(s) and the extent to which the services may be available from alternate provider(s) of the same service;~~
- Specify a timeline for reevaluation of the plan, based on the individual's assessed needs and anticipated progress, but not longer than one year;
- Document that the individual or representative participated in the development of the plan, signed the plan, and received a copy of the rehabilitation plan; and
- Document that the services have been determined to be rehabilitative services consistent with the regulatory definition.

We believe that a written rehabilitation plan would ensure that services are provided within the scope of the rehabilitative services and would increase the likelihood that an individual's disability would be reduced and functional level restored. In order to determine whether a specific service is a covered rehabilitative benefit, it is helpful to scrutinize the purpose of the service as defined in the care plan.

For example, an activity that may appear to be a recreational activity may be rehabilitative if it is furnished with a focus on medical or remedial outcomes to address a particular impairment and functional loss. Such an activity, if provided by a Medicaid qualified provider, could address a physical or mental impairment that would help to increase motor skills in an individual who has suffered a stroke, or help to restore social functioning and personal interaction skills for a person with a mental illness.

We are proposing to require in § 440.130(d)(3)(iii) that the written rehabilitation plan include the active participation of the individual (or the individual's authorized health care decision maker) in the development, review, and reevaluation of the rehabilitation goals and services. We recommend the use of a person-centered planning process. Since the rehabilitation plan identifies recovery-oriented goals, the individual must be at the center of the planning process.

D. Impairments to be Addressed

We propose in § 440.130(d)(4) that rehabilitative services include services provided to an eligible individual to address the individual's physical needs, mental health needs, and/or substance-related disorder treatment needs. Because rehabilitative services are an optional service for adults, a State has flexibility to determine whether rehabilitative services would be limited to certain rehabilitative services (for example, only physical rehabilitative services) or will include rehabilitative treatment for mental health or substance-related disorders as well.

Provision of rehabilitative services to individuals with mental health or substance-related disorders is consistent with the recommendations of the New Freedom Commission on Mental Health. The Commission challenged States, among others, to expand access to quality mental health care and noted that States are at the very center of mental health system transformation. Thus, while States are not required to provide rehabilitative services for treatment of mental health and substance-related disorders, they are encouraged to do so. The Commission noted in its report that, "[m]ore individuals would recover from even the most serious mental illnesses and emotional disturbances if they had earlier access in their communities to treatment and supports that are evidence-based and tailored to their needs."

Under existing provisions at § 440.230(a), States are required to provide in the State plan a detailed description of the services to be provided. In reviewing a State plan amendment that proposes rehabilitative services, we would consider whether the proposed services are consistent with the requirements in § 440.130(d) and section 1905(a)(13) of the Act. We would also consider whether the proposed scope of rehabilitative services is "sufficient in amount, duration and scope to reasonably achieve its purpose" as required at § 440.230(b). For that analysis, we will review whether any assistive devices, supplies, and equipment necessary to the provision of those services are covered either under the rehabilitative services benefit or elsewhere under the plan.

E. Settings

In §440.130(d)(5), consistent with the provisions of section 1905(a)(13) of the Act, we propose that rehabilitative services may be provided in a facility, home, or other setting. For example, rehabilitative services may be furnished in freestanding outpatient clinics and to supplement services otherwise available as an integral part of the services of facilities such as schools, community mental health centers, or substance abuse treatment centers. Other settings may include the office of qualified independent practitioners, mobile crisis vehicles, and appropriate community settings. The State has the authority to determine in which settings a particular service may be provided. While services may be provided in a variety of settings, the rehabilitative services benefit is not an inpatient benefit. Rehabilitative services do not include room and board in an institutional, community or home setting.

F. Requirements and Limitations for Rehabilitative Services

1. Requirements for Rehabilitative Services

In § 441.45(a), we set forth the assurances required in a State plan amendment that provides for rehabilitative services in this proposed rule. In § 441.45(b) we set forth the expenditures for which Federal financial participation (FFP) would not be available.

As with most Medicaid services, rehabilitative services are subject to the requirements of section 1902(a) of the Act. These include statewideness at section 1902(a)(1) of the Act, comparability at section 1902(a)(10)(B), and freedom of choice of qualified providers at section 1902(a)(23) of the Act. Accordingly, at § 441.45(a)(1), we propose to require that States comport with the listed

requirements.

At § 441.45(a)(2), we propose to require that the State ensure that rehabilitative services claimed for Medicaid payment are only those provided for the maximum reduction of physical or mental disability and restoration of the individual to the best possible functional level.

In § 441.45(a)(3) and (a)(4), we propose to require that providers of the rehabilitative services maintain case records that contain a copy of the rehabilitation plan. We also propose to require that the provider document the following for all individuals receiving rehabilitative services:

- The name of the individual;
- The date of the rehabilitative service or services provided;
- The nature, content, and units of rehabilitative services provided; and
- The progress made toward functional improvement and attainment of the individual's goals.

We believe this information is necessary to establish an audit trail for rehabilitative services provided, and to establish whether or not the services have achieved the maximum reduction of physical or mental disability, and to restore the individual to his or her best possible functional level.

A State that opts to provide rehabilitative services must do so by amending its State plan in accordance with proposed § 441.45(a)(5). The amendment must (1) describe the rehabilitative services proposed to be furnished, (2) specify the provider type and provider qualifications that are reasonably related to each of the rehabilitative services, and (3) specify the methodology under which rehabilitation providers would be paid.

2. Limitations for Rehabilitative Services

In § 441.45(b)(1) through (b)(8) we set forth limitations on coverage of rehabilitative services in this proposed rule.

We propose in § 441.45(b)(1) that coverage of rehabilitative services would not include services that are furnished through a non-medical program as either a benefit or administrative activity, including programs other than Medicaid, such as foster care, child welfare, education, child care, vocational and prevocational training, housing, parole and probation, juvenile justice, or public guardianship. We also propose in § 441.45(b)(1) that coverage of rehabilitative services would not include services that are intrinsic elements of programs other than Medicaid.

It should be noted however, that enrollment in these non-medical programs does not affect eligibility for Title XIX services. Rehabilitation services may be covered by Medicaid if they are not the responsibility of other programs and if all applicable requirements of the Medicaid program are met. One way to demonstrate that Medicaid rehabilitation services are not intrinsic elements of non-covered programs is to clearly and reasonably distinguish the funding stream for the Medicaid rehabilitation services as being identifiably separate from that of the non-covered services. Medicaid rehabilitative services must be coordinated with, but do not include, services furnished by other programs that are focused on social or educational development goals and are available as part of other services or programs. Further, Medicaid rehabilitation services must be available for all participants based on an identified medical need and otherwise would have been provided to the individual outside of the foster care, juvenile justice, parole and probation systems and other non-Medicaid systems. Individuals must have free choice of providers and all willing and qualified providers must be permitted to enroll in Medicaid.

For instance, therapeutic foster care is a model of care, not a medically necessary service defined under Title XIX of the Act. States have used it as an umbrella to package an array of services, some of which may be medically necessary services, some of which are not. In order for a service to be reimbursable by Medicaid, states must specifically define all of the services that are to be provided, provider qualifications, and payment methodology. It is important to note that provider qualifications for those who furnish care to children in foster care must be the same as provider qualifications for those who furnish the same care to children not in foster care. Examples of therapeutic foster care components that would not be Medicaid coverable services include provider recruitment, foster parent training and other such services that are the responsibility of the foster care system.

In § 441.45(b)(2), we propose to exclude FFP for expenditures for habilitation services including those provided to individuals with mental retardation or "related conditions" as defined in the State Medicaid Manual § 4398. Physical impairments and mental health and/or substance related disorder are not considered "related conditions" and are therefore medical conditions for which rehabilitation services may be appropriately provided. As a matter of general usage in the medical community, there is a distinction between the terms "habilitation" and "rehabilitation." Rehabilitation refers to measures used to restore individuals to their best functional levels. The emphasis in covering rehabilitation services is the restoration of a functional ability. Individuals receiving rehabilitation services must have had the capability to perform an activity in the past rather than to actually have performed the activity. For example, a person may not have needed to drive a car in the past, but may have had the capability to do so prior to having the disability.

Habilitation typically refers to services that are for the purpose of helping persons acquire new functional abilities. Current Medicaid policy explicitly covers habilitation services in two ways: (1) When provided in an intermediate care facility for persons with mental retardation (ICF/MR); or (2) when covered under sections 1915(c), (d), or (i) of the Act as a home and community-based service. Habilitation services may also be provided under some 1905(a) service authorities such as Physician services defined at 42 CFR 440.50, Therapy services defined at 42 CFR 440.110 (such as, Physical Therapy, Occupational Therapy, and Speech/ Language/Audiology Therapy), and Medical or other remedial care provided by licensed practitioners, defined at 42 CFR 440.60. Habilitative services can also be provided under the 1915(i) State Plan Home and Community Based Services pursuant to the Deficit Reduction Act of 2005. In the late 1980s, the Congress responded to State concerns about disallowances for habilitation services provided under the State's rehabilitative

services benefit by passing section 6411(g) of the OBRA 89. This provision prohibited us from taking adverse actions against States with approved habilitation provisions pending the issuance of a regulation that ''specifies types of day habilitation services that a State may cover under paragraphs (9) [clinic services] or (13) [rehabilitative services] of section 1905(a) of the Act on behalf of persons with mental retardation or with related conditions.'' Accordingly, this regulation would specify that all such habilitation services would not be covered under sections 1905(a)(9) or 1905(a)(13) of the Act. If this regulation is issued in final form, the protections provided to certain States by section 6411(g) of OBRA 89 for day habilitation services will no longer be in force. We intend to provide for a delayed compliance date so that States will have a transition period of the lesser of 2 years or 1 year after the close of the first regular session of the State legislature that begins after this regulation becomes final before we will take enforcement action. This transition period will permit States an opportunity to transfer coverage of habilitation services from the rehabilitation option into another appropriate Medicaid authority. We are available to States as needed for technical assistance during this transition period.

In § 441.45(b)(3), we propose to provide that rehabilitative services would not include recreational and social activities that are not specifically focused on the improvement of physical or mental health impairment and achievement of a specific rehabilitative goal specified in the rehabilitation plan, and provided by a Medicaid qualified provider recognized under State law. We would also specify in this provision that rehabilitative services would not include personal care services; transportation; vocational and prevocational services <u>that are not specifically focused on reducing disability-related symptoms or deficits and that are not provided by a qualified Medicaid provider</u>; or patient education not related to the improvement of physical or mental health impairment and achievement of a specific rehabilitative goal specified in the rehabilitation plan. The first two of these services may be otherwise covered under the State plan. But these services are not primarily focused on rehabilitation, and thus do not meet the definition of medical or remedial services for rehabilitative purposes that would be contained in § 440.130(d)(1).

It is possible that some recreational or social activities are reimbursable as rehabilitative services if they are provided for the purpose allowed under the benefit and meet all the requirements governing rehabilitative services. For example, in one instance the activity of throwing a ball to an individual and having her/him throw it back, may be a recreational activity. In another instance, the activity may be part of a program of physical therapy that is provided by, or under the direction of, a qualified therapist for the purpose of restoring motor skills and balance in an individual who has suffered a stroke. Likewise, for an individual suffering from mental illness, what may appear to be a social activity may in fact be addressing the rehabilitation goal of social skills development as identified in the rehabilitation plan. The service would need to be specifically related to an identified rehabilitative goal as documented in the rehabilitation plan with specific time-limited treatment goals and outcomes. The rehabilitative service would further need to be provided by a qualified provider, be documented in the case record, and meet all requirements of this proposed regulation.

When personal care services are provided during the course of the provision of a rehabilitative service, they are an incidental activity and separate payment may not be made for the performance of the incidental activity. For example, an individual recovering from the effects of a stroke may receive occupational therapy services from a qualified occupational therapy provider under the rehabilitation option to regain the capacity to feed himself or herself. If during the course of those services the individual's clothing becomes soiled and the therapist assists the individual with changing his or her clothing, no separate payment may be made for assisting the individual with dressing under the rehabilitation option. However, FFP may be available for optional State plan personal care services under § 440.167 if provided by an enrolled, qualified personal care services provider.

Similarly, transportation is not within the scope of the definition of rehabilitative services proposed by this regulation since the transportation service itself does not result in the maximum reduction of a physical or mental disability and restoration of the individual to the best possible functional level. However, transportation is a Medicaid covered service and may be billed separately as a medical assistance service under § 440.170, if provided by an enrolled, qualified provider, or may be provided under the Medicaid program as an administrative activity necessary for the proper and efficient administration of the State's Medicaid program.

