
Medication Practices in New York State Developmental Centers

A Post-Willowbrook
Report of Practices
at Five Developmental Centers

NYS Commission on



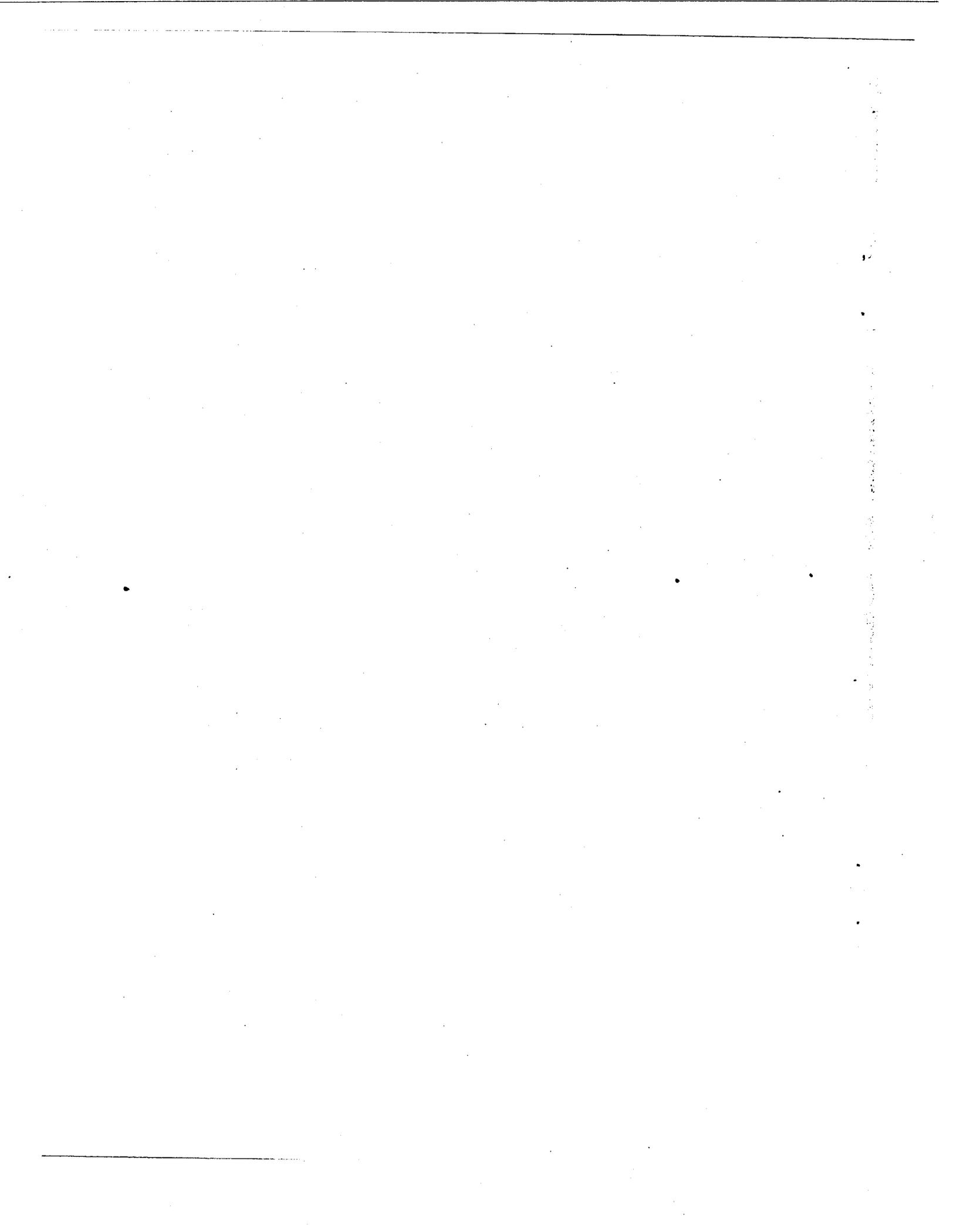
QUALITY
OF CARE

for the Mentally Disabled

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November, 1986



Preface

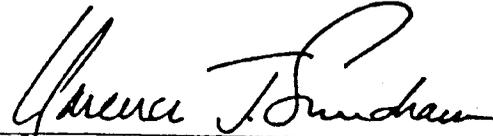
In accordance with the Commission's statutory responsibility for ensuring quality of care for the State's mentally disabled citizens, a systemic review of anticonvulsant and psychotherapeutic medication practices in five State developmental centers was undertaken. This review revealed many appropriate practices by these centers to ensure residents' health and the appropriate use of medications in promoting their rehabilitation. Compliance with the Office of Mental Retardation and Developmental Disabilities' guidelines and policies for specific drug prescribing practices and for ensuring medication security was particularly noteworthy.

The review also surfaced significant concerns in the areas of physician documentation and clinical monitoring of medication regimens. The Commission found that physicians' rationales for medication decisions were often either lacking or incompletely documented in residents' records; that routine checks for adverse side effects of medications were also frequently not recorded; and that routine monthly medication reviews often failed to specify the actual effects of the medications on resident behavior and/or seizure control, or to evaluate

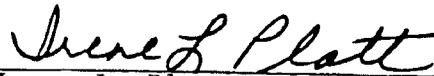
whether a drug free trial may be warranted to assess the continued benefits of the medication. The findings also indicated a strong likelihood that medication errors are not universally reported by staff.

Throughout the course of this review and its planning the Commission has worked closely with the Office of Mental Retardation and Developmental Disabilities. These cooperative efforts have resulted in many corrective actions by the Office to address the significant concerns and deficiencies noted by the Commission. Correspondence from the Office of Mental Retardation and Developmental Disabilities (March 1986 and July 1986) specifying these corrective actions and the Office's formal response to the report's recommendations is included in Appendix C.

