A Series of Technical Reports

II

TECHNICAL REPORT ON PSYCHIATRIC MEDICATIONS

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I especially want to acknowledge Lee Partridge, Executive Director of the National Association of State Medicaid Directors, for her essential contribution to the collaboration between State Medicaid Directors and NASMHPD regarding issues of mutual interest, including access to and the consistent use of psychiatric medications for people with mental illness.

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Finally, I want to thank Robert W. Glover, Ph.D., Executive Director of NASMHPD, and the NASMHPD staff who helped to produce this excellent document. I am confident that this Technical Report will play an important role in improving access to psychiatric medications and improve the consistency of their use for persons who have a mental illness.

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REPORT PREPARATION

Background and Purpose

This report is the fifth in a continuing series of reports initiated by the National Association of State Mental Health Program Directors (NASMHPD) Medical Directors Council. The purpose of this series is to provide information and assistance to state mental health directors on emerging clinical and service system issues. The topics for technical reports are identified by the NASMHPD Medical Directors Council in conjunction with NASMHPD leadership. Technical reports are developed by members of NASMHPD divisions, NASMHPD affiliates, and outside experts.

During the past decade, the pharmacological treatment of psychiatric conditions has expanded to include several new medications. These medications, while offering the opportunity to significantly improve the quality of care for persons with psychiatric disorders, are not always provided in a way that achieves their maximum benefit. The high cost of these medications and the benefit they provide to patients who have severe disabilities makes the management of these medications an important issue for providers of public mental health services.

This report is a collaborative project between NASMHPD and the National Association of State Medicaid Directors (NASMD). The purpose of this report is to present the most recent information on psychiatric medications and provide a summary of key policy issues related to Medicaid coverage for these medications. The recommendations identify mechanisms to improve access to the medications and improve the consistency of their use for persons who have a mental illness. These recommendations are directed to each of the national organizations, as well as state mental health and Medicaid program directors.

Preparation of Report

This report was prepared from proceedings of a meeting held November 12 through 14, 2000, in Alexandria, Virginia. Meeting participants included five representatives from state Medicaid agencies, five representatives from state mental health departments, and representatives from NASMHPD, the American Public Human Services Association (APHSA), the NASMHPD Research Institute (NRI), and the Substance Abuse & Mental Health Services Administration (SAMHSA). A facilitator directed the discussion to guide the creation of the document and a technical writer was present during the meeting to record the proceedings. A list of participants and their affiliations is included in Appendix 1. The views expressed by the participants were their own and do not necessarily reflect the views of the organizations they represent.

Prior to the meeting, participants reviewed literature regarding the use of new psychiatric medications, the development and implementation of clinical practice guidelines in mental health, and the organization of state Medicaid and mental health agencies. The materials provided background information to describe the context of the report and to serve as a basis for discussion during the meeting. This report builds on

information presented in the literature and incorporates information related to the use of new psychiatric medications from meeting participants, reflective of their thoughts and experiences.

Editorial Review

Drafts of the report were prepared by the technical writer and two editors. The editors included one representative from a Medicaid program and one representative from a state mental health agency. Drafts were distributed for review and comment to all meeting participants and members of the NASMHPD Medical Directors Council's Editorial Board. The final report was reviewed, amended, and approved by the NASMHPD Medical Directors Council and does not necessarily reflect the viewpoint of the NASMHPD membership.

PROBLEM STATEMENT

Definition of the Issues

In recent years, expenditures for pharmaceuticals have increased more rapidly than expenditures for any other health care product or service. This phenomenon is a product of the introduction of many new medications and the increased use of these medications across a wide range of conditions. Within mental health, antipsychotic medications have been the most rapidly growing class of medications over the past three years. The introduction and widespread use of several new, effective, and expensive agents has also placed antipsychotic medications at the top of several state Medicaid's pharmacy costs. Other classes of psychiatric medications, including antidepressants and mood stabilizers, are also listed among the highest cost medications in Medicaid programs. With eighty-five new psychiatric medications currently in research and development, medication issues will continue to have an impact on mental health policy.