Generally, vocational services are those that teach specific skills required by an individual to perform tasks associated with performing a job. Prevocational services address underlying habilitative goals that are associated with performing compensated work. To the extent that the primary purpose of these services is to help individuals acquire a specific job skill, and are not provided for the purpose of reducing disability and restoring a person to a previous functional level, they would not be construed as covered rehabilitative services. For example, teaching an individual to cook a meal to train for a job as a chef would not be covered, whereas, teaching an individual to cook in order to re-establish the use of her or his hands or to restore living skills may be coverable. <u>Furthermore, rehabilitative services in support of an individual employed as a chef may be coverable if those services teach the individual how to manage disability-related symptoms or deficits that create employment barriers such as paranoia that causes conflicts with co-workers or depression that causes absences or tardiness.</u> While it may be possible for Medicaid to cover prevocational services when provided under the section 1915(c) of the Act, home and community based services waiver programs, funding for vocational services rests with other, non-Medicaid Federal and State funding sources.

Similarly, the purpose of patient education is one important

determinant to whether the activity is a rehabilitative activity covered under § 440.130(d). While taking classes in an academic setting may increase an individual's integration into the community and enable the individual to learn social skills, the primary purpose of this activity is academic enhancement.

Thus, patient education in an academic setting is not covered under the Medicaid rehabilitation option. On the other hand, some patient education directed towards a specific rehabilitative therapy service may be provided for the purpose of equipping the individual with specific skills that will decrease disability and restore the individual to a previous functioning level. For example, an individual with a mental disorder that manifests with behavioral difficulties may need anger management training to restore his or her ability to interact appropriately with others. These services may be covered under the rehabilitation option if all of the requirements of this regulation are met.

In § 441.45(b)(4), we propose to exclude payment for services, including services that are rehabilitative services that are provided to inmates living in the secure custody of law enforcement and residing in a public institution. An individual is considered to be living in secure custody if serving time for a criminal offense in, or confined involuntarily to, State or Federal prisons, local jails, detention facilities, or other penal facilities. A facility is a public institution when it is under the responsibility of a governmental unit or over which a governmental unit exercises administrative control. Rehabilitative services could be reimbursed on behalf of Medicaid-eligible individuals paroled, on probation, on home release, in foster care, in a group home, or other community placement, that are not part of the public institution system, when the services are identified due to a medical condition targeted under the State's Plan, are not used in the administration of other non-medical programs.

We also propose to exclude payment for services that are provided to residents of an institution for mental disease (IMD), including residents of a community residential treatment facility of over 16 beds, that is primarily engaged in providing diagnosis, treatment, or care of persons with mental illness, and that does not meet the requirements at § 440.160. It appears that in the past, certain States may have provided services under the rehabilitation option to these individuals. Our proposed exclusion of FFP for rehabilitative services provided to these populations is consistent with the statutory requirements in paragraphs (A) and (B) following section 1905(a)(28) of the Act. The statute indicates that "except as otherwise provided in paragraph (16), such term [medical assistance] does not include—

(A)Any such payments with respect to care or services for any individual who is an inmate of a public institution; or
(B)any such payments with respect to care or services for any individual who has not attained 65 years and who is a patient in an IMD." Section 1905(a)(16) of the Act defines as "medical assistance" "* * * inpatient psychiatric hospital services for individuals under age 21 * * *". The Secretary has defined the term "inpatient psychiatric hospital services for individuals under age 21" in regulations at § 440.160 to include "a psychiatric facility which is accredited by the Joint Commission on Accreditation of Healthcare Organizations, the Council on Accreditation of Services for Families and Children, the Commission on Accreditation of Rehabilitation Facilities, or by any other accrediting organization, with comparable standards, that is recognized by the State." Thus, the term "inpatient psychiatric hospital services for individuals under age 21" includes services furnished in accredited children's psychiatric residential treatment facilities that are not hospitals. The rehabilitative services that are provided by the psychiatric hospital or accredited psychiatric residential treatment facility (PRTF) providing inpatient psychiatric services for individuals under age 21 to its residents would be reimbursed under the benefit for inpatient psychiatric services for individuals under age 21 (often referred to as the "psych under 21" benefit), rather than under the rehabilitative services benefit.

In § 441.45(b)(6), we propose to exclude expenditures for room and board from payment under the rehabilitative services option. While rehabilitative services may be furnished in a residential setting that is not an IMD, the benefit provided by section 1905(a)(13) of the Act is primarily intended for community based services. Thus, when rehabilitative services are provided in a residential setting, such as in a residential substance abuse treatment facility of less than 17 beds, delivered by qualified providers, only the costs of the specific rehabilitative services will be covered.

In § 441.45(b)(7), we propose to preclude payment for services furnished for the rehabilitation of an individual who is not Medicaid eligible. This provision reinforces basic program requirements found in section 1905(a) of the Act that require medical assistance to be furnished only to eligible individuals. An "eligible individual" is a person who is eligible for Medicaid and requires rehabilitative services as

defined in the Medicaid State plan at the time the services are furnished. The provision of rehabilitative services to non-Medicaid eligible individuals cannot be covered if it relates directly to the non-eligible individual's care and treatment. However, effective rehabilitation of eligible individuals may require some contact with non-eligible individuals. For instance, in developing the rehabilitation plan for a child with a mental illness, it may be appropriate to include the child's parents, who are not eligible for Medicaid, in the process. In addition, counseling sessions for the treatment of the child might include the parents and other non-eligible family members. In all cases, in order for a service to be a Medicaid coverable service, it must be provided to, or directed exclusively toward, the treatment of the Medicaid eligible individual.

Thus, contacts with family members for the purpose of treating the Medicaid eligible individual may be covered by Medicaid. If these other family members or other individuals also are Medicaid eligible and in need of the services covered under the State's rehabilitation plan, Medicaid could pay for the services furnished to them.

In § 441.45(b)(8), we propose that FFP would only be available for claims for services provided to a specific individual that are documented in an individual's case record.

We will work with States to

implement this rule in a timely fashion using existing monitoring and compliance authority.

III. Collection of Information Requirements

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

Section 440.130 Diagnostic, Screening, Preventative, and Rehabilitative Services

This section outlines the scope of service for rehabilitative services provided by States. The services discussed in this section must be provided under a written rehabilitation plan as defined in § 440.130(d)(1)(v). Specifically, § 440.130(d)(3) states that the written rehabilitation plan must meet the following requirements:

(i) Be based on a comprehensive assessment of an individual's rehabilitation needs including diagnoses and presence of a functional impairment in daily living.

(ii) Be developed by a qualified provider(s) working within the State scope of practice act with input from the individual, individual's family, the individual's authorized health care decision maker and/or persons of the individual's choosing.

(iii) Ensure the active participation of the individual, individual's family, the individual's authorized health care decision maker and/or persons of the individual's choosing in the development, review, and modification of these goals and services.

(iv) Specify the individual's rehabilitation goals to be achieved including recovery goals for persons with mental illnesses or substance related disorders.

(v) Specify the physical impairment, mental health and/or substance related disorder that is being addressed.

(vi) Identify the medical and remedial services intended to reduce the identified physical impairment, mental health and/or substance related disorder.

(vii) Identify the methods that will be used to deliver services.

(viii) Specify the anticipated outcomes.

(ix) Indicate the frequency and duration of the services.

(x) Be signed by the individual responsible for developing the rehabilitation plan.

(xi) Indicate the anticipated provider(s) of the service(s) and the extent to which the services may be available from alternate provider(s) of the same service.

(xii) Specify a timeline for reevaluation of the plan, based on the individual's assessed needs and anticipated progress, but not longer than one year.

(xiii) Be reevaluated with the involvement of the beneficiary, family or other responsible individuals.

(xiv) Be reevaluated including a review of whether the goals set forth in the plan are being met and whether each of the services described in the plan has contributed to meeting the stated goals. If it is determined that there has been no measurable reduction of disability and restoration of functional level, any new plan would need to pursue a different rehabilitation strategy including revision of the rehabilitative goals, services and/or methods.

(xv) Document that the individual or representative participated in the development of the plan, signed the plan, and received a copy of the rehabilitation plan.

(xvi) Document that the services have been determined to be rehabilitative services consistent with the regulatory definition.

The burden associated with the requirements in this section is the time and effort put forth by the provider to gather the information and develop a specific written rehabilitation plan. While these requirements are subject to the PRA, we believe they meet the exemption requirements for the PRA found at 5 CFR 1320.3(b)(2), and as such, the burden associated with these requirements is exempt.

Section 441.45 Rehabilitative Services

Section 441.45(a)(3) requires that providers maintain case records that contain a copy of the rehabilitation plan for all individuals.

The burden associated with these requirements is the time and effort put forth by the provider to maintain the case records. While these requirements are subject to the PRA, we believe they meet the exemption requirements for the PRA found at 5 CFR 1320.3(b)(2), and as such, the burden associated with these requirements is exempt.

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

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group, Attn: Melissa Musotto [CMS–2261–P], Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244– 1850; and

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–1321–P], katherine_astrich@omb.eop.gov. Fax (202) 395–6974.

IV. 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.

V. Regulatory Impact

Analysis *A. Overall Impact*

We have examined the impacts 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 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) 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 is a major rule because of the size of the anticipated reduction in Federal financial participation that is estimated to have an economically significant effect of more than $100 million in each of the Federal fiscal years 2008 through 2012.

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. The Secretary certifies that this major rule would not have a direct impact on providers of rehabilitative services that furnish services pursuant to section 1905(a)(13) of the Act. The rule would directly affect states and we do not know nor can we predict the manner in which states would adjust or respond to the provisions of this rule. CMS is unable to determine the percentage of providers of rehabilitative services that are considered small businesses according to the Small Business Administration's size standards with total revenues of $6.5 million to $31.5 million or less in any 1 year. Individuals and States are not included in the definition of a small entity. 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 (proposed documents) 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 Medicaid payment regulations and has fewer than 100 beds. The Secretary certifies that this major rule would not have a direct impact on small rural hospitals. The rule would directly affect states and we do not know nor can we predict the manner in which states would adjust or respond to the provisions of this rule.

Section 202 of the Unfunded Mandates Reform Act (UMRA) 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. Since this rule would not mandate spending in any 1 year of $120 million or more, the requirements of the UMRA are not applicable.

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 rule would not impose any costs on State or local governments, preempt State law, or otherwise have Federalism implications, the requirements of E.O. 13132 are not applicable.

B. Anticipated Effects

FFP will be available for rehabilitative services for treatment of physical, mental health, or substance-related disorder rehabilitation treatment if the State elects to provide those services through the approved State plan. Individuals retain the right to select among qualified providers of rehabilitative services. However, because FFP will be excluded for rehabilitative services that are included in other Federal, State and local programs, it is estimated that Federal Medicaid spending on rehabilitative services would be reduced by approximately $180 million in FY 2008 and would be reduced by $2.2 billion between FY 2008 and FY 2012. This reduction in spending is expected to occur because FFP for rehabilitative services would no longer be paid to inappropriate other third parties or other Federal, State, or local programs.

The estimated impact on Federal Medicaid spending was calculated starting with an estimate of rehabilitative service spending that may be subject to this rule. This estimate was developed after consulting with several experts, as data for rehabilitative services, particularly as it would apply to this rule, is limited. Given this estimate, the actuaries discounted this amount to account for four factors: (1) The ability of CMS to effectively identify the rehabilitative services spending that would be subject to this proposal; (2) the effectiveness of CMS's efforts to implement this rule and the potential that some identified rehabilitative services spending may still be permissible under the rule; (3) the change in States' plans that may regain some of the lost Federal funding; and (4) the length of time for CMS to fully implement the rule and review all States' plans.

The actual impact to the Federal Medicaid program may be different than the estimate to the extent that the estimate of the amount of rehabilitative services spending subject to this rule is different than the actual amount and to the extent that the effectiveness of the rule is greater than or less than assumed. Because a comprehensive review of these rehabilitative services had not been conducted at the time of this estimate and because we do not routinely collect data on spending for rehabilitative services, particularly as it relates to this rule, there is a significantly wide range of possible impacts.

Thus, we are unable to determine what fiscal impact the publication of this rule would have on consumers, individual industries, Federal, State, or local government agencies or geographic regions under Executive Order 12866. We invite public comment on the potential impact of the rule.

C. Alternatives Considered

This proposed rule would amend

the definition of rehabilitative services to provide for important individual protections and to clarify that Medicaid rehabilitative services must be coordinated with but do not include services furnished by other programs that are focused on social or educational development goals and available as part of other services or programs. We believe this proposed rule is the best approach to clarifying the covered rehabilitative services, and also because all stakeholders will have the opportunity to comment on the proposed rule. These comments will then be considered before the final document is published.

In considering regulatory options, we considered requiring States to license all providers as an alternative to only requiring that providers to be qualified as defined by the State. However we believe that giving States the flexibility to determine how providers are credentialed allows for necessary flexibility to States to consider a wide range of provider types necessary to cover a variety of rehabilitation services. We believe this flexibility will result in decreases in administrative and service costs.

We also considered restricting the rule to only include participant protections but not explicitly prohibiting FFP for services that are intrinsic elements of other non-Medicaid programs. Had we not prohibited FFP for services that are intrinsic elements of other programs, States would continue to provide non-Medicaid services to participants, the result would have been a less efficient use of Medicaid funding because increased Medicaid spending would not result in any increase in services to beneficiaries. Instead, increased Medicaid funding would have simply replaced other sources of funding.