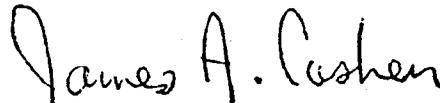
The findings, conclusions, and recommendations presented in this report represent the unanimous opinion of the members of the Commission.



Clarence J. Sundram
Chairman



Irene L. Platt
Commissioner



James A. Cashen
Commissioner

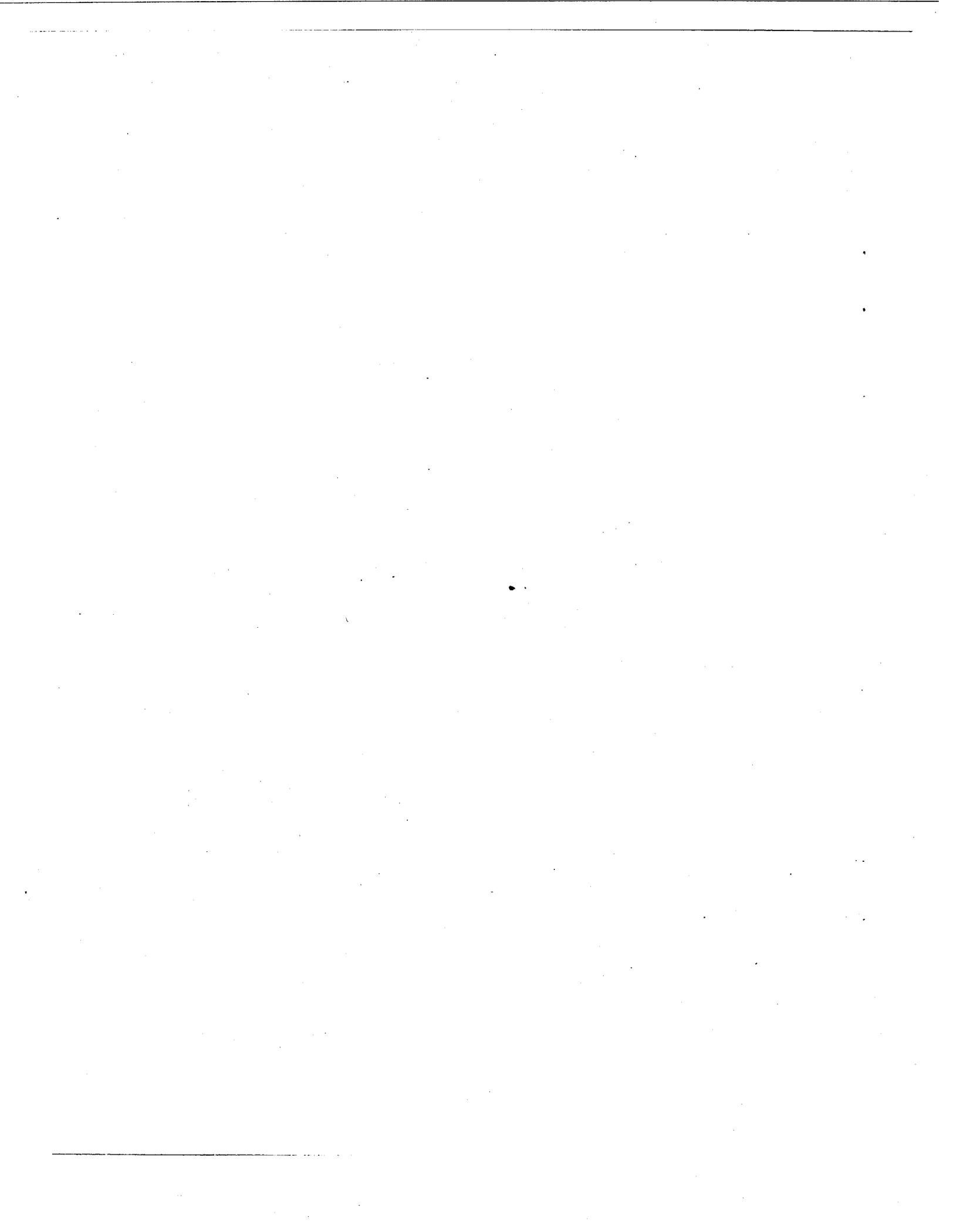


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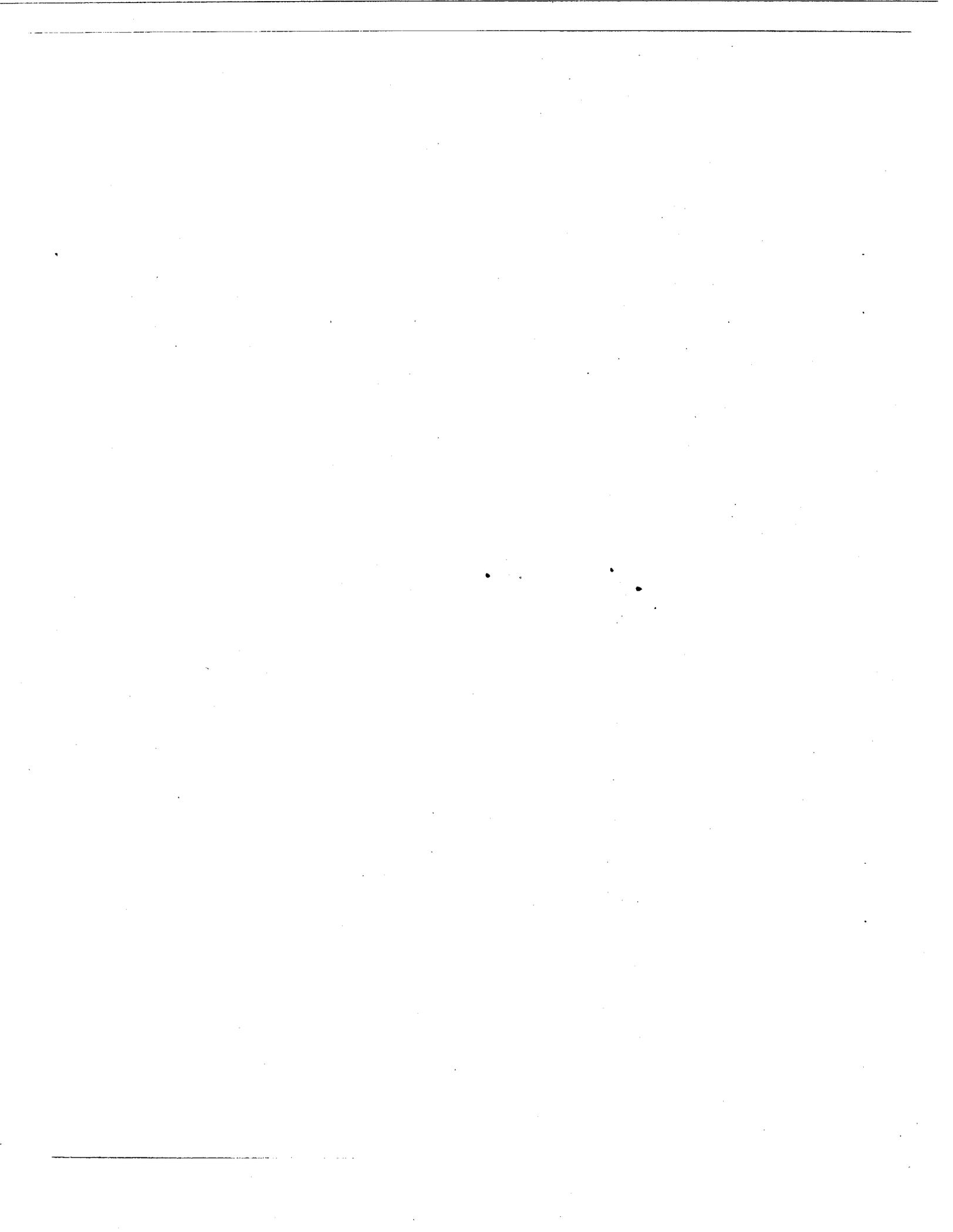
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Acknowledgments

The Commission is deeply appreciative of the cooperation and assistance of Central Office and facility staff of the New York State Office of Mental Retardation and Developmental Disabilities in the conduct of this review. Special thanks are extended to Mr. Thomas Cuite (Deputy Commissioner, Division of Quality Assurance), Ms. Barbara Hawes (Deputy Commissioner of Program Operations), Dr. Judith Rettig (Clinical Specialist, Medical Services), and Ms. Connie Sullivan (Director, Bureau of Children Services) for their assistance in reviewing the study instruments and protocol and in orchestrating needed policy, procedural, and training initiatives to address concerns raised by the review's findings. We are also very appreciative of the time and assistance provided by senior administrators and ward staff of Wilton, Brooklyn, West Seneca, Letchworth, and Bernard Fineson Developmental Centers, which served as primary sample sites for data collection. We also thank the Deputy Directors for Quality Assurance at all 20 centers who provided data on reported medication errors, and shared their insights as to the strengths and limitations of facility practices to detect and review these incidents.



Executive Summary

This study reflects one of the largest systemic studies of psychotherapeutic and anticonvulsant medication practices for persons with developmental disabilities residing in public institutions. The study examined medication practices for 150 randomly selected clients at five New York State developmental centers. These centers served approximately 4,000 residents, representing 35 percent of the total institutional developmental center population in New York State. A wide range of medication issues, including medication prescribing and administration practices, clinical monitoring, attention to medication security, reporting of medication errors, and internal clinical accountability for exceptional practices, were reviewed.