The majority of mental health treatment for persons with serious mental illness in the United States is provided through state funded mental health programs and the federal and state funded Medicaid program. As severe mental illness is a chronic, disabling condition, some patients may rely on public services throughout their life. State Medicaid and mental health agencies share the responsibility of allocating public dollars to maximize the benefit of behavioral health services. Cooperation between the two agencies to design, implement, and evaluate quality improvement programs directed at improving the quality of medication use can significantly improve the care of this population.

New Generation Psychiatric Medications

In the last two decades several new medications have been approved for the treatment of mental illness. These medications are at least equally as effective as medications of the past, yet result in significantly fewer disabling side effects. The selective serotonin reuptake inhibitors (fluoxetine, paroxetine, sertraline, citalopram), a group of antidepressants introduced in the 1980s, quickly replaced tricyclic antidepressants of the past as the treatment of choice for depression. Similarly, the atypical antipsychotics (clozapine, risperidone, olanzapine, quetiapine), introduced in the 1990s, have become the first line agents for schizophrenia. More recently, agents approved as anticonvulsants in the early 1980s (valproate, gabapentin) are becoming more prominent as mood stabilizers in the treatment of bipolar disorder.

All of these medications are similar in that they have significantly fewer side effects in comparison with their predecessors. These medications also have significantly greater acquisition costs. Few definitive studies exist that compare these new medications with each other, yet there are significant cost differences from one agent to another within a class. Of all the new agents approved, only clozapine has been convincingly shown to be more effective than other agents in the treatment of schizophrenia, yet it is associated with serious side effects and requires regular blood monitoring throughout therapy.

Psychiatric medications for persons who are indigent are often paid for by Medicaid, state funded mental health agencies, or pharmaceutical sponsored indigent care programs. The appropriate use of new psychiatric medications may provide long-term cost effectiveness through better compliance, fewer inpatient days, and improved social functioning; but the real world effectiveness and economic benefits of these agents is at best only partially understood. Nevertheless, these new medications have significant

clinical advantages over older agents for the treatment of mental illness and are regarded as first line agents by most recent evidence-based practice guidelines.

This report is limited in scope to new medications for the treatment of schizophrenia, depression, and bipolar disorder. It does not address the use of stimulants and other psychiatric medications in children, the use medications for anxiety, or the use of medications to treat mental disorders associated with aging, such as Alzheimer's disease.

State Medicaid Programs

Medicaid is an entitlement program established by the federal government and administered by states to provide payment for medical services for low-income Americans. Both the state and federal governments finance the Medicaid program. The amount of the federal government's contribution is determined by the state's per capita income and ranges from 50% to 83%. While the state governments have some discretion in the design and operation of the program, the federal government has a set of requirements that the states must adhere to in order to receive the federal matched funds. The Health Care Financing Administration (HCFA) of the Department of Health and Human Services (DHHS) is responsible for the federal oversight of the state programs.

Elderly persons, disabled adults, and parents and children are eligible to receive Medicaid benefits if they have income and resources below specified levels. In general, once a person meets eligibility criteria, they are entitled to receive all the benefits provided by the state's Medicaid program.[1] HCFA requires that Medicaid cover a specified range of services, including, but not limited to physician services, hospital care, and immunizations for children. In addition, states may choose to provide other optional services and still receive federal matching funds. Such services include prescription drugs, institutional care for mental retardation, and personal care services. Some services are covered only under Medicaid waivers. These services include community-based services for people with disabilities and home- and community-based care for the frail elderly. Although states may choose to expand eligibility or coverage beyond what is required or allowed by the federal government, they will not receive federal match funds for these persons or services. One service that Medicaid does not provide, which is of particular importance to mental health, is coverage during admission to an institution for mental disease (IMD). IMDs are defined as institutions primarily engaged in providing diagnosis, treatment, or care of persons with mental diseases, including medical attention, nursing care, and related services (e.g. state-operated mental hospitals).