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 savings associated with the provisions of this proposed rule. This table provides our best estimate of the savings to the Federal Government as a result of the changes presented in this proposed rule that Federal Medicaid spending on rehabilitative services would be reduced by approximately $180 million in FY 2008 and would be reduced by $2.24 billion between FY 2008 and FY 2012. All savings are classified as transfers from the Federal Government to State Government. These transfers represent a reduction in the federal share of Medicaid spending once the rule goes into effect, as it would limit States from claiming Medicaid reimbursement for rehabilitation services that could be covered through other programs.

ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED SAVINGS, FROM FY 2008 TO FY 2012
[In millions]

Category	Primary estimates	Year dollar	Units discount rate	Period covered
Federal Annualized Monetized ($millions/year)	443.4	2008	7%	2008–2012
	441.6	2008	3%	2008–2012
	448	2008	0%	2008–2012
From Whom to Whom?	Federal Government to State Government			

Column 1: Category—Contains the description of the different impacts of the rule; it could include monetized, quantitative but not monetized, or qualitative but not quantitative or monetized impacts; it also may contain unit of measurement (such as, dollars). In this case, the only impact is the Federal annualized monetized impact of the rule.

Column 2: Primary Estimate—Contains the quantitative or qualitative impact of the rule for the respective category of impact. Monetized amounts are generally shown in real dollar terms. In this case, the federalized annualized monetized primary estimate represents the equivalent amount that, if paid (saved) each year over the period covered, would result in the same net present value of the stream of costs (savings) estimated over the period covered.

Column 3: Year Dollar—Contains the year to which dollars are normalized; that is, the first year that dollars are discounted in the estimate.

Column 4: Unit Discount Rate—Contains the discount rate or rates used to estimate the annualized monetized impacts. In this case, three rates are used: 7 percent; 3 percent; 0 percent.

Column 5: Period Covered—Contains the years for which the estimate was made.

Rows: The rows contain the estimates associated with each specific impact and each discount rate used.

"From Whom to Whom?"—In the case of a transfer (as opposed to a change in aggregate social welfare as described in the OMB Circular), this section describes the parties involved in the transfer of costs. In this case, costs previously paid for by the Federal Government would be transferred to the State Governments. The table may also contain minimum and maximum estimates and sources cited. In this case, there is only a primary estimate and there are no additional sources for the estimate.

Estimated Savings—The following table shows the discounted costs (savings) for each discount rate and for each year over the period covered. "Total" represents the net present value of the impact in the year the rule takes effect. These numbers represent the anticipated annual reduction in Federal Medicaid spending under this rule.

ESTIMATED SAVINGS, FROM FY 2008 TO FY 2012
[In millions]

Discount rate (percent)	2008	2009	2010	2011	2012	Total
0	180	360	520	570	610	2,288
3	175	339	476	506	526	2,069
7	168	314	424	435	435	1,822

E. Conclusion

For these reasons, we are not preparing analyses for either the RFA or section 110 2(b) of the Act because a comprehensive review of these rehabilitative services had not been conducted at the time of this estimate and because we do not routinely collect data on spending for rehabilitative services. Accordingly, there is a significantly wide range of possible impacts due to this rule. As indicated in the Estimated Savings table above, we project an estimated savings of $180 million in FY 2008, $360 million in FY 2009, $520 million in FY 2010, $570 million in FY 2011, and $610 million in FY 2012. This reflects a total estimated savings of $2.240 billion dollars for FY 2008 through FY 2012. We invite public comment on the potential impact of this rule.

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

List of Subjects

42 CFR Part 440

Grant programs—health, Medicaid.

42 CFR Part 441

Family planning, Grant programs— health, Infants and children, Medicaid, Penalties, Prescription drugs, 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 440—SERVICES: GENERAL PROVISIONS

1. The authority citation for part 440 continues to read as follows:

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

2. Section 440.130 is amended by revising paragraph (d) to read as follows:

§ 440.130 Diagnostic, screening, preventative, and rehabilitative services.

* * * * *

(d) *Rehabilitative Services—(1) Definitions.* For purposes of this subpart, the following definitions apply:

(i) *Recommended by a physician or other licensed practitioner of the healing arts* means that a physician or other licensed practitioner of the healing arts, based on a comprehensive assessment of the individual, has—

(A) Determined that receipt of rehabilitative services would result in reduction of the individual's physical or mental disability and restoration to the best possible functional level of the individual; and

(B) Recommended the rehabilitative services to achieve specific individualized goals.

(ii) *Other licensed practitioner of the healing arts* means any health practitioner or practitioner of the healing arts who is licensed in the State to diagnose and treat individuals with the physical or mental disability or functional limitations at issue, and operating within the scope of practice defined in State law.

(iii) *Qualified providers of rehabilitative services* means individuals who meet any applicable provider qualifications under Federal law that would be applicable to the same service when it is furnished under other Medicaid benefit categories, qualifications under applicable State scope of practice laws, and any additional qualifications set forth in the Medicaid State plan. These qualifications may include minimum age requirements, education, work experience, training, credentialing, supervision and licensing requirements that are applied uniformly. Provider qualifications must be documented in the State plan and be reasonable given the nature of the service provided and the population served. Individuals must have free choice of providers and all willing and qualified providers must be permitted to enroll in Medicaid.

(iv) *Under the direction of* means that for physical therapy, occupational therapy, and services for individuals with speech, hearing and language disorders (see § 440.110, "Inpatient hospital services, other than services in an institution for mental diseases") the Medicaid qualified therapist providing direction is a licensed practitioner of the healing arts qualified under State law to diagnose and treat individuals with the disability or functional limitations at issue, is working within the scope of practice defined in State law and is supervising each individual's care. The supervision must include, at a minimum, face-to-face contact with the individual initially and periodically as needed, prescribing the services to be provided, and reviewing the need for continued services throughout the course of treatment. The qualified therapist must also assume professional responsibility for the services provided and ensure that the services are medically necessary. Therapists must spend as much time as necessary directly supervising services to ensure beneficiaries are receiving services in a safe and efficient manner in accordance with accepted standards of practice. Moreover, documentation must be kept supporting the supervision of services and ongoing involvement

in the treatment. Note that this definition applies specifically to providers of physical therapy, occupational therapy, and services for individuals with speech, hearing and language disorders. This language is not meant to exclude appropriate supervision arrangements for other rehabilitative services.

(v) *Rehabilitation plan* means a written plan that specifies the physical impairment, mental health and/or substance related disorder to be addressed, the individualized rehabilitation goals and the medical and remedial services to achieve those goals. The plan is developed by a qualified provider(s) working within the State scope of practice act, with input from the individual, individual's family, the individual's authorized decision maker and/or of the individual's choosing and also ensures the active participation of the individual, individual's family, individual's authorized decision maker and/or of the individual's choosing in the development, review, and modification of the goals and services. The plan must document that the services have been determined to be rehabilitative services consistent with the regulatory definition. The plan must have a timeline, based on the individual's assessed needs and anticipated progress, for reevaluation of the plan, not longer than one year. The plan must be reasonable and based on the individual's condition(s) and on general standards of practice for provision of rehabilitative services to an individual with the individual's condition(s).

(vi) *Restorative services* means services that are provided to an individual who has had a functional loss and has a specific rehabilitative goal toward regaining that function. The emphasis in covering rehabilitation services is on the ability to perform a function rather than to actually have performed the function in the past. For example, a person may not have needed to take public transportation in the past, but may have had the ability to do so prior to having the disability. Rehabilitation goals are often contingent on the individual's maintenance of a current level of functioning. In these instances services that provide assistance in maintaining functioning may be considered rehabilitative only when necessary to help an individual achieve a rehabilitation goal defined in the rehabilitation plan. **Acceptable rehabilitation goals in these instances could include avoidance of negative outcomes such as hospitalization or achievement of positive outcomes such as community participation.** Services provided primarily in order to maintain a level of functioning in the absence of a rehabilitation goal are not within the scope of rehabilitation services.

(vii) *Medical services* means services specified in the rehabilitation plan that are required for the diagnosis, treatment, or care of a physical or mental disorder and are recommended by a physician or other licensed practitioner of the healing arts within the scope of his or her practice under State law. Medical services may include physical therapy, occupational therapy, speech therapy, and mental health and substance-related disorder rehabilitative services.

(viii) *Remedial services* means services that are intended to correct a physical or mental disorder and are necessary to achieve a specific rehabilitative goal specified in the individual's rehabilitation plan.

(2) *Scope of services.* Except as otherwise provided under this subpart, rehabilitative services include medical or remedial services recommended by a physician or other licensed practitioner of the healing arts, within the scope of his practice under State law, for maximum reduction of physical or mental disability and restoration of a individual to the best possible functional level. Rehabilitative services may include assistive devices, medical equipment and supplies, not otherwise covered under the plan, which are determined necessary to the achievement of the individual's rehabilitation goals. Rehabilitative services do not include room and board in an institution or community setting.

(3) *Written rehabilitation plan.* The written rehabilitation plan shall be reasonable and based on the individual's condition(s) and on the standards of practice for provision of rehabilitative services to an individual with the individual's condition(s). In addition, the written rehabilitation plan must meet the following requirements:

(i) Be based on a comprehensive assessment of an individual's rehabilitation needs including diagnoses and presence of a functional impairment in daily living.

(ii) Be developed by a qualified provider(s) working within the State scope of practice act with input from the individual, individual's family, the individual's authorized health care decision maker and/or persons of the individual's choosing.

(iii) Follow guidance obtained through the active participation of the individual, and/or persons of the individual's choosing (which may include the individual's family and the individual's authorized health care decision maker), in the development, review, and modification of plan goals and services.

(iv) Specify the individual's rehabilitation goals to be achieved, including recovery goals for persons with mental health and/or substance related disorders.

(v) Specify the physical impairment, mental health and/or substance related disorder that is being addressed.

(vi) Identify the medical and remedial services intended to reduce the identified physical impairment, mental health and/or substance related disorder, **and identify the individuals or agencies responsible for providing these services.**

(vii) Identify the methods that will be used to deliver services.

(viii) Specify the anticipated outcomes.

(ix) Indicate the frequency, amount and duration of the

services.

(x) Be signed by the individual responsible for developing the rehabilitation plan, and if the individual refuses to sign the plan, document the reason(s).

(xi) ~~Indicate the anticipated provider(s) of the service(s) and the extent to which the services may be available from alternate provider(s) of the same service~~.

(xii)Specify a timeline for reevaluation of the plan, based on the individual's assessed needs and anticipated progress, but not longer than one year.

(xiii) Be reevaluated with the involvement of the individual, family or other responsible individuals.

(xiv) Be reevaluated including a review of whether the goals set forth in the plan are being met and whether each of the services described in the plan has contributed to meeting the stated goals. If it is determined that there has been no measurable reduction of disability and restoration of functional level, any new plan would need to pursue a different rehabilitation strategy including revision of the rehabilitative goals, services and/or methods. For some individuals such as those with serious mental illness, "reduction of disability and restoration of functional level" may be measured by comparing the effect of continuing rehabilitation versus discontinuing it. Where there is a reasonable expectation that if the rehabilitation services had been withdrawn the individual's condition would have deteriorated, relapsed further, or required hospitalization, this criterion would be met.

(xiv) Document that the individual or representative participated in the development of the plan, signed the plan, and received a copy of the rehabilitation plan.

(xv)Document that the services have been determined to be rehabilitative services consistent with the regulatory definition.

(xvi) Include the individual's relevant history, current medical findings, contraindications and identify the individual's care coordination needs, if any, as needed to achieve the rehabilitation goals.

(4) *Impairments to be addressed*. For purposes of this section, rehabilitative services include services provided to the Medicaid eligible individual to address the individual's physical impairments, mental health impairments, and/or substance-related disorder treatment needs.

(5) *Settings*. Rehabilitative services may be provided in a facility, home, or other setting.

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

1. The authority citation for part 441 continues to read as follows:

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

Subpart A—General Provisions

2. A new § 441.45 is added to subpart A to read as follows:

§441.45 Rehabilitative services.

(a) If a State covers rehabilitative services, as defined in § 440.130(d) of this chapter, the State must meet the following requirements:

(1) Ensure that services are provided in accordance with § 431.50, § 431.51, § 440.230, and § 440.240 of this chapter.

(2) Ensure that rehabilitative services are limited to services furnished for the maximum reduction of physical or mental disability and restoration of the individual to their best possible functional level.

(3) Require that providers maintain case records that contain a copy of the rehabilitation plan for all individuals.

(4) For all individuals receiving rehabilitative services, require that providers maintain case records that include the following:

(i) A copy of the rehabilitative plan.

(ii) The name of the individual.

(iii) The date of the rehabilitative services provided.

(iv) The nature, content, and units of the rehabilitative services.

(v) The progress made toward functional improvement and attainment of the individual's goals as identified in the rehabilitation plan and case record.

(5) Ensure the State plan for rehabilitative services includes the following requirements:

(i) Describes the rehabilitative services furnished.

(ii) Specifies provider qualifications that are reasonably related to the rehabilitative services proposed to be furnished.