Criteria for the review were drawn from existing guidelines and policies of the New York State Office of Mental Retardation and Developmental Disabilities. Client-specific data collection entailed an on-site review of each sampled client's record, for a one year retrospective period. Where necessary, follow-up interviews were conducted with relevant facility clinical staff to clarify record information. Unannounced ward and pharmacy visits assessed issues of medication security and the actual administration of medications to patients. Finally, mail surveys to all 20 New York State developmental centers and reviews of all medication error reports for a one month period from all centers were used to gather information about reporting of medication errors and their investigation. All data were collected during the summer and fall of 1984.

MAJOR FINDINGS

The findings of this review revealed many existing practices to ensure residents' health and the appropriate use of medications in promoting their habilitation. With the exception of one center, psychotherapeutic drugs were used to modify resident behavior only in conjunction with structured behavioral management programs, and there was no evidence that these drugs were used excessively as forms of chemical restraint. Psychotherapeutic drug dosages were usually well below the recommended maximum dosages in the OMRDD guidelines, and very few instances of "PRN" or "Stat" psychotherapeutic drug administration were noted over the year review period.

- Appropriate Drug Prescribing Practices

Similarly, physician practices in anticonvulsant drug choice and dosage levels were almost universally in accord with OMRDD guidelines. Compliance with other OMRDD prescribing guidelines for psychotherapeutic and anticonvulsant drugs relating to the preference for oral tablet (versus liquid) administration, for the use of long-established (versus newer) medications, and for the limited use of certain drug classes (i.e., antiparkinson, somnifacient, antianxiety, and cerebral stimulant drugs) was also generally noted across all the five centers. Finally, medication security was safeguarded, consistent with OMRDD policies and procedures, on almost all living units, and in all pharmacies, during the times of the Commission's unannounced visits.