There are four requirements for any service provided by the Medicaid program. Each service must be sufficient in amount, duration, and scope to reasonably achieve its purpose; the benefits must be equal for all Medicaid beneficiaries; the benefits must be the same across the state; and a beneficiary must have free choice of participating providers. At the request of a state, HCFA may provide a waiver to the state allowing the state to receive federal matching funds for expenditures that are not in strict compliance with certain requirements or limitations of the federal Medicaid statute but are consistent with the overall purpose of the program.

All 50 states and the District of Columbia have opted to provide prescription drug coverage as a part of their Medicaid plan. In addition to the regulatory requirements dictating the design of other Medicaid benefits,

[1] Some persons are eligible for a more limited benefit, such as Qualified Medicare Beneficiaries (QMBs), for whom Medicaid pays only their Medicare Part B premiums and cost sharing.

Medicaid prescription drug plans must comply with requirements described in the Omnibus Budget Reconciliation Act of 1990 (OBRA 90). The statute requires the state Medicaid programs to have an open formulary, requires manufacturers to provide rebates to Medicaid, and requires each state Medicaid program to establish drug utilization review (DUR) programs and a DUR board to oversee these programs. States may only limit access to prescription drugs using the following mechanisms:

A. Prescription limits – limit the number of prescriptions per year or per month

B. Cost-sharing – impose nominal copayments for prescription drugs, ranging from $0.50 to $5.00. Providers may not deny service due to a beneficiaries inability to pay a copayment

C. Restricting access to specified drugs – restrict access to a small list of specific classes of medications defined by legislation (over the counter drugs, for example)

D. Prior authorization – require prior approval of a drug before it is dispensed

E. Drug Utilization Review – identify medication errors and drug interactions when the medication is dispensed or review claims to identify utilization patterns that may be unsafe

In practice, Medicaid has evolved independently in every state, and there is enormous variation in the eligibility requirements and services provided across the states.

Medicaid pays between 18 to 33% of the nation's mental health expenditures, yet mental health only consumes about 3-5% of Medicaid's budget. Mental health care in Medicaid is provided through direct payment to providers in fee-for-service arrangements, through managed behavioral health carve-outs in otherwise fee-for-service Medicaid plans, and through managed care plans that administer state Medicaid programs through a waiver from HCFA.

State Mental Health Agencies

State and local governments spend approximately $18-20 billion on mental health care. Fourteen percent of this money is federal, and 80% of the federal funding comes from Medicaid. In many states, responsibility for administering mental health services and allocating mental health resources is designated to local and county governments. In the past, this system consisted primarily of psychiatric hospitals, and the treatment of severe mental illness often involved long-term institutionalization. Long-term hospitalization is now a rare event and most mental health treatment is provided in the community. Local control over the state mental health system allows for greater control of eligibility, services, and physician practice when compared with Medicaid.

A wide variety of organizational relationships between Medicaid agencies and mental health agencies exist within states. These relationships impact the ability of the agencies to share information and coordinate efforts on policy development and planning. In some states, such as Maryland, both the mental health and Medicaid agencies are departments under a single umbrella agency. Other states, such as Virginia, have Medicaid and mental health agencies under two separate government divisions. Texas and New York have the responsibilities for Medicaid and the mental health system split across many departments. A few states provide Medicaid through managed care programs. Some of these states have behavioral health

arrangements in which the state mental health agency has some responsibility over the quality of care in mental health services.

Consensus Reached by Participants

Participants at the November 2000 meeting agreed that new antipsychotics, antidepressants, and mood stabilizers are a significant advancement in the treatment of mental illness. Efforts should be made to ensure that these medications are used appropriately and are available to those who need them. Participants agreed that providing the best quality mental health care is the best policy, and that managing costs is a challenge that both organizations must work together to overcome.

The group also agreed that the use of medications could be improved. Many patients who could benefit from the medications are not receiving them, and when medications are available, they are not always appropriately used. Areas for improvement include increasing patient access to medication, increasing the education of prescribers, increasing the availability of specialty consultation in underserved areas, and addressing the off-label use of these medications. Further elaboration of these issues and suggested system improvements are included in the following section of the report.