(iii) Specifies the methodology under which rehabilitation providers are paid.

(b) Rehabilitation does not include, and FFP is not available in expenditures for, services defined in § 440.130(d) of this chapter if the following conditions exist:

(1) The services are furnished through a non-medical program as either a benefit or administrative activity, including services that are intrinsic elements of programs other than Medicaid, such as foster care, child welfare, education, child care, vocational and prevocational training, housing, parole and probation, juvenile justice, or public guardianship. Services would not be considered to be intrinsic elements of these non-medical programs if they are medically necessary rehabilitation services for an eligible individual that are clearly distinct from the non-covered program services and that are provided by qualified Medicaid providers. One way to demonstrate this distinction is to clearly and reasonably distinguish the funding stream for the Medicaid rehabilitation services as being identifiably separate from that of the non-covered services. Examples of services that are intrinsic elements of other programs and that would not be paid under Medicaid include, but are not limited to, the following:

(i) Therapeutic foster care services furnished by foster care providers to children, except for

medically necessary rehabilitation services for an eligible child that are clearly distinct from packaged therapeutic foster care services and that are provided by qualified Medicaid providers.

(ii) Packaged services furnished by foster care or child care institutions for a foster child except for medically necessary rehabilitation services for an eligible child that are clearly distinct from packaged therapeutic foster care services and that are provided by qualified Medicaid providers.

(iii) Adoption services, family preservation, and family reunification services furnished by public or private social services agencies.

(iv) Routine supervision and non-medical support services provided by teacher aides in school settings (sometimes referred to as ''classroom aides'' and ''recess aides'').

(2) Habilitation services, including services for which FFP was formerly permitted under the Omnibus Budget Reconciliation Act of 1989. Habilitation services include ''services provided to individuals'' with mental retardation or related conditions. (Most physical impairments, and mental health and/or substance related disorders, are not included in the scope of related conditions, so rehabilitation services may be appropriately provided.)

(3) Recreational or social activities that are not focused on rehabilitation and not provided by a Medicaid qualified provider; personal care services; transportation; vocational and prevocational services that are not focused on reducing disability-related symptoms or deficits and not provided by a qualified Medicaid provider; or patient education not related to reduction of physical or mental disability and the restoration of an individual to his or her best possible functional level.

(4) Services that are provided to inmates living in the secure custody of law enforcement and residing in a public institution. An individual is considered to be living in secure custody if serving time for a criminal offence in, or confined involuntarily to, public institutions such as State or Federal prisons, local jails, detention facilities, or other penal facilities. A facility is a public institution when it is under the responsibility of a governmental unit; or over which a governmental unit exercises administrative control. Rehabilitative services could be reimbursed on behalf of Medicaid-eligible individuals paroled, on probation, on home release, in foster care, in a group home, or other community placement, that are not part of the public institution system, when the services are identified due to a medical condition targeted under the State's Plan, are not used in the administration of other non-medical programs.

(5) Services provided to residents of an institution for mental disease (IMD) who are under the age of 65, including residents of community residential treatment facilities with more than 16 beds that do not meet the requirements at § 440.160 of this chapter.

(6)Room and board.

(7) Services furnished for the treatment of an individual who is not Medicaid eligible.

(8) Services that are not provided to a specific individual as documented in an individual's case record.

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

Dated: March 22, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: July 12, 2007.

Michael O. Leavitt,

Secretary.

[FR Doc. 07–3925 Filed 8–8–07; 4:00 pm] BILLING CODE 4120–01–P

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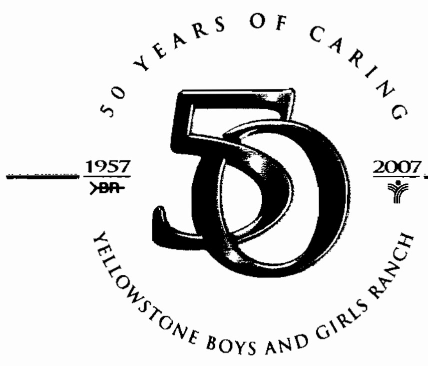


YELLOWSTONE
Boys and Girls Ranch

"It sure makes a difference when you know somebody cares"

October 8, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 21244-1850

Attn: CMS-2261-P
Proposed rule making on the Coverage for Rehabilitative
Services 42 CFR parts 440 and 441
Federal Register (72 FR 45201)

To Whom It May Concern:

Yellowstone Boys and Girls Ranch (YBGR) has served the needs of high risk children and families in Montana and other states for 50 years through its residential treatment center and community based services. We are a member of the Montana Children's Initiative Provider Association (MCI) and currently serve an average of approximately 600 youth a day in these various programs.

We are very concerned about the proposed rehabilitation rule changes by the Centers for Medicaid & Medicaid Services (CMS). These changes would result in a mandate to Montana that we unbundle our Therapeutic Foster Care (TFC), Therapeutic Family Living (TFL) and Therapeutic Group Care (TGC) services for seriously emotionally disturbed children. In this last fiscal year Montana served over 800 youth in TFC and TFL and over 500 youth were served in 4-8 bed TGC. If implemented, these changes could ultimately destroy Montana's array of out of home services and essentially wipe out all services between foster care and residential treatment.

MCI has been involved with the Montana Department of Public Health and Human Services and the Children's Mental Health Bureau regarding how to unbundle these services. There appears to be some possibility to restructure our Therapeutic Group Care services. It is a very important level of care. Many youth who do not need residential treatment or are stepping down from this level of are, but cannot function in a family setting do well in a community based Therapeutic Group Home, where they can go to school or day treatment and participate in other community activities. However, our Therapeutic Foster Care and Therapeutic Family Living services, where youth live in a family setting, could end up being totally dismantled.

1732 South 72nd Street West • Billings, Montana 59106-3599 • 406-655-2100 • FAX 406-656-0021 • 1-800-726-6755 • www.ybgr.org

Following, are the concerns we have regarding the proposed rule changes and the impact on our excellent out of home children's services:

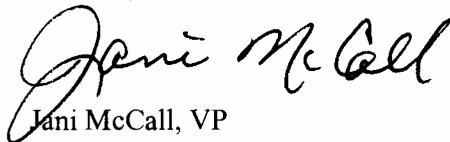
- The basic definition of "rehabilitative services" is retained as: "medical or remedial services recommended by a physician or other licensed practitioner of the healing arts.........for maximum reduction of physical or mental disability or restoration of an individual to the best possible functional level." This definition is confusing when it comes to children, because of their ever-changing developmental levels.
- The definition of requiring all treatment foster parents to meet "qualified providers of rehabilitation services" will likely result in most of them not being able to meet the standards. The qualifications might include education, work experience, training, credentialing, supervision, and licensing. Treatment foster parents come from a variety of backgrounds. The vast majority do not have professional training in human services.
- Currently CMS is maintaining that Therapeutic Foster Care is not considered a medically necessary service. The proposed rule would prohibit reimbursement for this service under the Medicaid Rehabilitation Services benefit, including recruitment, training, and other foster care support services;
    - According to SAMSHA, Therapeutic Foster Care is supported as the most effective out of home placement option for children, yet CMS contradicts this, with rule changes that would not allow these support services to be paid for by Medicaid dollars.
    - Therapeutic Family Living services are geared to work with children in their own home and provide the same level of support as TFC, yet the CMS rule changes would not allow these support services to be paid for by Medicaid dollars.
    - The President's Freedom Commission Report supports family driven services and the creation of comprehensive, multi-agency children's system of care options, yet the CMS rule changes contradict the priorities in this report.
- A written rehabilitation plan (with 17 components) will help ensure state accountability and regular re-evaluation will ensure progress. The plan also requires input from the youth and family.
    - However, the rule does not take into account other plans such as individual treatment plan and how they will be coordinated to avoid duplication, additional time, and additional burden.
- The "Intrinsic To" test, states that rehabilitation does not include services furnished through a non medical program as either a benefit or administrative activity including services that are intrinsic to elements of programs such foster care, child welfare, education, child care, and juvenile justice.
    - According to the Child Welfare League of America, Congress explicitly rejected adopting an 'intrinsic to" test in regards to Medicaid rehabilitative services when finalizing the Deficit Reduction Act, yet it is occurring in these proposed changes.
    - The proposed changes exclude federal financial participation for TFC or TFL, except for "medically necessary rehabilitation services that are clearly distinct from packaged therapeutic foster care services." It is extremely difficult to unbundle TFC and TFL services to meet these terms. TFC and TFL gives children the chance to heal and grow in the midst of a family setting.
    - Montana's child welfare system requires that children in care receive all of the services they need, physical, dental and mental health. Most children in the system have experienced some type of trauma resulting from some form of child abuse and/or neglect.

- Montana's Children's System of Care, supported by a SAMSHA grant and the President's New Freedom Commission report on Mental Health acknowledge and promote the need for comprehensive, wrap around and supportive community based services for children and families. If Medicaid dollars no longer pay for these kinds of support services, how can we provide the treatment and care they deserve? How can we meet the requirements of our SAMSHA Children's System of Care grant of least restrictive, most appropriate family and community based services?
- Both our child welfare system and our mental health system must ensure the provision of all medically necessary services but cannot cover the costs alone without Medicaid assistance.

We believe that CMS will receive similar comments from virtually all states across the country regarding these changes and the impact on children's out of home services. We ask that CMS not implement the proposed rules as scheduled in June 2008 and that substantial time be given to evaluate the impact of these changes. If this is not done, we will see less restrictive, cost effective community based services dismantled, more children being served at the highest levels of care and Montana, along with many other states, faced with huge general fund budget concerns to offset the loss of Medicaid funding.

Thank you for your cooperation and consideration of these critically important issues. If I can be of further assistance, please contact me at 406-655-2100 or janim@ybgr.org.

Sincerely,



Jani McCall, VP
Government Affairs

Copy: MCI Members
MT DPHHS

JM/jm

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Advancing the human and civil rights of people with disabilities

SELF-ADVOCACY ASSISTANCE ★ LEGAL SERVICES ★ DISABILITY RIGHTS EDUCATION ★ PUBLIC POLICY ADVOCACY ★ ABUSE INVESTIGATIONS

October 10, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

RE: File Code CMS-2261-P
Notice of Proposed Rule
Medicaid Coverage: Coverage for Rehabilitative Services

Dear Sir or Madam:

Equip for Equality is an independent, statewide nonprofit organization designated to administer the federally mandated protection and advocacy system for people with mental and physical disabilities in Illinois. We submit these comments in response to the Notice of Proposed Rule entitled "Medicaid Program: Coverage for Rehabilitation Services," published in the Federal Register on August 13, 2007.

Equip for Equality concurs with the comments and recommendations of The National Health Law Program, the Judge David L. Bazelon Center for Mental Health Law, and the Consortium for Citizens with Disabilities and urges the withdrawal of the proposed rule or, at the very least, extensive amendment of the proposed regulations including the following:

- Address the substantial direct compliance costs on the States of the proposed regulations as required by Executive Order 13132. 72 Fed. Reg. at 45209 (Preamble, V.A.). Most states will probably have to change their billing and authorization procedures. In addition, if states choose to continue to provide services that would be categorized as day habilitation services under the proposed regulations, they will have to pay for them with state only funds or drastically alter the way in which they provide services.

- Correct the assertion that this rule will not have a direct impact on providers of rehabilitation services as the requirement for a written rehabilitation plan, although a good addition, and the separate billing requirements will, in fact, require additional work by providers. 72 Fed. Reg. at 45206 (Preamble, II.F.2).

THE INDEPENDENT, FEDERALLY MANDATED PROTECTION & ADVOCACY SYSTEM FOR THE STATE OF ILLINOIS

MICHAEL A. PARKS, BOARD CHAIRPERSON ★ ZENA NAIDITCH, PRESIDENT & CEO

MAIN OFFICE: 20 N. MICHIGAN AVENUE, SUITE 300 ★ CHICAGO, IL 60602 ★ EMAIL: CONTACTUS@EQUIPFOREQUALITY.ORG ★ TEL: (312) 341-0022

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- Address the potential conflicts with Medicaid's Early and Periodic Screening, Diagnostic and Treatment Service (EPSDT) requirements by amending the proposal to clearly state that states must ensure that children receive all federally-covered Medicaid rehabilitation services when necessary to correct or ameliorate a physical or mental illness or condition, that states must make certain rehabilitation services available to children when necessary to correct a physical or mental illness or condition even when a state plan does not include these services and specifically refer to the EPSDT requirement and instruct states to comply with it. (Sec. 441.45)

- Amend the proposal to recognize that measurable progress toward a particular goal within a certain time period does not necessarily indicate that a service is not necessary to help achieve a rehabilitation goal (Sec. 440.130 (d)(1)(vi) and that services that cannot be covered as a rehabilitative service may be covered under another category of Medicaid services. (Sec.441.45)

- Clarify that rehabilitation services should be covered in any setting permitted by state law and add to Sec. 440.130(d) the other settings listed in the preamble such as schools and community mental health centers.