- Adequate Annual Physical Exams and Orderly Records

Equally important, almost all of the randomly sampled residents had had a complete physical exam within the past year, and treatment recommendations emanating from the exams had been implemented. With the exception of one unit of one of the five centers, the residents' case records were also reasonably organized, and medication order sheets, medication review notations, and progress notes were easy to find and review. Physicians also exercised care to renew medication orders at least every 30 days, as required by OMRDD policies.

Together, these findings are heartening and highlight the success of the New York State OMRDD in implementing major systemic change to correct many of the more egregious deficiencies in medication practices that were alleged to have plagued the State's institutions prior to the Willowbrook Consent Decree. Given that the centers reviewed collectively serve nearly 4,000 severely developmentally disabled individuals, and that over 5,000 direct care and clinical staff personnel are involved in the care and treatment of these individuals, these accomplishments are impressive.

AREAS OF CONCERN

The findings of the review also pointed, however, to several areas where additional improvements in medication practices were critical. Of special importance were the two areas of (1) physician documentation; and (2) clinical monitoring and oversight practices. In these areas deficiencies were prevalent at most or all of the five developmental centers reviewed. These deficiencies raised concerns about the system's overall

accountability for medication decisions and, specifically, for its capability to identify and correct poor practices which could adversely affect residents' health and long term well-being.

Another area of concern related to the reliability of reporting medication errors and to certain isolated problems in on-ward medication administration to clients.

- Limited Physician Documentaion of Rationales for Medication Decision-Making

Deficient physician documentation was most serious in the lack of specific seizure diagnoses and descriptions of seizure conditions for clients maintained on anticonvulsant medications (40 percent of the relevant cases), and in the lack of specific physician rationales justifying the initiation of psychotherapeutic drug therapy as an adjunct to programmatic interventions (40 percent of the relevant cases). Physician rationales justifying changes in clients' anticonvulsant and psychotherapeutic drug regimens were also absent in 18 and 32 percent of the respective relevant cases. Finally, in the relatively infrequent instances where psychotherapeutic and anticonvulsant drug prescriptions were contrary to OMRDD prescribing guidelines, physician rationales justifying the exceptional practices were missing in nearly half of the cases.

- Weaknesses in Clinical Monitoring

The review also surfaced systemic concerns regarding the adequacy of clinical monitoring practices to assure the safe and appropriate continued administration of psychotherapeutic and anticonvulsant medications. Major areas of concern included the lack of documentation in monthly review notes relating the effects of psychotherapeutic drugs on the residents' daily functioning (in 41 percent of the relevant cases), and the practically nonexistent use of periodic "drug free trials" to safeguard against the unwarranted long-term administration of psychotherapeutic medications. The failure to use drug holidays was of particular concern in light of noted weaknesses in physician documentation of their rationales for the initiation of medication therapy in the first place.

Clinical monitoring practices for residents receiving anticonvulsant drugs appeared to be even more limited. Monthly medication reviews frequently failed to make any substantive reference to a client's anticonvulsant drug regimen or seizure activity (36 percent of the relevant cases), and seizure records were uniformly maintained by only one center. Additionally, the

use of EEGs to refine seizure diagnoses and to monitor seizure conditions and of blood serum levels to regulate seizure-control medications appeared idiosyncratic across all centers.

Most seriously, regular monitoring for side effects was not documented for 43 percent of the sampled residents receiving psychotherapeutic drugs, and for 36 percent of the sampled residents receiving anticonvulsant drugs.

While many of these Commission findings reflect a review of record documentation and do not necessarily indicate that physicians and other appropriate clinicians were inattentive to these issues, it was clear that even when such attentiveness was assured, the record was of little assistance to other physicians and clinicians charged with subsequent decision-making for residents. This limitation is of particular concern in large congregate care settings, like State developmental centers, where physician/clinical staffing usually rotates in shifts, and where relatively high turnover rates among these clinicians are common. In these circumstances, the lack of documentation can pose problems in the detection of gradual or subtle intended or unintended effects of medications. These changes may suggest a need for changes in a resident's medication. Thus, the absence of documentation related to medication decisions or clinical monitoring is not just a "paperwork" error. Rather, it can ultimately short-circuit the entire process of rational treatment planning, as well as future medication decision making for residents.

- Likely Underreporting of Medication Errors

Finally, although the Commission was impressed with the overall security of medications and the safe clinical practices with regard to medication administration exercised by the five centers, we were concerned that available reports strongly suggested the likelihood of substantial underreporting of medication errors, especially at the centers not using the unit dose drug dispensing system. Among the 12 low reporting centers, which collectively served nearly 9,000 residents, a total of only 40 error reports were filed for the one month review period, and only two centers (both of which utilized the unit dose drug dispensing system) had estimated medication error rates within the national norm of 3 to 5 percent. Special Review Committee Chairpersons at the centers, who oversee the review of reported errors, also registered concerns regarding the system's overall limited accountability for medication administration and, particularly, its nearly total reliance on staff self-reports to detect medication errors.

- Isolated Poor Practices in Medication Administration

The Commission was also concerned at the isolated, but serious instances of the infringement of residents' dignity in the administration of medications to clients while they were using the toilet and just exiting from showers. Similarly, isolated instances where staff administered medications without washing their hands or crushed tablet medications for several clients using the same mortar and pestle without cleaning these implements raised concerns. The Commission also believes that the routine use of jelly or apple butter to ease the acceptance of medications should be reevaluated in view of the potential for these "mixers" to promote tooth decay. This issue is of particular concern for individuals residing in developmental centers because many are particularly prone to dental problems and, when dental problems occur, dental work often must be done under anesthesia which poses increased risks for client welfare (as well as increased costs).

