

**Moving Forward**  
**Medication Optimization in the Service of Recovery: Policy Recommendations**  
**FINAL DRAFT**  
**04/04/11**

**Background and Purpose**

We propose to fundamentally change the way mental health services are delivered with particular respect to the provision of psychiatric medications. From the evidence of personal experience and a reappraisal of research findings, it is clear that recovery from mental health challenges is probable and should be expected. We assert that mental health challenges no longer result in presumed inevitable or long-term disability. This change in perspective challenges us all (persons with mental health challenges, their families, clinical providers, researchers, payers, regulators, policy makers) to reconsider our beliefs and to create new and effective public policies and practices. We are distressed by the research evidence (or lack of evidence) and lived experiences that point to the ineffectiveness and hazards regarding the use of psychiatric medications.

As our understanding of the recovery process advances, we imagine a future in which psychiatric medications are best utilized in the context of recovery supports, as part of a broader array of clinical, social, spiritual, and environmental supports.

We have come together, a diverse group of concerned and thoughtful stakeholders in the provision of mental health services, to articulate policy recommendations and implementation guidelines that will progressively encourage and facilitate optimized use or non-use of medications combined with other clinical and social services and community supports with the primary goal of promoting recovery. These policies must assure that health system, clinical, educational, and social support approaches are consistent with current and future evidence-based research associated with long-term positive outcomes. The policies must respect and incorporate cultural relevance, a trauma-informed perspective, personal preference, self-determination, person-centered planning, and shared decision making.

Current mental health policies in the United States do not adequately support or incentivize use of psychiatric medications in support of recovery and, in fact, in many cases undermine or prevent actual recovery for many persons with mental health challenges. This reflects a mismatch between the beliefs upon which current policies are based, the preferences of persons who are the recipients of services, and a comprehensive reassessment of the actual meaning of scientific research into these conditions and treatments.

Definition of Medication Optimization

Medication Optimization is a mental health recovery utility which supports the judicious use or non-use of psychotropic medications based on valid evidence-based research findings and balanced with an array of other effective, recovery-based services and supports. The goal of all of these interventions is to improve and maximize the self-determination, functioning, and quality and meaning of life of people affected by mental health challenges. Medication optimization includes postponing or avoiding the use of medications in favor of recovery-based psychosocial supports and services, sensitive and collaborative initiation of medication protocols,

timely medication tapering or withdrawal protocols, and regular reassessment of recovery status to guide shared decision making to adjust medication treatment.

If the health system and the key policy makers who guide its development and evolution ignore the need for medication optimization as defined by this policy paper, they increase the risk of continued harm to individuals, families, and the larger community in the form of worsened health outcomes, increased health care costs and waste, and lost contributions to society in the form of productive activity, tax revenues, and the intangible benefits of the social inclusion of persons with mental health challenges into the fabric of our society.

### **Mental Health Recovery**

Medication optimization is rooted in the expectation that people will recover from mental health challenges. We support the definition and components of recovery that were developed through a consensus building process led by SAMHSA. The document was developed through deliberations by more than 110 expert panelists representing mental health consumers, families, providers, advocates, researchers, managed care organizations, state and local public officials, and others.

#### Definition of Recovery

“A journey of healing and transformation enabling a person with a mental health problem to live a meaningful life in a community of his or her choice while striving to achieve his or her potential.” See Appendix A for the full statement developed by SAMHSA.

### **Policy Recommendations**

The following policy recommendations are intended to improve the development of and access to protocols, services and supports necessary to realize the goals and objectives of medication optimization.

1. Medication optimization protocols must be developed by qualified physicians and psychiatrists, in collaboration with consumers and multiple stakeholder groups and with other people who are familiar with the entire range of evidence regarding medications and recovery supports for children, adolescents, adults and older adults with mental health challenges. The studies of greatest interest will be those that incorporate financially unbiased reviews of short-term as well as long-term outcomes. In addition, any participants in policy development or recommendations should be vetted for potential conflicts of interest and all decisions and any reports utilized to support them should be made a matter of public and accessible in their entirety.
2. Medication optimization policies must emphasize the principles of self-determination, shared decision-making, upholding individual rights, person-centered planning and strengths-based approaches conducive to empowerment and recovery for persons responding to mental health challenges in their lives.
  - a. Information on reducing and coming off psychiatric medications: Provide information through support groups and literature about reducing and coming off psychiatric medications to everyone, not with the expectation that everyone can or should reduce or come off, but with the understanding that each person is

different and everyone should have the opportunity to discover for themselves what works best for them.