- Add language to Sec. 440.130(d)(1)(vi) stating that peer guidance is a covered rehabilitation service in accordance with the CMS guidance letter: *Dear State Medicaid Director,* Peer Support Services – SMDL #07-011 (August 15, 2007).

- Omit Sec. 441.45(b) because it conflicts with the EPSDT requirements and other parts of the Medicaid statute.

- Withdraw Sec. 441.45(b)(2) excluding coverage of habilitation services or, at least, clarify that a diagnosis of mental retardation or related conditions does not automatically exclude a person from coverage of mental health services, that habilitation services may also be provided under other Medicaid services categories (Sec 441.45(b)(2), and that services for individuals with a dual diagnosis of mental retardation/related condition and mental illness may be covered and how that may be achieved.

Thank you for the opportunity to submit these comments.

Sincerely,

Marsha Koelliker
Director of Public Policy

ALABAMA DISABILITIES

ADVOCACY PROGRAM

Protection & Advocacy for Persons with Developmental Disabilities

Protection & Advocacy for Individuals with Mental Illness

Protection & Advocacy of Individual Rights

Protection & Advocacy for Assistive Technology

Protection & Advocacy for Individuals with Traumatic Brain Injury

Protection & Advocacy for Beneficiaries of Social Security

Protection & Advocacy for Voting Accessibility

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www.ADAP.net

October 10, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS-2261-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: **File Code CMS-2261-P. Comments on the Proposed Rule for Coverage for Rehabilitative Services under the Medicaid program**

Dear Sir or Madam:

Thank you for providing opportunities for individuals living with mental illness, their family members and others to provide comments on the proposed rule regarding coverage for rehabilitative services under the Medicaid program. As you may know, ADAP is Alabama's federally funded Protection and Advocacy Program on behalf of persons with disabilities, including mental health issues. Through our work, we advocate on behalf of persons who have mental illness and bring that unique perspective to our comments on these rules.

Non-covered services: 441.45(b)

This section introduces a completely new concept into Medicaid, one that conflicts with federal statutory requirements. It denies Medicaid coverage for covered services to covered individuals if such services are furnished through another program, including when they are considered "intrinsic elements" of that program. There is little clarity in the regulation on how this provision would be applied because the regulation provides no guidance on how to determine whether a service is an "intrinsic element" of another program.

There appear to be only two situations in which Medicaid might have been paying for services that fall under this test. First, a provider bills Medicaid for a service that is not a Medicaid-covered service B, in which case this is a fraud-abuse issue and does not warrant a change in rule for all providers and systems. Or, second, CMS is concerned that non-medical programs are furnishing Medicaid-covered services (and meeting all Medicaid requirements) but have other resources available to them for providing the service (even though these other resources are generally targeted to non-Medicaid individuals). In the latter case, what is the legal basis for denying federal financial participation for the Medicaid-covered individual?

Furthermore, few of the other cited programs have a clear legal obligation to provide these services or have the resources to do so. Without revision, this new rule would conflict with the federal statutory mandate to provide all medically necessary services covered by the state Medicaid plan, and for children, all medically necessary services covered by 42 U.S.C. § 1396d(a). See 42 U.S.C. §§ 1396a(a)(10), 1396d(r). The net result of this new rule will be that Medicaid-eligible individuals will be denied services, both by Medicaid and by the other cited program (due to lack of resources in the other program). Thus, the rule effectively denies them medically necessary Medicaid services, in direct contradiction of the statute.

Recommendation:

It is strongly recommend that this entire section be dropped, because it conflicts with the Medicaid statute.

Alternatively, the section should be clarified and narrowed to focus on situations where an entity (e.g. an insurer) has a specific legal obligation to pay for the services for the specific Medicaid-covered individual. Programs operated through capped or discretionary appropriations from states or localities should be specifically excluded from this provision.

The preamble states that Medicaid-eligible individuals in programs run by other agencies are entitled to any rehabilitative service that would have been provided to individuals outside of those other programs. The preamble also makes clear that Medicaid rehabilitative services must be coordinated with services furnished by other programs. The regulation should include this language.

It is especially important that mental health providers be able to work with children and adults with serious mental disorders in all appropriate settings. For children, the school day can be an especially critical time. While classroom aides may not be eligible mental health providers, the presence of a mental health provider in the classroom to address a specific child's functional impairments should be a covered service.

Similarly, a child with a serious mental disorder being reunified with his or her family may have specific issues directly stemming from the mental disorder. Mental health rehabilitation services to address these problems (as distinct from generic reunification services) should be covered.

Therapeutic Foster Care: 441.45(b)(1)(i)

The regulation denies payment for therapeutic foster care as a single program, requiring instead that each component part be separately billed.

Therapeutic foster care is the least restrictive out-of-home placement for a child with a serious mental disorder. Therapeutic foster care is a widely covered evidence-based practice with more than half a dozen controlled clinical trials demonstrating improved outcomes (*see* the Report on Mental Health from the U.S. Surgeon General). The alternative for most such children would be immediate placement in an institutional setting, such as a residential treatment program or psychiatric hospital, at significantly higher expense.

If states are not able to create a package of covered services such as therapeutic foster care and pay on that basis, this will result in inefficiencies and raise administrative costs.

Recommendation:

Therapeutic foster care should be listed as a covered rehabilitation service for children with serious mental disorders at imminent risk of placement in a residential treatment facility. States should be given the discretion to define therapeutic foster care as a single service and pay through a case rate, daily rate or other appropriate mechanism.

Language should also be included in 441.45(b)(1)(i) to clarify that mental health rehabilitation providers may always furnish any covered rehabilitation service to children in therapeutic foster care.

Rehabilitative Services: 441.45(a)(2)

This section limits rehabilitative services to those furnished for the maximum reduction of physical or mental disability and restoration of the individual to the best possible functional level, as defined in the law. However, it would be helpful to reiterate here when services may be furnished to retain or maintain functioning.

It would also be valuable to include the language now in the preamble (page 45204) regarding how to determine whether a particular service is a rehabilitation service, based on its purpose.

Recommendation:

Insert additional language into 441.45(a)(2) to describe when services may be furnished with the goal of retaining or maintaining functioning.

Insert additional language into this section (from the preamble) to state that it is helpful to scrutinize the purpose of the service as defined in the care plan in order to determine whether a specific service is a covered rehabilitative benefit.

Definition of Restorative Services: 440.130(d)(1)(vi)

This definition stipulates that restorative services are those that enable an individual to perform a function, and that the individual does not have to have actually performed the function in the past. This language is critical, as loss of function may have occurred long before restorative services are provided. This would be particularly true for children, as some functions may not have been possible (or age-appropriate) at an earlier date. The regulation needs modification to make the meaning of this section clearer.

This definition also includes as appropriate rehabilitation services designed to maintain current level of functioning but only when necessary to help an individual achieve a rehabilitation goal. While rehabilitation services should not be custodial, for people with

serious mental or emotional disabilities, continuation of rehabilitative services is at times essential to retain their functional level. Failure to provide a supportive level of rehabilitation would result in deterioration, necessitating a reinstatement of intensive services. There is concern that states and providers will interpret the current proposed regulation as prohibiting coverage of services necessary for retention of improved functioning and for maintaining the highest possible functional level, leading individuals to deteriorate to the point where they will be eligible for services. This serves no one's interest.

Section 1901 of the statute specifically authorizes funds for "rehabilitation and other services" to help individuals "retain" capability for independence and self-care. This provides authority for CMS to allow states to furnish services that will maintain an individual's functional level.

Recommendation:

Further clarify that a child need not demonstrate that he or she was once capable of performing a specific task in the past if it was not possible or age-appropriate for the child to have done so. Specifically, the language should state that restorative services include services to enable a child to achieve age-appropriate growth and development and that it is not necessary that the child actually performed the activity in the past. (Note, this phrasing is taken from current CMS regulation of managed care plans at 42CFR 438.210(a)(4)(ii)(B)). An example of a child who was developmentally on track to perform a function, but did not because it was not yet age-appropriate would be helpful. Currently, the regulation only has an example of an adult.

Second, revise the definition of when services may be furnished to maintain functioning to include as an acceptable goal of a rehabilitation plan the retaining of functional level for individuals who can be expected to otherwise deteriorate.

Related Medicaid Rehabilitation Issues:

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Although not specifically described in this regulation, recent CMS insistence on accounting and billing for services through 15-minute increments and denying payment through daily rates, case rates and similar arrangements is supported by language in the regulation, at least by inference.

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The regulation appears to ignore the Title XIX mandate that children under age 21 are eligible for all federal Medicaid-covered services, regardless of whether that service is defined in the state plan or covered for adults. In several places, the regulation needs to be amended to reflect the EPSDT provision.

Recommendation:

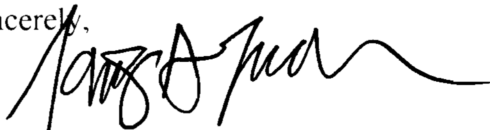
Section 441.45(a), insert a new paragraph clearly stating that states must ensure that children receive all federally covered Medicaid rehabilitation services when medically necessary to correct or ameliorate a physical or mental illness or condition.

Section 441.45(b)(4), which refers to services having to be targeted under the state's plan should be amended to reference EPSDT for children.

Section 441.45(a)(5) should clarify that even when the state plan does not include certain rehabilitative services, these services must nonetheless be made available to children when medically necessary.

Thank you for your consideration of these comments.

Sincerely,



James A. Tucker, Esq.

Assoc. Dir.

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Office of Vermont Health Access
312 Hurricane Lane Suite 201
Williston, VT 05495-2086
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[phone] 802-879-5900

Agency of Human Services

October 10, 2007

Ms. Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS -2261-P
P.O. Box 8018
Baltimore, Maryland 21244-8018

Dear Ms. Norwalk:

Vermont appreciates the opportunity to comment on the proposed rules for Coverage of Rehabilitative Services in the Medicaid program, as published in the Federal Register on August 13, 2007.

Attached are our comments, and we look forward to hearing the responses to all the comments.

Sincerely,

Esther Perelman

Esther Perelman
Policy Director

Vermont's Comments on Proposed Rules in Medicaid Program; Coverage for Rehabilitative Services

Federal Register/Vol.72, No. 155/Monday, August 13, 2007/Proposed Rules

File code CMS 2261-P

October 10, 2007

Proposed rule section:

Summary

Language in the proposed rule:

"...Medicaid rehabilitative services must be coordinated with but do not include services furnished by other programs that are focused on social or educational development goals and available as part of other services or programs."

Comment:

In 1988 Title XIX was amended to allow services provided in a school setting to be reimbursable by Medicaid. The proposed changes to rehabilitative services seem to contradict this amendment which states "Nothing in this title shall be constructed as prohibiting or restricting, or authorizing the Secretary to prohibit or restrict, payment under subsection (a) for medical assistance for covered services furnished to a child with a disability because such services are included in the child's individualized education program established pursuant to part B of the Individuals with Disabilities Education Act..."

Proposed rule section:

§ 440.130 (d) (1) (i) (A)

Language in the proposed rule:

The rule states that "a physician or other licensed practitioner of the healing arts" has "determined that receipt of rehabilitative services would result in reduction of the individual's physical or mental disability and restoration to the best possible functional level of the individual"

Comment:

This definition may not include all possible uses for therapies that are part of rehabilitative services. For example, children may receive physical therapy to alleviate an impaired physical function. In some cases, services may be designed to foster a developmentally appropriate but "new" function. We believe these therapies qualify under a reduction of the disability and restoration of functioning.

Proposed rule section:

§ 440.130 (d) (1) (vi)

Language in the proposed rule:

The rule states that the "emphasis in covering rehabilitation services is on the ability to perform a function rather than to actually have performed the function in the past."

Comment:

It is clear how this applies to adults. However we suggest clarification for children who may have had the capacity to perform an activity had it not been for a medical condition or an acute episode, including a traumatic experience. Similarly, if there are delays in an emergent function interventions aimed at fostering or restoring the young person to the expected level given their developmental state should be allowable. From the description above it would appear that that rehabilitation plan is allowable in most situations given the fundamental nature of child development and the belief that children are resilient and have the ability to perform various skills at certain ages even though they may have never actually performed a task. The rehabilitation intervention would serve to provide a maximum reduction of the disability as stated in §440.130 (d) (i) in order for normal or expected development to occur or compensatory skills to replace those that were expected but never formed.

Proposed rule section:

§ 440.130 (d) (1) (vi)

Language in the proposed rule:

The rule states that "Rehabilitation goals are often contingent on the individual's maintenance of a current level of functioning...Services provided primarily in order to maintain a level of functioning in the absence of a rehabilitation goal are not within the scope of rehabilitative services."

Comment:

Day Health Rehabilitation Services (Adult Day Services) are provided with the purpose to maintain optimal functioning, and prevent or delay admission to a nursing facility. We believe this is a critical service to our beneficiaries and is also cost-effective. We believe that the prevention of regression to maintain optimal functioning should be allowable.