CONCLUSIONS

In sum, despite the findings of many areas of sound and quality practices, the review also surfaced several significant and serious areas of concern. These concerns were shared with the individual facilities reviewed, as well as senior officials of the New York State Office of Mental Retardation and Developmental Disabilities (OMRDD), soon after data collection and analysis was completed in the winter and spring of 1985. Subsequent to this communication of the study's findings, OMRDD as well as the individual centers, have undertaken a variety of initiatives to correct deficiencies and to strengthen medication practices.

OMRDD INITIATIVES TO ADDRESS CONCERNS

For example, OMRDD has issued new policy guidelines related to clinical monitoring practices for clients receiving anticonvulsant medications, and to annual drug free periods for clients receiving psychotherapeutic medications. Both policies reinforce existing standards, and also add greater clarity for specific clinical practices which must be followed. Concerns regarding the documentation and conduct of side effects checks for clients have also been shared with the Medical Deputies at all 20 developmental centers, and OMRDD reports that many centers have developed new monitoring programs. In August 1986, the OMRDD also issued a new section of the policy manual addressing the

critical importance of side effects checks, as well as specific protocols and documentation requirements for the monitoring of side effects.

The OMRDD has also undertaken statewide efforts to ensure that the relationship between psychotherapeutic drug therapy and client functioning is regularly assessed and carefully documented in clients' records. The OMRDD acknowledges that this concern has also been cited by other external monitors, as well as their own auditors, and that more recent reports indicate improvement in centers' practices in this area. Additionally, the new Nursing Policy Manual, issued by OMRDD in July 1985, systemically addresses the deficiencies cited in medication administration, and center-specific concerns in this area have reportedly been corrected.

Finally, with regard to the major issue of improving physician documentation related to medication practices, the Office has recognized the need to improve physician participation in medication monitoring and documentation, as well as the need to ensure that all physicians working in State developmental centers are aware of OMRDD's medication policies and guidelines. These concerns are reportedly being addressed directly with medical deputies and the centers' quality assurance staff, and through local and regional training efforts.

In total, these prompt actions to ensure corrective action are impressive, and they further testify to the commitment and high expectations of OMRDD Central Office and developmental center staff to ensure the cautious and safe administration of psychotherapeutic and anticonvulsant medications. The substantial involvement of Medical Deputies in the initiation of these changes is also noteworthy, and should facilitate the necessary cooperation between Central Office and center physicians in ensuring their full implementation.

OTHER NEEDED CORRECTIVE ACTIONS

While acknowledging the importance of the initiatives already undertaken by OMRDD, the Commission feels several other actions are also needed. Many of the cited deficiencies reflected weaknesses in internal facility monitoring and oversight for medication practices. We believe that periodic reviews of randomly selected client records by medical and quality assurance deputies, as well as the strengthening of developmental centers'

Drug Monitoring Committees are important additional steps in this area. Across the five centers visited, the Drug Monitoring Committees assumed very different responsibilities. The Commission believes that these committees should function as clinical forums involving peer clinician and physician review of medication practices. In addition, routine random record checks for compliance with OMRDD guidelines and policies should be standard practice at all of the centers.

The Commission also feels that additional regional seminars and training sessions for center physicians are needed to improve physician awareness and compliance with OMRDD expectations in medication prescribing and monitoring practices, and to foster communication of physician insights and concerns pertaining to medication regimens. This initiative would be especially beneficial in view of the limited clinical research regarding the effects and use of psychotherapeutic medications in structural behavioral management programs for persons with developmental disabilities. These forums could provide opportunities for physicians to share their experiences and clinical results, participate in collegial problem solving, and perhaps publish joint research reports.

The review also revealed several systemic resource needs of the centers. The availability of board-certified neurologists and psychopharmacologists to provide specialized clinical expertise was limited at the centers. Limited access to neurologists was cited by some centers as the reason behind infrequent comprehensive neurological exams for clients with active seizure disorders, whereas the virtual lack of psychopharmacologists curtailed the critical review of psychotherapeutic drug regimens. This latter issue was particularly significant given the wide variability in the frequency of psychotherapeutic drug use among the centers. As noted in Chapter 1 (Table 1, page 11), at one of the centers (Bernard Fineson) 50 percent of the residents were receiving psychotherapeutic medications, while at another (Brooklyn) only 16 percent of the residents were receiving these medications at the time of the Commission's review.

The Commission believes that the difficulties in recruiting these professionals to provide on-going consultant services to developmental centers should be fully evaluated. Necessary adjustments in salary scales/consultant fees, as well as possible recruitment enhancements for major medical centers to share their expert clinicians with developmental centers should be identified. In addition, consideration should be given to a statewide

evaluation, involving expert clinicians, of the variation in psychotherapeutic drug use among the 20 developmental centers to discern the reasons behind this variation, and whether drug use at some centers could be reduced without adverse effects on clients.

Finally, the study's findings reinforced the long-accepted priority of the Office of Mental Retardation and Developmental Disabilities to implement the unit dose drug dispensing system in all of its centers. This drug dispensing system has universal support for its advantages in strengthening the accountability and accuracy of medication administration and in ensuring reports of administration errors. In addition, implementation of the system should significantly reduce the time spent by ward staff in preparing and pouring medications, freeing their services for more direct client interaction in care and active treatment.