Finally, participants acknowledged that state mental health and Medicaid agencies share responsibility in the financing and oversight of mental health services. They also acknowledge an overlap in the patients and providers that their organizations serve. Due to this overlap, improving collaboration between state Medicaid and mental health agencies can result in mutually beneficial outcomes. Combining data to track medication use and outcomes, collaborating on the development of policy to consistently and efficiently provide medications to patients, working together to educate providers on medication use policies, and planning for the challenge surrounding the expanded use of these medications are all areas in which collaboration could be beneficial.

RESEARCH FINDINGS AND RELEVANT ISSUES

Overview of Findings

Mental illness is a complex disease, and medication is only one component of psychiatric treatment. However, quality of medication use may be more easily monitored and evaluated than other forms of treatment, and the appropriate use of medications can have a significant positive effect on the patient's quality of life and the effectiveness of other treatments. A realistic strategy to improve the quality of medication use addresses improvement in the accuracy of diagnosis, the selection of the correct medication, and continuous patient access to medication. Evidence-based guidelines, which can assist providers in making consistent and informed choices, are available from a variety of reputable sources. Not unlike experiences with asthma and diabetes, compliance with guidelines in mental health is very low and improving quality will involve taking additional measures to influence physician practice.

Strategies to Improve the Appropriate Use of Medications

Several mechanisms are available to evaluate and improve the use of medications in that portion of the population that has mental illness. The following topics and suggestions were addressed at the meeting.

- The development, implementation, and evaluation of evidence-based treatment guidelines can improve the consistency and quality of health care within a system.

    - Well designed treatment guidelines focused on providing care based on effectiveness and not just cost offer a mechanism to improve quality of care by standardizing diagnosis, treatment, and monitoring.

    - Guidelines for schizophrenia, depression, and bipolar disorder are available from many reputable sources, including:

        - National Guideline Clearinghouse
        - American Medical Association
        - American Psychiatric Association
        - Agency for Healthcare Research and Quality

    - Lack of physician compliance with guidelines may result from a lack of incentives, unfamiliarity with the guidelines, lack of involvement of leadership within the system, and advertising and promotion on behalf of a particular psychotropic agent.
    - In order for guidelines to be successful, mechanisms must be in place to improve physician compliance. Such mechanisms seek to:

        - Improve collaboration between Medicaid and state mental health agencies to develop a common set of guidelines for psychiatric disorders across the system;

        - Conduct research to demonstrate positive outcomes associated with adherence to guidelines;

        - Provide feedback to physicians to compare their performance to other practitioners; and

        - Involve medical leadership within the community to support and promote the use of guidelines.

- Using specialized case managers to work with patients as they move through the health care system can be an effective program for improving mental healthcare services. Case managers can provide education and support to a patient, and help to coordinate care received in various treatment settings.

    - The development of standardized process and outcome measures, as used in diabetes and asthma, can help guide and evaluate the effectiveness of this process.

    - Involving non-physician practitioners, such as nurses, physician assistants, or pharmacists, can help to increase the patients' role in their care and improve the consistency of treatment across healthcare settings without shifting the entire responsibility of improving care to physicians.

- Standard performance indicators for evaluating the quality of treatment with new psychiatric medications are not currently available.
    - Developing a core set of performance indicators allows for standardized comparison across treatment sites. Performance indicators may include:
        - Medication usage rate – The percentage use of new medication by practitioner or program;
        - Polypharmacy – The use of more than one medication in a single therapeutic class;
        - Frequency of dosage change – An indicator for whether patients are given adequate time to respond to a new medication; and
        - Relationship between diagnosis and medication – To determine how often appropriate medications are used for various diagnoses.
- There are many issues regarding the real world effectiveness of the new medications that are still unknown. Such issues include:
    - Improved compliance with medication regimens is often assumed based on reduced side effects, but this effect has not been proven.
    - It is still unknown to what degree patients are able to function better in the community through the use of new medications.
    - Cost-effectiveness, particularly within therapeutic classes, has not been established. More research independent from the sponsorship of pharmaceutical manufacturers is needed in this area.
- Non-psychiatric health care providers are more readily accepting new psychiatric medications. The use of these medications is expanding in primary care physician practice.
    - The improved safety profile of new medications makes them more acceptable to non-psychiatric physicians.
    - New prescribers must be adequately educated on these medications to produce valuable outcomes. Education on basic principles – diagnosis, treatment, dose, monitoring, the duration of an adequate trial, the use of multiple medications – can improve the quality of their service.
    - Improving the knowledge base of primary care practitioners allows more patients to be treated in a primary care setting, with potential to improve both access and cost.
    - The use of these medications outside of specialty care will require closer monitoring to ensure appropriate use.