Please clarify how you separate the impact of a rehab goal from the maintenance goal when the rule states that a rehab goal is contingent on the maintenance of a current level of functioning

People in nursing facilities with developmental disabilities currently receive outpatient rehabilitation services directed at providing the required specialized services under PASARR; the services focus on the acquisition of behaviors necessary to function with as much independence as possible and the prevention or deceleration of regression or loss of

current functioning. As long as a rehabilitation plan was in place, we believe these services continue to be included as rehabilitation services.

Proposed rule section:
§ 440.130 (d) (3) (xiv)

Language in the proposed rule:
The rule states that each rehabilitation plan must "Be reevaluated including a review of whether the goals set forth in the plan are being met and whether each of the services described in the plan has contributed to meeting the stated goals."

Comment:
For school-based services many of the requirements of the Rehabilitation Plan are redundant to IDEA B requirements. We suggest that CMS be clear that an IEP can be used as a Rehabilitation Plan, even if all of the elements of a Rehabilitation Plan are not required by IDEA B and therefore not included in the child's Individual Education Plan.

Proposed rule section:
§ 440.130 (d) (3)

Language in the proposed rule:
Written Rehabilitation Plan section in total

Comment:

1. The requirements for the care plan documentation are admirable, and in the case of some elements listed they represent best practice. However taken together as absolutes they create requirements that are susceptible to error and overly burdensome on the clinicians and care providers. We suggest that the elements be considered guidelines and not absolute requirements.

2. There is no guidance as to the interplay between a treatment plan and a rehabilitation plan. Given the complex natures of many disabilities and the possibility of a co-morbid acute and chronic condition being present at the same time, it is possible for a single individual to be reviewing multiple services for various purposes. This rule is silent on the relationship between the two documents and simply adds more administrative burden in situations where care planning is difficult enough.

3. Emphasis on utilizing consumer participation and language in treatment plan development is at odds with the CMS guidance for rehabilitation service options that more clearly document medical necessity and prescriptive service frequency.

4. We do believe it is essential that a consumer be involved in their care, care planning and delivery, it is possible that in individual may engage in the rehabilitative services yet refuse to sign their care plan. There must be an allowance for these situations.

Proposed rule section:

§ 440.130 (d) (3) (iv -ix)

Language in the proposed rule:

The Rule states that each rehabilitation plan must "Specify the individual's rehabilitation goals to be achieved, including recovery goals for persons with mental health and/or substance abuse related disorders"; "Specify the physical impairment, mental health, and/or substance related disorder that is being addressed";. "identify the methods that will be used to deliver services"; and "specify the frequency, amount, and duration of the services".

Comment:

Vermont places high value on the 10 Fundamental Components of Recovery as outlined in the National Consensus Statement on Mental Health Recovery. The consensus statement emphasizes the importance of "Self-Direction: Consumers lead, control, exercise choice over, and determine their own path of recovery by optimizing autonomy, independence, and control of resources to achieve a self-determined life. By definition, the recovery process must be self-directed by the individual, who defines his or her own life goals and designs a unique path towards those goals". As such, consumers of mental health services frequently identify personal recovery goals that are understandable to them, rather than comporting to traditional rehabilitation goals, the mental health disorder being addressed, and medical or remedial services and methods planned. Additionally, outcomes and service levels tend to follow a non-linear course, which is another fundamental component of recovery. How does the prescriptive specificity of the written rehabilitation plan, outlined in the proposed rules, support providers and consumers in identifying "recovery as being an ongoing journey and an end result as well as an overall paradigm for achieving wellness and optimal mental health."

Proposed rule section:

§ 441.45 (b), § 441.45 (b) (1) (i) and (iii)

Language in the proposed rule:

Rehabilitation does not include, and FFP is not available.....if the following conditions are exist....1. The services are furnished through a non-medical program as either a benefit or administrative activity, including services that are ***"intrinsic elements"*** of programs other than Medicaid..... Include (iii) adoption services, family preservation and family unification services furnished by public & private social service agencies.

Comment:

This "intrinsic element" standard is troubling and we would request the rule be clearer in discerning the variables whereby rehabilitation services will be allowed. For example, we assume that type of agency or custody status is not a pivotal factor if the rehabilitative

service is being provided under the supervision of licensed practitioner of the healing arts in the State of Vermont and it is a medically necessary rehabilitation services for an eligible child or youth. If the intervention alleviated an acute episode of a mental health, physical or substance abuse problem, or restores the child or youth a higher level of functioning then we assume that the service is allowable regardless of the type of agency or any secondary benefit of stabilizing the family unit or intervening in a post adoptive situation.

Proposed rule section:

§ 441.45 (b) (2)

Language in the proposed rule:

Rehabilitation services do not include habilitation services, which include" services provided to individuals with mental retardation or related conditions".

Comment:

The categorical exclusion of a group of people is discriminatory. It presumes that all people with developmental disabilities do not have current abilities and skills that can regress and therefore benefit for rehabilitative services. The rule as written states that people with developmental disabilities only benefit from habilitative services, which is incorrect.

Proposed rule section:

§ 441.45 (b) (3)

Language in the proposed rule:

Rehabilitation services do not include "recreational or social activities that are not focused on rehabilitation and not provided by a Medicaid qualified provider; personal care services; transportation..."

Comment:

This definition seems to eliminate the reimbursement of personal care aides in the school setting even if they are considered a medical necessity to an eligible child.

Proposed rule section:

§ 441.45 (b) (7) and (8)

Language in the proposed rule:

Rehabilitation does not include "services furnished for the treatment of an individual who is not Medicaid eligible, " and "services that are not provided to a specific individual as documented in the individual's care record. "

Comment:

Collateral contact may include contact with family, area resources, services, significant others to insure an effective treatment or rehabilitative environment for the individuals. The Medicaid individuals must always be central to such collateral services. We assume that

these services furnished for the treatment of the Medicaid eligible person are allowable under the current proposal. If this is not true, we suggest that CMS reconsidered and clearly state the allowance of such collateral contact services as they are pivotal in aiding in a timely and enduring restoration of functioning.

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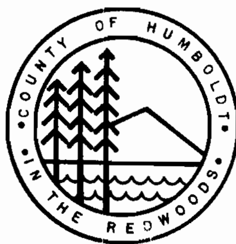

PROBATION DEPARTMENT

COUNTY OF HUMBOLDT

2002 HARRISON AVENUE EUREKA, CA 95501-3296

ADULT/JUVENILE PROBATION 445-7401 JUVENILE HALL 445-7644 ADULT COURT SERVICES 445-7786

October 2, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-2261-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore MD 21244-1850

To Whom It May Concern;

As Chief Probation Officer for the County of Humboldt I am writing to provide comment to changes in the Medicaid rules proposed by the Centers for Medicare and Medicaid (CMS) to govern Medicaid's rehabilitation service category. These proposed amendments, as currently written, would significantly restrict access to community-based rehabilitative services needed by children and adults with disabilities to help avoid institutionalization.

The proposed amendments to the rehabilitative services option could have devastating consequences upon national health policy, especially in terms of creating an environment that increases hospital emergency room visits and, in turn, increased healthcare costs. Absent the current supportive provisions currently provided for under the Rehabilitation Option, we can expect clients to decompensate and wind up in more costly institutionalized care – either in hospitals or jails.

The potential for unintended consequences in these ill-advised proposals is difficult to understate. While recognizing the desire to reduce general domestic spending, I firmly believe placing additional restrictions and limitations on comprehensive rehabilitation services under Medicaid will have a significant impact upon our communities and simply result in increased local costs or, more probably, increased federal costs in the form of Medicaid payments for emergency room treatment that could have been avoided if needed services had been provided in a timely manner.

As such, I am respectfully submitting the following comments on the Proposed Rule for Coverage for Rehabilitation Services under the Medicaid program.

Reference: File code CMS-2261-P

Non-covered services: 441.45(b)

This section introduces a whole new concept into Medicaid, one that conflicts with federal statutory requirements. It denies Medicaid coverage for covered services to covered individuals if such services are furnished through another program, including when they are considered "intrinsic elements" of that program. There is little clarity in the regulation on how this provision would be applied, as the regulation provides no guidance on how to determine whether a service is an "intrinsic element" of another program.

There appear to be only two situations in which Medicaid might have been paying for services that fall under this test. Either a provider bills Medicaid for a service which is not a Medicaid-covered service B, in which case this is a fraud-abuse issue and does not warrant a change in rule for all providers and systems. Or CMS is concerned that non-medical programs are furnishing Medicaid-covered services (and meeting all Medicaid requirements) but have other resources available to them for providing the service (even though these other resources are generally targeted to non-Medicaid individuals). In the latter case, what is the legal basis for denying federal financial participation for the Medicaid-covered individual?

Furthermore, few of the other cited programs have a clear legal obligation to provide these services or have the resources to do so. Without revision, this new rule would conflict with the federal statutory mandate to provide all medically necessary services covered by the state Medicaid plan, and for children, all medically necessary services covered by 42 U.S.C. § 1396d(a). See 42 U.S.C. §§ 1396a(a)(10), 1396d(r). The net result of this new rule will be that Medicaid-eligible individuals will be denied services, both by Medicaid and by the other cited program (due to lack of resources in the other program). Thus, the rule effectively denies them medically necessary Medicaid services, in direct contradiction of the statute.

Recommendation:

It is strongly recommend that this entire section be dropped, because it conflicts with the Medicaid statute.

Alternatively, the section should be clarified and narrowed so as to focus on situations where an entity (e.g. an insurer) has a specific legal obligation to pay for the services for the specific Medicaid-covered individual. Programs operated through capped or discretionary appropriations from states or localities should be specifically excluded from this provision.

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outside of those other programs. The preamble also makes clear that Medicaid rehabilitative services must be coordinated with services furnished by other programs. The regulation should include this language.

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Recommendation:

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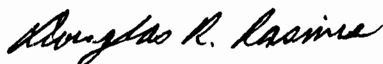
Sincerely,



Douglas R. Rasines
Chief Probation Officer
Humboldt County Probation Department
2002 Harrison Avenue
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Martique S. Jones
Director,
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OSORA/RDG
Centers for Medicare & Medicaid Services
410-786-4674
Martique.Jones@cms.hhs.gov
>-----Original Message-----
>From: OC AIMS Support [mailto:AIMSSupport@OC.FDA.GOV]
>Sent: Monday, October 08, 2007 12:47 PM
>To: Braxton, Shawn L. (CMS/OSORA); Jones, Martique S. (CMS/OSORA)
>Subject: FW: Public Submission
>
>
>
>-----Original Message-----
>From: no-reply@erulemaking.net [mailto:no-reply@erulemaking.net]
>Sent: Saturday, October 06, 2007 7:42 AM
>To: OC AIMS Support
>Subject: Public Submission
>
>Please Do Not Reply This Email.
>
>Public Comments on Medicaid Program; Coverage for Rehabilitative
>Services:========
>
>Title: Medicaid Program; Coverage for Rehabilitative Services FR
>Document Number: 07-03925 Legacy Document ID:
>RIN: 0938-A081
>Publish Date: 08/13/2007 00:00:00
>Submitter Info:
>
>
>First Name: Marla
>Last Name: Mills
>Category: Health Care Professional or Association - HC001 Mailing
>Address:
>City:
>Country: United States
>State or Province:
>Postal Code:
>Organization Name:
>
>Comment Info: =================
>
>General Comment:In reviewing 42 CFR Parts 440 and 441 Medicaid Program
>Coverage for Rehabilitatve Services The definition of coverage for
>rehabilitative services to restore to a level of functioning may not be
>applicalbe to infants and young children where rehab services such as
>occupational therapy and speech therapy may be ordered to assist an
>infant or toddler achieve expected developmental milestones for age but
>because of abnormal muscle tone or movement patterns or delays in
>speech and language the child will not be able to progress in his or
>her developmental progress.
>

95

Faulkner County Day School, Inc.

October 3, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-2261-P
P. O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-2261-P

The CMS proposed regulations on the Medicaid Program: Coverage for Rehabilitative Services appear to eliminate day habilitation services for persons who can thrive in the community with proper supports, specifically persons with developmental disabilities and persons with chronic mental illnesses. To remove them from eligibility for rehabilitative services because they may always require some services is a short-sighted effort to save money. These same individuals, left without community-based supportive services, may require far more expensive institutional services such as ICFs/MR, and destroy families who are trying to maintain persons with chronic conditions in less expensive community options. It also ignores the fact that persons with developmental disabilities can gain skills which increase their potential to be successful in the community, even though they are not regaining skills lost due to some type of injury or illness, which appears to be the definition of rehabilitation services that CMS intends to impose.

On page 45203 of the Federal Register printed August 13, 2007 (v72, #155), CMS addresses the matter of Section 6411 (g) of the Omnibus Budget Reconciliation Act of 1989. Congress in that legislation specified that CMS could not take adverse action against states with approved habilitation services in their state plans pending the issuance of a regulation that "specifies types of day habilitation services that a State may cover under paragraphs (9) (clinic services) or (13) (rehabilitation services) of section 1905 (a) of the Act on behalf of persons with mental retardation or with related conditions." CMS apparently is now ignoring the specific statutory protections which were enacted in 1989 by Congress, since the proposed rule eliminates habilitation services altogether. The law as written provides CMS the authority to take only affirmative actions concerning habilitation services, but may not eliminate them. These proposed regulations fail to meet the Congressional mandate which exists in the law.