RECOMMENDATIONS

In accordance with these conclusions, the Commission offers the following recommendations:

1. The New York State Office of Mental Retardation and Developmental Disabilities should consider a variety of initiatives, including but not limited to those listed below, to strengthen internal center oversight and monitoring of medication practices.
 - ° Medical and Quality Assurance Deputies in the centers should be required to periodically review a random sample of case records to check compliance with the Office of Mental Retardation and Developmental Disabilities' medication policies and guidelines. Reports of these reviews, together with the corrective actions instituted should be submitted to Central Office;
 - ° The Office of Mental Retardation and Developmental Disabilities should clearly articulate the responsibilities and required activities of Drug Monitoring

Committees, and take such other actions as may be required to ensure that these committees function as effective forums for the peer clinical review of medication practices;

- On a frequent basis the Office of Mental Retardation and Developmental Disabilities should sponsor seminars/training workshops for center physicians, pharmacists, and other relevant clinical staff to share findings of recent clinical research, to discuss their own clinical observations and insights, and to promote peer problem-solving and case review of difficult cases on issues related to psychotherapeutic and anticonvulsant drug use.
- 2. The New York State Office of Mental Retardation and Developmental Disabilities should evaluate the adequacy of available board certified neurologists and psychopharmacologists for each of the 20 developmental centers, as well as the reasons/factors behind their limited availability to some centers. Workable initiatives to enhance the recruitment of these professionals should be identified, and the Office, in conjunction with the Division of the Budget, should implement these initiatives.
- 3. The New York State Office of Mental Retardation and Developmental Disabilities, in conjunction with IBR and other relevant clinical experts, should design and carry out a systemic evaluation of psychotherapeutic drug use in State developmental centers. This study should seek to explain the variation in the use of these drugs among the centers, and to identify clinically appropriate protocols which could assist centers in evaluating client-specific drug regimens, with a goal toward reducing drug use, where this would result in no adverse effects on clients.

4. The Legislature and the Division of the Budget should provide sufficient resources to allow the implementation of the unit dose drug dispensing system in all State developmental centers. Simultaneously, the New York State Office of Mental Retardation and Developmental Disabilities should make the implementation of this system a high priority for all centers, with a goal to have the system fully operational in all centers by December 31, 1987.

* * * * *

As reflected in the above narrative, the findings, conclusions, and recommendations of the Commission's review, as well as a draft copy of this report, have been shared with the Commissioner and senior staff of the New York State Office of Mental Retardation and Developmental Disabilities. These periodic discussions have resulted in many concrete corrective actions designed to address the areas of concern and deficiencies noted by the Commission's review. An interim report from the Office's Division of Quality Assurance (March 6, 1986) specifying numerous corrective actions underway by the Office at that time is provided in Appendix C. Also included in Appendix C is a letter from Commissioner Arthur Webb (July 28, 1986) of the Office relating comments on the draft report and further agency plans to address the report's recommendations.

CHAPTER I INTRODUCTION

STATEMENT OF THE PROBLEM

The introduction of phenothiazine drugs in the 1950s was hailed as a major advancement in the treatment of mental illness. These drugs, which act upon the perceptual side of the brain, had major implications for controlling and reducing some of the major symptoms of serious mental illness, including disorientation, bizarre thinking, anxiety, and hallucinations. With the capability of holding many of the serious symptoms of mental illness in check, phenothiazine drugs facilitated the treatment of many persons with serious mental illness outside of an institution through community-based outpatient services. In New York State, the use of these drugs, together with antidepressant agents, introduced shortly thereafter, fostered the implementation of a policy of deinstitutionalization which reduced the census of State institutions for the mentally ill from over 93,000 in 1955, to less than 23,000 in 1985.

Concurrent with the use of these drugs (collectively referred to as psychotherapeutic agents) in treating the symptoms of mental illness, was their use in treating behavioral disorders of persons with developmental

and/or mental retardation. Early clinical research demonstrated that certain psychotherapeutic agents were effective with this population in reducing aggressive and abusive behaviors and in promoting the learning of appropriate behaviors and specific functional skills. The changes in the treatment of persons with developmental disabilities coincided with recognition that many individuals with these disabilities were considerably more capable of achieving independence in self-care and life skills than was generally recognized. When carefully planned and implemented, individualized behavior management programs, as well as other education and training programs, improved the functioning level of most participating clients.

Thus, by the mid-sixties the clinical professionals were using two new approaches--psychotherapeutic drug therapy and individualized treatment programs, largely based on behaviorist learning theory. Like the introduction of psychotherapeutic medications in the treatment of mental illness, these approaches promised advances in enabling persons with developmental disabilities to live fuller lives in communities outside of institutions.

Notwithstanding this promise, concerns regarding the use of psychotherapeutic drugs in treating the chronically and mentally disabled surfaced early in their use and

increased as their popularity as a treatment intervention grew. There was particular concern about the high incidence of their use, given the lack of a significant body of clinical research to substantiate their benefits and to document their possible adverse side effects, especially over the long term. These concerns were amplified by clinical experts' acknowledgment that there were many unanswered questions about the effect of these drugs on the brain and other organs, as well as about their differentiated impact for persons with developmental disabilities versus those with mental illness. In addition, the substantial tranquilizing (sedative) effect of many psychotherapeutic agents, particularly when administered in high dosages, led to claims by relatives and advocates that these drugs, especially in institutional settings, were being used inappropriately as a form of "chemical" restraint. These latter claims were lent credibility by the extreme vulnerability of many institutionalized persons with developmental disabilities and their inability to provide personal consent for the administration of these drugs.

In the general outcry over conditions which existed in public institutions for the developmentally disabled in the 1970s, concerns about the appropriate use and alleged abuse of psychotherapeutic drugs as a treatment approach became a

major focal point--second only to concerns about general living conditions and the residents' safety and physical well-being. As this outcry reached the federal and state courts, judicial intervention in articulating guidelines for the administration of psychotherapeutic drugs became prominent. In two major class action law suits, N.Y.S.A.R.C. v. Carey* (the Willowbrook case) and Wyatt v. Stickney,** the court issued a number of specific guidelines for the use of psychotherapeutic agents, mandating careful clinical monitoring and safeguards to ensure that drugs were used only in conjunction with a carefully planned treatment program.