- Telepsychiatry has applications in both patient and provider education and reaching populations that do not have direct access to specialty care. Several barriers currently exist to using this technology in practice.

    - Telepsychiatry requires large startup and maintenance costs and a technology infrastructure to support its use.

    - Telepsychiatry for direct patient care is not considered an encounter by HCFA since it is not face-to-face. Therefore, Medicaid is unable to provide reimbursement.

    - Some state-funded processes reimburse telepsychiatry consultations and Medicaid may be able to pay for the service by having a third party in the room with the patient. This additional person can provide the face-to-face encounter and bill for the service.

- The off-label use of new psychiatric medications is increasing, particularly in patients with dementia, development disorders, mental retardation, and organic psychotic disorders not including schizophrenia.

    - These populations often reside in long-term care facilities financed by Medicaid.

    - The treatment of elderly with dementia and children with developmental disorders is shifting to home environment. State mental health programs may have greater involvement in providing these medications and services to patients formerly treated in long-term care environments.

    - Although off-label use has increased, systematic research on the benefits and risks in these populations has not accumulated.

Strategies to Improve Consistent Access to Medications

Continuity of care was identified in the meeting as a significant barrier to delivering high quality care to psychiatric patients. Stabilization on a medication regimen often occurs across treatment settings. For example, patients may transition from the hospital to outpatient community setting, or from jail/prison to community mental health service providers. Lack of continuity can interrupt pharmacotherapy, increasing the risk of relapse. The following statements address the issues of continuity of care and provide suggestions for improving continuity in the system.

- Medicaid benefits are terminated when a patient enters an institution for mental diseases (IMD) or jail. Upon discharge the patient does not have coverage to pay for their medication.

    - The policy exists to prevent federal Medicaid funds from paying for programs that are not eligible for federal matching funds. The actual termination of coverage during admission is not a procedure mandated by Medicaid, but is established to prevent illegal federal reimbursement.

- The rapidity at which Medicaid reenrollment takes place after discharge is a state procedure issue.

- It is unclear who is responsible for reenrolling patients into Medicaid after the patient is discharged from an IMD or jail.

- Possible solutions to this temporary loss of eligibility include:

  - The IMD or jail may be able to fill the patient's first prescription upon discharge and bill Medicaid after the patient reestablishes coverage.

  - The IMD or jail can hire an enrollment manager to work directly with Medicaid to facilitate smooth transitions from inpatient treatment into the community.

  - Mental health and Medicaid agencies within the state can work together to develop a policy to address this problem.

- SSDI income above a certain level makes patients ineligible for Medicaid benefits.

  - Increasing the scope of Medicaid eligibility is not a realistic option.

  - Possible solutions include having state mental health agencies expand indigent medication programs to serve this population.

Strategies to Manage the Growth of Medication Expenditures

The cost of providing new medications to a large, highly disabled population presents a challenge to public healthcare providers. Attempts to cut costs through benefit restriction often results in cost shifting to inpatient care and poorer outcomes for patients. More refined measures aimed at ensuring appropriate care may be the most useful strategy in the long term. The following issues describe challenges to providing these medications and mechanisms utilized in attempt to control costs.

- Many restrictive mechanisms to control cost in Medicaid programs have not been successful.

  - Medicaid legislation limits prescription management options to prior authorization, prescription limits, and spending caps.

  - Prior authorization to control costs is often unsuccessful.

    - As many as 90% of prior authorization requests for psychiatric medications are approved.

    - The cost savings often does not cover the costs to administer the program.

    - Prior authorization may be used to improve compliance with treatment guidelines in particular physicians who are identified as outliers.