P.O Box 219 • Conway, Arkansas 72033• Phone (501) 329-2164• Fax (501) 329-2113

On page 45204 there is a statement "It is important to note that this benefit is not a custodial care benefit for individuals with chronic conditions but should result in a change in status." Day habilitation programs are not custodial care, but use individualized program plans to tailor staff efforts in active treatment so that children and adults can gain new skills which they can use to function better in their environment.

Throughout its introductory comments, it appears that CMS authors of the proposed regulation have seized on only ½ of the definition of rehabilitation services. The two levels of rehabilitation include 1) services necessary to restore functioning to a previously attained level (due to skills being lost as a result of injury or illness) and 2) services necessary to maintain a current level of functioning that would otherwise decline in the absence of rehabilitation. There may not be a linear progression of improvement in an individual's functional skills, especially if they are due to a developmental disability or chronic health condition, and it may not be possible to write "recovery-oriented" goals for these individuals. To say that those individuals are not eligible for services until such time that they decline and lose skills to the extent that they must then be institutionalized is a false economy as best and an incredible ignorance of the great strides which persons with developmental disabilities may be able to achieve, given the proper services.

Section 440.130 (d) (i) (A) requires that a physician has "Determined that receipt of rehabilitative services would result in reduction of the individual's physical or mental disability and *restoration* [ital. mine] to the best possible functional level of the individual;". Section 441.45 (a) (2) requires states to "Ensure that rehabilitative services are limited to services furnished for the maximum reduction of physical or mental disability and *restoration* [ital. mine] of the individual to their best possible functional level." Since persons with developmental disabilities are gaining new skills rather than having skills restored, they are automatically disqualified from participating in rehabilitative services.

CMS hammers that home in 441.45 (b) (2) when it states "Habilitation services, including services for which FFP was formerly permitted under the Omnibus Budget Reconciliation Act of 1989. Habilitation services include services provided to individuals with mental retardation or related conditions." For CMS to so callously disregard the potential of persons with developmental disabilities is blatant discrimination, and may present issues for CMS under the Americans with Disabilities Act. Specialized habilitation services have for 40+ years been diverting persons away from institutionalization in ICFs/MR, enabling them to reside at home or in community settings, to participate in employment, civic affairs, and as citizens of this country, they are entitled to the protections offered under the law against discrimination. Please reword these sections to allow for persons gaining new skills to be eligible for services.

These services in Arkansas cost less than $50 per day for adults, while care at one of the state's ICFs/MR cost $253.26 in FY 06, the latest for which DHHS has statistics posted. In FY 06, there were at least 6,279 adults receiving some type of community based service, and 6,225 children under 5. If community supports are no longer available, then

some percentage of the families of these adults and children will be requesting the more expensive and less inclusive ICF option to obtain the services they need for their family member. If only 20% of the adults require ICF placements, then the institutionalized population in the state will more than double and there will have been an increase in FFP required, rather than a decrease.

For CMS to cavalierly decide that services under a 1915 waiver will be able to replace the structured congregate day habilitation programs, and that they will be less expensive, seem to be based on absolutely no foundation at all. During FY 06, there were 3,356 persons served under the ACS Waiver in the state of Arkansas. It is impossible to develop a daily rate charged for these services, because there is no indication of how many days of service were provided to these individuals. It would appear, though, that the average cost of waiver services was $24,771 per person, while the average cost of day habilitation for an adult with developmental disabilities was only about ½ of that amount.

The other major difficulty with waiver services is that the state will be forced to pick a number of "slots" and only that number of persons with developmental disabilities will receive services. The potential with that scenario is that some children will "age out" of the day habilitation services age range without ever receiving services at all. Research in the field of early intervention services sponsored by the federal government shows that the greatest developmental gains are made in children before their brains finish forming at about age five. To allow hospitals to save neonates who are profoundly premature, some literally being million dollar babies, and then to send them home to no services to help continue their optimal development so that they can become productive citizens, seems to be a curious policy decision.

I strongly urge CMS to withdraw these proposed regulations until a more thoughtful set can be issued which will take into consideration the unique needs of persons with developmental disabilities. Please do not abandon the most needy group of American citizens.

Please note that I attempted to submit these comments via eRulemaking, but I was unable to attach the comments to the CMS form either time. Thank you for the opportunity to comment on these proposed regulations.

Sincerely,

Ruth Castleberry
Executive Director

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enable

individualized services
for children & adults with disabilities

October 5, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS–2261–P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: File Code CMS–2261–P

To Whom It May Concern:

We are writing to comment on the notice of proposed rulemaking (NPRM) with respect to Medicaid coverage of rehabilitative services that was published in the *Federal Register* on August 13, 2007. These comments are submitted on behalf of

Enable has been in service Since 1948. Our mission has been to enable people with disabilities to participate fully in all aspects of life. We provide assessment, training, therapy and support for nearly 2,000 children and adults with disabilities and their families annually. Enable empowers people with disabilities to achieve their goals at home, school, work, and play.

Without the Day Habilitation program at Enable, our participants would lose the opportunity to choose a meaningful way to discover and enhance the personal riches that are innately bestowed upon all individuals. Community Networks serves as a blue print for other visionaries who tirelessly advocate for the underserved populations in their communities.

Choice-Inclusion-Empowerment-Family Involvement, these are the corner stones of the Community Networks program at Enable. Networks focus on the strengths, abilities, and interests of all individuals who have chosen our agency. Volunteering, increasing literacy skills, exercise, music, and art offer wonderful possibilities for our staff to design and implement creative one-on-one and group activities. Community Networks employs a staff of nineteen and serve a population of fifty-one people diagnosed with developmental disabilities

We are commenting on the impact of the proposed rule on people with intellectual and other developmental disabilities and access to habilitation services.

1603 Court Street, Syracuse, New York 13208
Phone (315) 455-7591 • FAX (315) 455-2494 • TDD (315) 455-1794 • www.enablecny.org
United Cerebral Palsy and Handicapped Children's Association of Syracuse, Inc. • A United Way Agency

Printed on Recycled Paper

We strongly oppose the provisions related to excluding federal financial participation (FFP) for habilitation services. We urge you to withdraw this proposed rule.

The proposed rule would severely harm people with intellectual and other developmental disabilities in two major ways: (1) it eliminates longstanding programs for providing day habilitation services to people with developmental disabilities, and (2) it imposes a discriminatory and arbitrary exclusion from receiving many rehabilitative services for people with intellectual disabilities/mental retardation and related conditions.

(1) Elimination of FFP for habilitation services provided under the rehabilitative and clinic options - We believe that this proposed restriction violates the intent of the Congress to protect access to day habilitation services for people with developmental disabilities when it enacted Section 6411(g) of the Omnibus Budget Reconciliation Act of 1989, P.L. 101-239 (OBRA '89). This section reads:

> (g) DAY HABILITATION AND RELATED SERVICES-
>
> (1) PROHIBITION OF DISALLOWANCE PENDING ISSUANCE OF REGULATIONS- Except as specifically permitted under paragraph (3), the Secretary of Health and Human Services may not--
>
> (A) withhold, suspend, disallow, or deny Federal financial participation under section 1903(a) of the Social Security Act for day habilitation and related services under paragraph (9) or (13) of section 1905(a) of such Act on behalf of persons with mental retardation or with related conditions pursuant to a provision of its State plan as approved on or before June 30, 1989, or
>
> (B) withdraw Federal approval of any such State plan provision.
>
> (2) REQUIREMENTS FOR REGULATION- A final regulation described in this paragraph is a regulation, promulgated after a notice of proposed rule-making and a period of at least 60 days for public comment, that--
>
> (A) specifies the types of day habilitation and related services that a State may cover under paragraph (9) or (13) of section 1905(a) of the Social Security Act on behalf of persons with mental retardation or with related conditions, and
>
> (B) any requirements respecting such coverage.
>
> (3) PROSPECTIVE APPLICATION OF REGULATION- If the Secretary promulgates a final regulation described in paragraph (2) and the Secretary determines that a State plan under title XIX of the Social Security Act does not comply with such regulation, the Secretary shall notify the State of the determination and its basis, and such determination shall not apply to day habilitation and related services furnished before the first day of the first calendar quarter beginning after the date of the notice to the State.

In enacting this provision of law, the Congress was clearly intending to protect access to day habilitation programs for people with intellectual disabilities/mental retardation and related conditions. It establishes that the Secretary may not deny federal financial participation (FFP) for habilitation services unless the Secretary promulgates a final regulation that *"specifies the types of day habilitation and related services that a State may cover...on behalf of persons with mental retardation or with related conditions."*

In contradiction to the plain language of Section 6411(g) of OBRA '89, the proposed rule **does not** specify which day habilitation services that a state may cover. Instead, the proposed regulation would prohibit provision of *any* habilitation services under paragraphs (9) and (13) of section 1905(a) of the Social Security Act. We believe that this NPRM exceeds the regulatory authority granted by the Congress and must be withdrawn. At a minimum, since the regulation does not comply with the OBRA '89 language, the Secretary would not have authority to deny FFP for habilitation services provided in those states with approved state plan coverage prior to June 30, 1989.

We also oppose the prohibition of habilitation services on policy grounds. We believe the proposed rule represents a missed opportunity for the Secretary to specify the types of services that may be provided in a way that ensures that individuals receive the highest quality habilitative and rehabilitative services according to current standards of treatment. The preamble of the proposed rule states that the rehabilitative option is not a "custodial" benefit. We agree with the Secretary that state programs operated under the rehabilitative and clinic options should set high standards for delivering active treatment and for innovating to develop programs for people with intellectual and other developmental disabilities that enhances their ability to attain, maintain, and retain their maximum ability to function, consistent with the original conception of rehabilitation, as found in section 1901 of the Social Security Act.

The preamble to the proposed rule also states that the Secretary intends "to work with those states that have habilitation programs under the clinic services or rehabilitative services benefits under their state plans to transition to appropriate Medicaid coverage authorities, such as Section 1915(c) waivers or the Home and Community-Based Services State plan option under Section 1915(i)." We take issue with the assertion that these are more appropriate coverage authorities. In particular, waiver programs operate as discretionary alternatives to their core Medicaid programs, which operate under the state plan. We believe that states should have the flexibility to continue operating habilitation programs under the longstanding state plan options. Further, Section 1915(c) waivers and Section 1915(i) are not equivalent to the rehabilitative or clinic options. Section 1915(c) waiver programs require individuals to meet a nursing facility level of care requirement, something which is not required for rehabilitative or clinic option services. Further, the 1915(c) and 1915(i) coverage authorities have different financial eligibility standards. Most significantly, these coverage authorities do not extend an enforceable entitlement to services. Indeed, the disability community opposed the aspects of section 1915(i), established in the Deficit Reduction Act of 2005, that permit enrollment caps and that do not extend an entitlement to services. Nonetheless, this option was enacted to give states added flexibility and was not intended to supplant the rehabilitative and clinic options by requiring states to shift to more restrictive coverage authorities. It should also be observed that the 1915(c) waiver programs are notable for their long and large waiting lists. In 2004, more than 206,000 people were on Medicaid waiting lists for community services, an increase of roughly 50,000 people in just two years. In some cases, average wait times to receive waiver services are more than two years (Kaiser Commission on Medicaid and the Uninsured, 2006).

We strongly recommend that the proposed exclusion of FFP for habilitative services under the clinic and rehabilitative options not be implemented.

(2) Discriminatory and arbitrary exclusion from receiving rehabilitative services for people with mental retardation and related conditions - We strongly oppose the proposed rule's definition of habilitation services [see Section 441.45(b) (2)] as including "services provided to individuals with mental retardation and related conditions." Coupled with the prohibition on habilitation services, this effectively excludes a population from services in violation of a fundamental principle of Medicaid, that medical assistance provided to one Medicaid beneficiary shall not be less in amount, duration, and scope than the medical assistance made available to any other Medicaid beneficiary [see Section 1902(a)(10(B) of the Social Security Act].

The proposed rule also states that, "Most physical impairments, and mental health and/or substance related disorders, are not included in the scope of related conditions, so rehabilitative services may be appropriately provided." This policy would, at a minimum, create uncertainty that states can receive FFP for medically necessary rehabilitative option services for people with intellectual and other related disabilities. Additionally, it exposes a false premise that people with intellectual disabilities and those with "related conditions" have achieved no prior capacity to function for which a rehabilitative service would be appropriately furnished under the rehabilitative option. That sweeping assumption includes those defined by CMS elsewhere in regulations as having "related conditions" – people who have cerebral palsy, epilepsy, or any other conditions, other than mental illness, found to be closely related to mental retardation because it results in impairment of general intellectual functioning or adaptive behavior similar to that of people with mental retardation, with similar treatment needs; which manifests before age 22; is likely to continue indefinitely; and results in substantial functional limitations in three or more of the following areas of major life activities: self care, understanding and use of language, learning, mobility, self-direction, and capacity for independent living.