- b. Person/patient education and consent: Ensure people's rights are protected when providing education and informed consent, including decision-making regarding medication use both short term and long term and discontinuation. This includes the ability of person to seek a second opinion and obtain the latest known information about side-effects and research about medication cessation or continuance. Personal preferences (i.e. to reduce or come off medication) should not be contingent upon ongoing receipt of other mental health services, housing or income subsidy.
  - c. Policy development must include consumer/survivor input, and be informed by such documents as the Medication Optimization, Choice, and Alternatives statement.
  - d. Informed consent documents and process should be reevaluated and changed to a more person-driven, collaborative approach. The full extent of the negative consequences (e.g. long term effects) of medication should be presented with the same level of emphasis as the positive benefits.
  - e. In order to give people a fair opportunity to make a fully informed and well-considered decision about medication, more time with the psychiatrist is needed. Assuming that psychiatrists are properly retrained, there are several ways to realize this, including increasing the time in a standard psychiatric appointment from a few minutes to 30 or more minutes, and adopting team-based approaches using shared decision-making strategies.
  - f. Services must be tailored to age, cultural and diagnostic population groups. Cultural variation is particularly important with respect to mental health issues. Much of cultural competency is based on an assumption of the superiority of western biomedicine with attempts to understand other sociocultural systems only as a needed to convince people to accept western biomedical approaches. However, there is high variation of mental health conceptions across cultures and there needs to be an understanding and acceptance of these models among western mental health professionals. Self-determination needs to be practiced at the individual and sociocultural levels, within a framework of human rights.
3. Medication optimization includes wellness activities and interventions that support recovery and may achieve benefits without the use of medications:
- *Supports* include peer recovery groups (like Dual Diagnosis Anonymous, Recovery Anonymous, etc) and initiatives like warm-lines and consumer-operated drop-in centers and consumer-run organizations that promote peer support services and the development of individual recovery plans.
  - *Wellness activities* To counterbalance over-dependence on the use of psychotropic medications, it is important to emphasize activities and awareness of the dimensions of wellness including exercise programs, spiritual practices, tobacco cessation, sleep hygiene, abstinence from alcohol and other drugs that destabilize, diet and nutrition, and general health promotion and prevention. Integrated care should emphasize social, psychological, and narrative approaches. Wellness Recovery and Action Plan,

- Person-Centered Planning, self-direction, and Psychiatric Advance Directives also need to be included as mechanisms for supporting wellness activities.
- *Service Planning and Interventions:* Programs should include evidence-based psychotherapeutic approaches like Open Dialog and cognitive behavioral therapy; peer support; skills training and other rehabilitative activities; wraparound service planning ; care coordination; Supported Housing (with the goal of permanency); Supported Education; Assertive Community Treatment; Supported Employment; symptom management techniques, especially those that assist with decreasing medication dosages, numbers of medications, and duration of taking prescribed psychotropic medications; and, where possible, the use of protocols for tapering off from and discontinuing psychotropic medications.
4. Program Development and Implementation of Medication Optimization: Protocols for medication optimization must be fully integrated into other aspects of program planning, design and implementation with recognition that the most challenging of these will be the assurance of high fidelity implementation. Guidelines for a community based standard of support needs to be established and supported at the federal, state, and local levels.
  5. Alignment of Medication Optimization with anticipated health system reforms: Health system reforms are being implemented at the state and federal levels, leading both to increased numbers of persons with health insurance and transformation of the delivery system to provide more access to team-based primary care services and efforts to integrate many aspects of care. Because of the emergence of integrated person-centered primary care homes (and other coordinated care organizations) and efforts to more effectively integrate behavioral health services into those primary care settings, much of the provision of psychiatric medications may be implemented by primary care and other non-psychiatric prescribing providers. This could lead to a large cohort of persons who continue to be at risk of harm from the premature, inappropriate, or excessive reliance on psychiatric medications to the exclusion of other effective health and social services. It is essential that applicable medication optimization protocols be proactively developed and implemented in these primary care settings.
  6. Financial Implications: Financial support and alignment of reimbursement incentives should explicitly reinforce medication optimization in public and private health systems and health plans. Shared risk and shared cost savings supporting recovery outcomes should be considered. States that have medications carved out of their mental health plans should reconsider the degree to which these arrangements contribute to overuse of psychotropic medications.
  7. Quality Assurance and Performance Improvement of Medication Optimization: Continuous quality improvement models at local, state and federal levels should establish clear standards based on use of medication optimization protocols; reviews should routinely assess programs for compliance with target population-appropriate protocols and true informed consent; standard reports on quality reviews should always include reference to the degree to which programs and prescribers adhere to approved protocols. Protocols should be development independently without pharmaceutical company