- Prescription limits and spending caps may result in cost shifting and inadequate care if continuity of care is interrupted.

- Cooperation between mental health authorities and Medicaid agencies in the development of restrictive policies may improve the use of prior authorization and prescription limits.

- The future of pharmaceutical prices is uncertain.

  - The media, the public, and the federal government are increasing pressure on pharmaceutical companies to lower cost.

  - State mental health agencies may be able to establish a buying group across community mental health centers and hospitals. Buying groups may also be able to extend across states. State mental health agencies may benefit from sharing cost information with one another to negotiate better prices with the pharmaceutical industry.

  - The availability of several new medications within the same therapeutic classes may reduce the growth in cost per prescription over the next few years.

  - Generic formulations of clozapine are now available and generic fluoxetine will be available within the next year. Despite news reports to the contrary, the meeting participants believe generic formulations are as effective as the brand equivalent as long as patients are stabilized and monitored on a single formulation. Promoting generic substitution can help manage costs without affecting therapeutic outcome.

RECOMMENDATIONS FOR NASMHPD AND NASMD

This technical report is intended to serve as an initial guide to quality improvement programs directed at the use of new psychotropic medications provided by public mental heath providers. This report is presented with the understanding that the structures and relationships between Medicaid and mental health agencies within each state have wide variation across the country, and the applicability of any specific quality improvement mechanism may vary. The NASMHPD Medical Directors council recommends that NASMHPD and NASMD leadership take steps to encourage states to report their experiences and further define successful strategies for implementing quality improvement programs within the context of their specific structure. In addition, the Medical Directors Council recommends that NASMHPD and NASMD take the following actions:

- Promote working partnerships between Medicaid agencies and mental health agencies at the state level.

- Facilitate the sharing of data and between state Medicaid and mental health agencies.

- Assist in the development of a core set of quality measures for monitoring the use of mental health medications. The performance measures are to be used as a standard across states for measuring the quality of psychotropic medication use and to identify areas for performance improvement.

- Encourage and support research on the appropriate use, effectiveness, and cost of psychiatric medications in a real-world practice setting.

- With leadership from Medicaid and mental health authorities, address current and future issues regarding the use of new psychotropic medications in different populations.

- Develop a standard definition to identify the flow of funds into public mental health services, including money flowing to non-designated mental health providers providing mental health services. This may provide a better measure than currently exists to calculate the actual amount of public resources allocated to mental health care.

RECOMMENDATIONS FOR STATE MENTAL HEALTH AGENCIES AND STATE MEDICAID AGENCIES

The NASMHPD Medical Directors Council recommends that state mental health agencies and state Medicaid agencies work together to improve the quality of medication use in their populations. Specifically, these agencies should:

- Work towards developing and promoting a common infrastructure across the two agencies to implement performance improvement initiatives, in order to:
    - Establish a common data structure to facilitate research on process and outcome measures related to the appropriate use of psychotropic medications;
    - Monitor the impact of performance improvement strategies designed to improve the consistency of new psychotropic medication use; and
    - Develop and implement programs to improve prescriber compliance with accepted guidelines for medication use.
- Embrace opportunities to collaborate on policy development or implementation across the two organizations in order to improve the consistency of care across treatment settings.
- Identify mechanisms for educating health care practitioners providing mental health services and consumers receiving these services about the appropriate use of new psychiatric medications.
- Address areas for improvement in continuity of medication provision across community settings or from hospital to community settings, in order to:
    - Explore alternative administrative mechanisms to improve continuity of care associated with loss of Medicaid coverage in IMDs and jails; and
    - Explore alternative mechanisms for providing medications to populations who are not eligible for Medicaid.
- Encourage state mental health agencies to share pharmacy cost information across agencies. State mental health agencies should explore mechanisms to establish buying groups within and across states.
- Explore use of modern technologies, such as telepsychiatry, to interact with patients in rural areas who lack access to psychiatric care.

Appendix 1: Selected References

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Appendix 2: List of Meeting Participants

NASMHPD Medical Directors Council and State Medicaid Directors
Technical Report Meeting on Psychiatric Medications

Alexandria, Virginia

November 12-14, 2000

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