The Willowbrook Consent Decree, emanating from the N.Y.S.A.R.C. v. Carey litigation in New York State, was issued in 1975 and focused on New York's then largest institution for the mentally retarded, the Willowbrook State School.*** The decree had especially substantial implications

*N.Y.S.A.R.C. v. Carey, 393 F. Supp. 715 (EDNY 1975) (Consent Judgment, Appendix A, Section Q).

**344 F. Supp 373 (M.D. Alabama, N.D. 1971), aff'd in part and remanded in part sub nom, Wyatt v. Aderholt, 503 F. 2d 1305 (5th Cir., 1974).

***In 1974, the Willowbrook State School served over 5,400 residents in buildings originally designed for only 4,200 individuals. Since that time, a massive deinstitutionalization has resulted in a census decline at the institution, renamed Staten Island Developmental Center, to only 251 residents. By 1987, the State plans to close the institution.

for New York. In signing the decree, the State acknowledged not only the deplorable living conditions and inadequate treatment services of the institution, but also its many deficient medication practices, which subjected residents to immediate harm, as well as long-term and irreversible side effects from inadequately monitored drug regimens.

Unjustified concomitant use of multiple psychotherapeutic drugs, excessive drug dosages, and the virtual lack of clinical monitoring of the intended effects and unintended side effects of the drugs were cited among the deficient practices. The plaintiffs addressed these deficiencies in the court hearings, and the Willowbrook Consent Decree itself mandated many safeguards for medication use including, but not limited to, the following:

- o No prescription drugs shall be administered except upon order of a physician, and all such orders must be reviewed and rewritten at least every 30 days;
- o Physicians must review weekly the drug regimens of residents under their care, and record notations must specify the effects of psychoactive drugs on the resident, as well as justifying physician rationales for psychoactive medication changes;
- o Residents have the right to be free from unnecessary or excessive medications, and medications shall not be used as punishment, for the convenience of staff, or as a substitute for program;

- o Pharmacy services at the institution shall be directed by a professionally competent and licensed pharmacist, and only appropriately trained staff shall be allowed to administer drugs; and
- o Medication errors and drug reactions shall be recorded and reported immediately to the physician who ordered the drug.*

PURPOSE AND OBJECTIVES OF THE STUDY

New York State reacted to the concerns raised in the Willowbrook case, as well as in other forums, through a combination of policy measures, designed to extend the provisions of the Willowbrook Consent Decree to all of its State institutions for the developmentally disabled. These policies provide explicit safeguards and directions for physician practices in prescribing and monitoring psychotherapeutic drugs in State institutions. Other policies focused on institutional security for psychotherapeutic drugs and ensuring their safe and accurate administration to residents by facility staff.

In many respects, these initiatives have placed New York in the forefront of safeguarding developmentally disabled persons from institutional abuse of psychotherapeutic drugs. But, despite these initiatives, allegations of

*N.Y.S.A.R.C. v. Carey, 393 F. Supp. 715 (EDNY 1975)
(Consent Judgment, Appendix A, Section Q).

the inappropriate use and poor clinical monitoring of medications continue to recur.

As the statutorily mandated State oversight agency of the New York State OMRDD, and also as New York's federally-designated Protection and Advocacy Agency for the developmentally disabled, the New York State Commission on Quality of Care for the Mentally Disabled receives a number of complaints annually from relatives and advocates concerning the use and administration of medications. Other deficiencies in prescribing and administration practices have surfaced from time to time in the Commission's routine reviews of deaths of residents of State institutions for the developmentally disabled.* These allegations, together with the acknowledgment of the New York State OMRDD that no systemic evaluation of institutional psychotherapeutic drug

*The Commission on Quality of Care for the Mentally Disabled was established through State legislation in 1977, to provide independent oversight of the quality of care and treatment in State-operated and -licensed mental hygiene facilities. Among its other statutory functions is the review of the deaths of any patient/client of a State-operated or -licensed mental hygiene facility and the investigation of any death due to unnatural causes or unusual circumstances. In October 1981 the Commission was also designated to serve as New York's federally-designated Protection and Advocacy Agency pursuant to the provisions of The Developmentally Disabled Assistance and Bill of Rights Act of 1975 (Public Law 94-103 amended in 1984, Public Law 98-527).

practices had been conducted, spurred the Commission to conduct a review of medication practices in these institutions.

The review examined the practices of five State institutions (called developmental centers) which serve nearly 4,000 residents. While focusing on the psychotherapeutic medication practices of the centers, the review also targeted the centers' practices in prescribing and monitoring anticonvulsant drugs. These drugs are also frequently administered in the centers and there is consensus on the equal need for stringent clinical monitoring in their use. Other components of the review assessed drug security practices and actual drug administration procedures for residents, especially the oversight of medication errors.

In conducting the review, the Commission relied upon the standards of the New York State OMRDD, as specified in official agency policies and its guidelines for physicians, in prescribing and monitoring psychotherapeutic and anticonvulsant drugs (Manual of Psychotherapeutic and Antiepileptic Drugs, New York State OMRDD, 1978). The Commission consulted with the New York State OMRDD in interpreting specific criteria statements from these policies and guidelines, and the Office reviewed and approved the final criteria statements utilized in the study.

DATA COLLECTION

On-site data collection was conducted during the summer and fall of 1984 at five New York State developmental centers (Bernard Fineson, Brooklyn, Letchworth, West Seneca, and Wilton). During these on-site visits, which usually extended over three-four days, we assessed facility practices regarding:

- o medication prescribing and clinical monitoring practices;
- o medication administration practices; and
- o medication storage and security practices.