interests. All policies established need to include mechanisms for accountability and enforcement. QA and QI efforts are contingent upon improvements in the process for approval of medications as safe and effective and are dependent on major reforms of the FDA, a subject that is beyond the scope of these recommendations. The appropriate oversight and enforcement of prescribing practices, including certain off-label uses, must be clarified in terms of federal, state, and local authorities. Data collection on prescribing practices should be made transparent and accessible. These data should be utilized to educate prescribing providers regarding their practice patterns.

8. Workforce Development: The implementation of these MO policies must be supported and incorporated into the process of defining core competencies for various clinical providers. Curricula provided in any relevant undergraduate, graduate, post-graduate, and continuing education programs and credentialing, certification, and professional licensing criteria need to be adapted to incorporate MO practice guidance as appropriate.
9. Training and Education for Medication Optimization: Professional training programs, starting with medical schools and psychiatry training programs should teach science-based curricula regarding the short-term, medium-term and long-term use of psychotropic medications. Training materials should include the impact and interaction effects of all medications the individual is on. These programs should also assure knowledge, skills and attitudes in professionals' education regarding non-medication approaches to controlling and coping with psychiatric symptoms and syndromes. All professional in-service training should provide education on these same issues, adapted for each professional and paraprofessional training level. State licensing boards should require evidence of training in science-based approaches to medication optimization and the role of holistic and alternative and complementary treatment approaches.
  - a. Diagnosis Education: Educate accurately about what is known and not known about mental illness diagnosis to ensure informed consent to treatment. Patients should be educated that mental illness remains a medical mystery and there is a wide range of possible explanations, rather than only be told mainstream and unproven theories about genetic predisposition, chemical imbalance, and brain disorder.
  - b. Medication Education: Educate accurately about what is known and not known about medication. Patients should understand that medications often basically function as psychoactive tranquilizers and stimulants that change brain chemistry and may carry long term risk of worsening their condition that may outweigh possible short term usefulness.
  - c. Peers need to be trained in the full risks and benefits of medications and incorporated in shared decision making models.
10. Research and Evaluation of Medication Optimization: Federal funds should be made available to research centers at universities and medical schools to study and evaluate innovative approaches and comparative effectiveness to medication optimization and alternatives to medication. These studies should be without financial support from pharmaceutical corporations to assure the public of unbiased scientific research and data interpretation. The federal government should initiate independent reviews of all existing

relevant studies and other datasets, published and unpublished. The results of these reviews should serve as the foundation for the development of a federally funded strategic initiative of research to investigate how to best utilize psychiatric medications in the recovery context. Federal support should be provided to evaluate and report, on an ongoing basis, what is known about the benefits and hazards of their use

11. Use of Electronic Health Records that promote Medication Optimization: EHRs should provide support for collection of clinical and program data regarding medication optimization protocols and practice and the relationship of M.O to alternative and complementary treatments and services.
12. Outcomes: Local, state and federal agencies should agree upon a standardized set of practice data and comparative outcomes.

## APPENDIX A

### The 10 Fundamental Components of Recovery

*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.

*Individualized and Person-Centered*: There are multiple pathways to recovery based on an individual's unique strengths and resiliencies as well as his or her needs, preferences, experiences (including past trauma), and cultural background in all of its diverse representations. Individuals also identify recovery as being an ongoing journey and an end result as well as an overall paradigm for achieving wellness and optimal mental health.

*Empowerment*: Consumers have the authority to choose from a range of options and to participate in all decisions—including the allocation of resources—that will affect their lives, and are educated and supported in so doing. They have the ability to join with other consumers to collectively and effectively speak for themselves about their needs, wants, desires, and aspirations. Through empowerment, an individual gains control of his or her own destiny and influences the organizational and societal structures in his or her life.