We urge the Secretary to rescind this constraint on rehabilitative and clinic option services that is so blatantly stigmatizing and discriminatory to people with intellectual and other developmental disabilities.

Sincerely,

Sara Wall-Bollinger, Executive Director

cc: Senator Charles Schumer
Senator Hillary Rodham Clinton
Congressman James Walsh
Congressman Michael Arcuri
Congressman John McHugh

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1 College Park Drive
Oneonta, NY 13820
October 5, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS-2261-P
P.O. Box 8018
Baltimore MD 21244-8018

Re: File code CMS-2261-P. Proposed regulations on Coverage for Rehabilitative Services.

Dear Sir or Madam:

I am writing as a member of NAMI, the nation's largest grassroots organization representing individuals living with serious mental illnesses and their families. Thank you for providing opportunities for people living with mental illness and their family members and advocates to provide comments on the proposed rules regarding coverage for rehabilitative services under the Medicaid program.

Individuals with serious mental illness can and do live well in the community if they have appropriate services and support. People with mental illness who cannot get help may sometimes have multiple stays in jails and hospitals.

In all the states, there are gaps in services and many people who have serious mental illnesses are not getting the help that they need, according to a survey conducted by NAMI.

There are a few areas of concern where we hope the agency will reconsider its rules.

Re: Section 440.130 (d)(1)(v) and 440.130(d)(3) Rehabilitation Plan:
It would be important to clarify the provisions in the regulations to allow payment for outreach and emergency services.

Section 440.130(d)(1) Rehabilitation and Restorative Services:
Recommendation:

Revise the proposed rule to allow payment for rehabilitative services to prevent deterioration as well as to restore functioning.

Section 441.45(b) Exclusion of services, including those that are an "intrinsic element" of other programs:
Recommendation:

Delete all references to other systems and pay for rehabilitative services for individuals with serious mental illnesses when they need them and where they need them.

Section 441.45(b) Exclusions for therapeutic foster care and classroom aides;
Recommendation:

Amend the proposed rule to allow therapeutic foster care and let states combine the services in one rate if that works best for them. The federal government can meet its goals by making sure that the rate only includes rehabilitative services.

Amend the regulations to say that the exclusion does not include behavior aides or other related serviced providers who are providing services to a particular child.

Section 441.45 (b) (2) Exclusion for Mental Retardation and other conditions and Habilitation Services:

Recommendation:

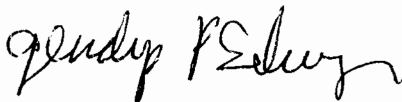
The proposed rules should not exclude people with mental retardation and related conditions and habilitation services.

Conclusion:

Rehabilitation services can change the course of a person's life. Too many people cannot access these treatments. The federal government should be doing everything possible to encourage states to provide better and more effective services for people who have mental illnesses. We do not want to see billions of dollars taken out of the Medicaid funded system of care for people with mental illnesses.

We ask that you revise these regulations to make it clear that the federal government encourages any state system to do all they can to provide effective treatments to people who have serious mental illnesses.

Thank you,



Gladys P. Selwyn

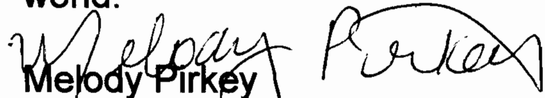
October 3rd, 2007

To Whom It May Concern,

This letter is in reference to the file code CMS-2261-P and CFR Part 441.45.

I must be honest in saying I don't understand S-CHIP I'm and not even sure what it stands for. Normally I am better at researching things before I jump on my soapbox. I truly apologize for my ignorance on the situation. However, I have a child that will be affected by the removal of day habilitation services. My son is 4 years old, and was diagnosed with Autism and developmental delays at early age 3. There are many things Cameron will never be able to do. He is so behind in many skills and I have come to terms with the fact he will never be like other children. For example, he cannot brush his own teeth, put on shoes/socks or turn simple doorknobs.(all of which are things he should have mastered by now) He cannot produce a complete sentence, his words are very jumbled and I am sooo thankful for even that. For a very long time, he couldn't say anything at all. BUT......he now knows a toothbrush is for the mouth, socks/shoes are for the feet and a doorknob has to be turned to open. The Sunshine School has been working with my son and his skills are showing improvement. I am so grateful everyday when he comes home, the teachers always write something on his paper he accomplished, no matter the size of the task. As you know, there are thousands of children like my son and worse who benefit from the dayschool programs. I cannot imagine how much my son will regress without the support of these services. His quality of life will worsen without the intense therapy and I cannot bear to see that happen to my child. He is so innocent in this world, and doesn't understand much, but he knows he is doing better. I am a nurse and work as much as I can. My job carries insurance for our family because my husband is recently disabled after an accident. He is in college but not working. We are hurting financially, but I try not to let Cameron see any of this. He has his own burdens to face daily. My insurance does not pay for the therapies, that is why we are using the school he

is in. Please consider my son and the thousands of others affected by the removal of these services. I am my son's advocate, please help me help him. What I prayed for during my pregnancy, I did not get-a healthy, normal child. I love him unconditionally, but now what I pray for is your help to keep him moving forward in a judgemental world.



Melody Pirkey
11 Cresswell Lane
Bella Vista, AR
savdbygrace28@wmconnect.com

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October 4, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-2261-P
P.O. Box 8018
Baltimore, MD 21244-8018

To Whom It May Concern:

Reference: File Code CMS-2261-P
Comments on 42 CFR Parts 440 and 441: Medicaid Program: Coverage for Rehabilitative Services

I am submitting the following comments on the Proposed Rule for Coverage for Rehabilitative Services under the Medicaid program, as published in the Federal Register, August 13, 2007.

It is critical that the proposed regulations support the individuals with serious and persistent mental illness, and the community programs providing the much needed services to these individuals, maximize their ability to function in the community. I am seriously concerned that the proposed regulations, as written, may create significant obstacles to the recovery process for adults and children. Therefore, I respectfully submit these comments in hopes of eliminating these potential barriers and promoting the well being of these individuals. I ask that you consider changing the following specific areas:

440.130(d)(1)(vi) Definition of Restorative Services and 3(xiv) Measurable Reduction of Disability

It is critical that these regulations fully recognize the nature of mental illnesses and the recovery process. The regulatory language must reflect the flexibility needed to help children grow and develop and to support adults in dealing with relapse and the challenges in sustaining levels of functioning. Therefore the following changes to language are recommended:

Section 440.130 (d)(1)(vi) Definition of "restorative services"

Recommendations:

1 Include language that states that restorative services include services to enable a child to achieve age-appropriate growth and development and that it is not necessary that the child actually performed the activity in the past.

1 Add the following language to the end of section:

"Examples of acceptable rehabilitation goals in this context would include: living in the community without long-term or intermittent hospitalization; reduction or control of symptoms to avoid further deterioration or hospitalization."

440.130 (d)(3) (xiv) Requirement of "Measurable Reduction of Disability"

Recommendation: Add the following language to the end of the section:

"For some individuals, particularly those with serious mental illness, 'reduction of disability' and 'restoration of functional level' may be measured by comparing the effect of continuing rehabilitation versus discontinuing it. Where there is reasonable expectation that if rehabilitation services had been withdrawn the individual's condition would have deteriorated, relapsed further, or required hospitalization, this criterion is met."

440.130 (3) preamble, (3)(xi), (xv), (xvi) Written Rehabilitation Plan

There are four specific areas we would like this section to address. First, the preamble of this section refers to a written rehabilitation plan. While it does not prohibit an integrated treatment and rehabilitation plan, it also does not specifically allow for one. Since integrated planning and service delivery is in the consumer's best interest, we feel that the regulations should support an integrated plan. Second, (re: 3xi) while there is great value in consumers knowing their options for alternate providers, we think that information should be shared earlier in the process than during rehabilitation planning, at any time the consumer expresses a desire to consider other options or at specific progress review periods. The rehabilitation planning process is an important time of partnership. The routine inclusion of information about alternate providers during this process may disrupt the therapeutic bond, may cause confusion and anxiety for the consumer and also places an unnecessary burden on the provider. Third, (re: 3 xv) due to the episodic nature of serious mental illness and sometimes due to specific symptoms, some consumers may not be able or willing to sign the treatment/rehabilitation plan at a given time. The need for the services is still likely to be critical. The individual may not have appointed a representative who could sign on behalf of him/her. Therefore, CMS should allow for documentation of efforts of the provider to secure the signature and the reasons that the consumer or his/her representative is not able to sign the plan. Finally, (re: 3xvi) since the provider is already bound by Medicaid requirements, the inclusion of the statement in the last bullet below seems unnecessary and inappropriate for inclusion in the service plan

and seems to add no real value. In the interest of time and clarity, we recommend it be deleted from this section.

Recommendations:

2 Specifically clarify that a single integrated treatment and rehabilitation plan is acceptable (3 preamble)
3 Delete the section that reads "Indicate the anticipated provider(s) of the service(s) and the extent to which the services may be available from alternate provider(s) of the same service." (3xi)
4 Allow providers to document attempts to involve consumers in the development of their treatment/rehabilitation plans and to secure their signatures. (3xv)
5 Delete the section that reads "Document that the services have been determined to be rehabilitative services consistent with the regulatory definition." (3xvi)

441.45 (a) (2) : Rehabilitative Services

This recommendation serves to reinforce what has been said regarding restorative services and "measurable reduction of disability."

Recommendation: Reiterate here when services may be provided to retain or maintain functioning.

441.45 (b) (1) Non-Covered Services

In order to strongly support the concept of integrated and coordinated services and to ensure that consumers have access to covered rehabilitation services, the following clarifications are recommended.

Recommendations:

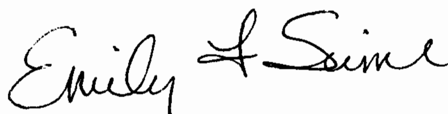
1 Add the following to the end of the first paragraph in Section 441.45(b) (1):

"...except for medically necessary rehabilitation services for an eligible individual that are clearly distinct from these non-covered program services and are provided by qualified Medicaid providers. One way to demonstrate this distinction is by clearly and reasonably distinguishing the funding stream for the rehabilitation services as being distinct from that of non-covered services."

2 Clarify that pre-vocational services are allowable services when appropriately tied to a rehabilitation goal.

Thank you for this opportunity for commenting and for your consideration of these recommendations.

Sincerely,



September 26, 2007

To: Centers for Medicare & Medicaid Service
Department of Health & Human Services
P O Box 8017
Baltimore, Maryland 21244-8017

From: Johnson Physical Therapy and Rehab P.C.
1280 North Mildred Rd suite 2
Cortez, Colorado 81321

To Whom It May Concern:

I would like to take this opportunity to comment on the proposed rule CMS-6006-P-1. As an occupational Therapist in a private practice, specializing in the treatment of the upper extremity patient, I have significant concerns re: the effect of this rule on my practice and patients.

The supply of DMEPOS is an important component in the treatment of my patients. The overall impact of orthoses and the ability to provide these orthoses immediately and concurrently with therapy has an immeasurable effect on the final outcome. We utilize orthoses to protect, support, affect motion, and improve independent ADL function. The nature of our patients' acute and changing conditions requires the frequent adjustment of these orthoses, often immediately following their treatment to maintain and improve on gains made therapy. The importance of our continued ability to fabricate orthoses and make timely adjustments cannot be underestimated.

Impact: I feel that this rule may affect my ability to fabricate and supply orthoses. As a small business, the estimated $2000 cost of the surety bond per NPI# in addition to the new costs of accreditation would be an undo hardship on my office. You estimate that up to 15% of individual suppliers will discontinue enrollment. It is my opinion that many of these will be practitioner suppliers whose DMEPOS billing is only a percentage of their business. While you are predicting that their patients will be able to find comparable benefits from other local suppliers, I feel the acute and frequently changing nature of this type of DMEPOS, intimately connected to the therapy they are receiving, would preclude these patients from finding an effective alternative supplier. The loss of practitioner/supplier enrollees- and subsequently their ability to supply DMEPOS- will adversely affect both cost of treatment and the final outcome of these enrollee's patients. We are in a small county in South-Western Colorado, and we are the ***only*** Outpatient Physical and Occupational DMEPOS supplier within a fifty mile drive. Some of our patients travel from out of state and at times they have to travel well over two to three hours just to get to our facility. And the majority of our community is within or close to a poverty level income, therefore they will not be able to afford these items as an out of pocket expense. Loosing our ability to supply our community with DMEPOS supplies will greatly affect the outcome of our patients therapy results.

I support the exemption of physician and non-physician practitioners from this rule unless there is a previous adverse history of Medicare fraud. I also feel that a surety bond would offer little or no additional protection to CMS since accreditation is already providing a greater level of security.

Thank you for the opportunity to comment of the this proposed rule.

Julie Carpenter OTR
Owner and Practicing Occupational Therapist