*Holistic*: Recovery encompasses an individual's whole life, including mind, body, spirit, and community. Recovery embraces all aspects of life, including housing, employment, education, mental health and healthcare treatment and services, complementary and naturalistic services, addictions treatment, spirituality, creativity, social networks, community participation, and family supports as determined by the person. Families, providers, organizations, systems, communities, and society play crucial roles in creating and maintaining meaningful opportunities for consumer access to these supports.

*Non-Linear*: Recovery is not a step-by-step process but one based on continual growth, occasional setbacks, and learning from experience. Recovery begins with an initial stage of

awareness in which a person recognizes that positive change is possible. This awareness enables the consumer to move on to fully engage in the work of recovery.

*Strengths-Based:* Recovery focuses on valuing and building on the multiple capacities, resiliencies, talents, coping abilities, and inherent worth of individuals. By building on these strengths, consumers leave stymied life roles behind and engage in new life roles (e.g., partner, caregiver, friend, student, employee). The process of recovery moves forward through interaction with others in supportive, trust-based relationships.

*Peer Support:* Mutual support—including the sharing of experiential knowledge and skills and social learning—plays an invaluable role in recovery. Consumers encourage and engage other consumers in recovery and provide each other with a sense of belonging, supportive relationships, valued roles, and community.

*Respect:* Community, systems, and societal acceptance and appreciation of consumers — including protecting their rights and eliminating discrimination and stigma—are crucial in achieving recovery. Self-acceptance and regaining belief in one’s self are particularly vital. Respect ensures the inclusion and full participation of consumers in all aspects of their lives.

*Responsibility:* Consumers have a personal responsibility for their own self-care and journeys of recovery. Taking steps towards their goals may require great courage. Consumers must strive to understand and give meaning to their experiences and identify coping strategies and healing processes to promote their own wellness.

*Hope:* Recovery provides the essential and motivating message of a better future— that people can and do overcome the barriers and obstacles that confront them. Hope is internalized; but can be fostered by peers, families, friends, providers, and others. Hope is the catalyst of the recovery process. Mental health recovery not only benefits individuals with mental health disabilities by focusing on their abilities to live, work, learn, and fully participate in our society, but also enriches the texture of American community life. America reaps the benefits of the contributions individuals with mental disabilities can make, ultimately becoming a stronger and healthier Nation.

## **APPENDIX B**

### **Resources for Policy Development**

This section provides resource information on a variety of related topics to aid in applying these recommendations to both public and private sectors of mental health care in the United States.

#### Private Insurance

Most private insurance plans do cover psychiatric services, although there may be significant limitations on time and frequency of visits. The federal Mental Health and Addiction Parity Act of 2008 does prohibit group health plans that offer coverage for mental health and substance-use conditions from imposing treatment limitations and financial requirements on those benefits that

are stricter than for medical and surgical benefits. Behavioral health coverage is required for group health plans with 51 or more employees.

### Medicaid Services

Since physician services (including psychiatric services) are mandatory Medicaid State Plan services, these services should be considered targets for changes in practice patterns to facilitate medication optimization. Early and periodic screening, diagnosis, and treatment for persons under age 21 (EPSDT) is also required for Medicaid-enrolled individuals and should be considered for advocacy efforts to implement medication optimization policies and practices. Advocates should also review each state's Optional Medicaid State Plan Services for the way in which these optional services support medication optimization. These optional services include the following:

- *Rehabilitation Option* [42 CFR 440.130(d)] which can fund some of the necessary services to support medication optimization such as peer supports, Supported Employment, etc.
- *Other Licensed Practitioners* [42 CFR 440.60(a)] which could fund a licensed professional as defined by the State as a way to carve out a specialty within psychiatry or social work to implement shared decision-making as one example of support for medication optimization protocols.
- *Case management* [42 CFR 441.18) could be targeted to support a wide range of services funded under a number of Medicaid and non-Medicaid authorities.
- *1915(i) Home and Community Based State Plan Services option* include an option for self-direction and 1915(c) flexible waiver type services including “other” as part of the Affordable Care Act (ACA)—see below for ACA details.
- *1915(j) Self Directed Personal Assistance Services Program State Plan Option (Cash and Counseling)*[42 CFR 441.450] could be used for peer supports as personal care attendants (e.g. IADLs) and self-direction.
- *Other Medicaid Waiver* programs that could provide financial and administrative supports for medication optimization include:
  - *1915(a) waivers* permit States to enter into voluntary contracts with entities to provide State plan services. Its authority provides a vehicle for voluntary enrollment into capitated managed care otherwise unavailable to states providing Home and Community-Based Services on a fee-for-services basis.
  - *1915(b) waivers* are the traditional managed care options which allow for the flexibility needed to promote medication optimization but require advocate attention to assure that the kinds of policies recommended in this document are established, implemented and monitored.
  - *1915(c) waivers* allow for most of the medication optimization services though very few states have these waivers for mental health (approximately 4-5)—mostly because of challenges in meeting institutional level of care requirements and cost neutrality requirements.

### Affordable Care Act (ACA) Provisions

Health system reforms are being implemented at the state and federal levels, leading both to increased numbers of persons with health insurance and transformation of the delivery system to provide more access to team-based primary care services and efforts to integrate many aspects of



care. With particular reference to the emergence of integrated person-centered primary care homes (and other practice organizations) and efforts to more effectively integrate behavioral health services into those primary care settings, consequently much of the provision of psychiatric medications will be done by primary care and other non-psychiatric prescribing providers. This could lead to a large cohort of persons who continue to be at risk of harms from the premature, inappropriate, or excessive reliance on psychiatric medications to the exclusion of other effective health and social services. It is essential that applicable medication optimization protocols be proactively developed and implemented in these settings.

*Establishment of Center for Medicare and Medicaid Innovation within the federal Center for Medicare and Medicaid Services (CMS) in Section 3021:* This provision allows for testing innovative payment and service delivery models primarily for Medicare and Medicaid programs to reduce program expenditures while preserving or enhancing quality of care. Such models need not be budget neutral and may be limited geographically. This section provides waiver authority and limits judicial review. Preference will be given to models that also improve the coordination, quality and efficiency of health care services—all of which medication optimization initiatives can produce. There must be evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. Integrated care – mind/body/spirit and M.O. (or SAMHSA uses 8 dimension of wellness) might fit nicely here. The Center for Innovation has a website and is in the process of developing a portal through which ideas for projects can be submitted <http://innovations.cms.gov/>.

*Health Homes (ACA Sec. 2703)* allows for a team-based approach that may be consistent with the Open Dialog approach. This needs additional exploration but there is a specific mental health component that requires interested states to consult with SAMHSA prior to submitting a State plan. See State Medicaid Directors Letter at <http://www.cms.gov/smdl/downloads/SMD10024.pdf>

*133% expansion (ACA Sec. 2001)* requires an expansion of Medicaid essential benefits to all citizens under 133% of poverty. The effective date for this provision is 2014. Essential benefits will likely only include something close to mandatory Medicaid services, but not many of recovery based optional services

*Oversight and Assessment of Home and Community Based Services [ACA Sec. 2402(a)]* regulations would provide overarching requirements for HCBS including person-centered planning, self-direction and quality across all HHS (Health and Human Services) funded programs.

*Shared Decision Making (ACA Sec. 3506)* currently unfunded. Consider making recommendations to SAMHSA (eg., RTP project) and/or HHS for M.O. perhaps as part of SDM.

#### SAMHSA Block Grants

Substance Abuse and Mental Health Services Block Grants: Each state submits a plan for the proposed use of these funds, which amount to *a relatively small but flexible portion of most state*

*mental health and addictions budget.* While they are often fairly locked into longstanding state programs, there may be opportunity for advocacy to set aside at least some funding for medication optimization programs or integrated components as described above.

#### **Disclaimer**

**The information on this website represents some of the views of the doctors and professionals serving on the Foundation for Excellence in Mental Health's Scientific Advisory Committee and Board. These views are based on interpretation of studies published in medical journals, as well as professional experience.**

**The treatment information in this document is not official policy of the Foundation and is not intended as medical advice to replace the expertise and judgment of your mental health care team. It is intended to help you and your family make informed decisions, together with your doctor and/or other mental health professionals.**

**Your doctor/mental health professional may have reasons for suggesting a treatment plan different from these general views and treatment options found on the Foundation's website. Don't hesitate to ask questions about your treatment options.**