These five centers served 3,991 inpatients, or approximately 35 percent of the total inpatient census of New York's 20 developmental centers for persons with developmental disabilities. In addition, these five centers were representative of the then four regional administrative catchment areas of the New York State OMRDD,* with two centers (Bernard Fineson and Brooklyn) representing the large New York City metropolitan area. The centers also included a range of larger, medium-sized, and smaller centers, and

*In April 1984 the New York State OMRDD discontinued its four regional administrative units for State-operated and -licensed programs for persons with developmental disabilities, and initiated a new administrative structure with one Deputy Commissioner for New York City programs and another Deputy Commissioner for upstate programs.

centers which evidenced substantially variable usage rates of psychotherapeutic medications for their residents. (See Table 1.)

At each of the sample centers, 15 residents receiving psychotherapeutic drugs and 15 residents receiving anticonvulsant drugs were randomly selected from lists provided by the New York State OMRDD. Since a number of the residents who were randomly selected were receiving both psychotherapeutic and anticonvulsant drugs, the resulting sample included 106 residents receiving psychotherapeutic drugs and 98 residents receiving anticonvulsant drugs. (See Table 2.)

During the on-site visits to each developmental center, four living units were also randomly selected to review staff practices in administering medications to residents and to assess compliance with New York State OMRDD policies for medication storage and security. The pharmacies at all five centers were also reviewed to assess medication storage and security concerns. In addition to these steps, an interview was conducted with the chief pharmacist to gather further information about drug dispensing, storage, and security.

Resident-specific data pertinent to compliance with OMRDD guidelines and policies for medication prescribing and monitoring practices were obtained through a 12-month retrospective review of each resident's full clinical

TABLE 1. NUMBER OF INPATIENTS AND PERCENT OF INPATIENTS
RECEIVING PSYCHOTHERAPEUTIC MEDICATIONS AT
THE FIVE SAMPLE DEVELOPMENTAL CENTERS

<u>Sample Develop- mental Centers</u>	<u>Location</u>	<u>Inpatient Census (April 1984)</u>	<u>Percent of Inpatients Receiving Psychothera- peutic Medications (April 1984)</u>
Statewide		11,446	34
Bernard Fineson DC	Queens, NY	450	50
Brooklyn DC	Brooklyn, NY	610	16
Letchworth DC	Thiells, NY	1,568	37
West Seneca DC	West Seneca, NY	993	36
Wilton DC	Wilton, NY	370	30

TABLE 2. NUMBER OF SAMPLE RESIDENTS RECEIVING AT LEAST
ONE PSYCHOTHERAPEUTIC AND/OR AT LEAST
ONE ANTICONVULSANT MEDICATION

<u>Sample Develop- mental Centers</u>	<u>Number of Sample Residents Receiving at Least One Psychotherapeutic Medication</u>	<u>Number of Sample Residents Receiving at Least One Anticonvulsant Medication</u>
TOTAL	106	98
Bernard Fineson DC	22	19
Brooklyn DC	19	19
Letchworth DC	21	19
West Seneca DC	23	22
Wilton DC	21	19

record. Since all records were reviewed on site, clinical staff of the centers were consulted when there were questions or when clarification was required. On-site observations of the administering of the medications to residents on the four living units, as well as of medication storage and security on the living units, were made during unannounced unit inspections.

A major off-site data collection step involved the review of all medication error reports for a one-month period from all 20 New York State developmental centers. This aspect of the review sought to describe the incidence and nature of reported medication errors and to assess the centers' compliance with existing policies for the investigation of reported errors and the implementation of appropriate corrective and/or disciplinary action. All centers sent the Commission documentation related to medication errors reported during September 1984, including the minutes of Special Review Committees. These Committees are charged by New York State policy to review these errors.

LIMITATIONS OF THE REVIEW

While this study reflects one of the largest statewide reviews of medication practices in public institutions for persons with developmental disabilities documented in the literature, certain limitations should be acknowledged.

First, the on-site sample of 30 residents from each of the five selected centers represents only a small proportion of the residents in these centers receiving psychotherapeutic and/or anticonvulsant medications. In addition, the review of medication practices for these residents represents an examination of only one component of their overall active treatment/habilitation program at each center. As such, the findings of this review in no way represent a scorecard for each individual facility's performance.

Findings statements which identify facilities are presented for clarity and, particularly, to highlight differences among facilities with regard to particular practices. The study was not designed to rank the facilities in terms of their medication practices and readers should be cautious in attempting to draw such conclusions from the findings presented in the report. At the same time, the random sample of 150 residents from five State developmental centers, serving approximately 35 percent of the total resident population of the State's 20 centers, is deemed reliable for identifying systemic strengths and weaknesses of the system's overall psychotherapeutic and anticonvulsant medication practices.

Secondly, the data collection strategies, with the exception of the on-site observations of the administering of medications and of medication security and storage, relied

primarily on clinical record and other paperwork reviews. As is always the case in "paperwork" reviews, one must be cautious in directly correlating the quality of the paperwork to the quality of actual care and treatment.

Finally, data were collected for this review in the summer and fall of 1984. Following data collection at each sample developmental center, a facility-specific report of the findings was sent to the center's director for comment and a plan of correction. Subsequently, when the data from all sites had been collected and analyzed, Commission staff shared preliminary findings and major areas of concern with senior administrative staff of the New York State Office of Mental Retardation and Developmental Disabilities. This crucial step in the study process allowed discussion between the Commission and the New York State Office of Mental Retardation and Developmental Disabilities to solidify major study conclusions. More importantly, it allowed the New York State Office of Mental Retardation and Developmental Disabilities to begin discussions with its medical deputies at the State developmental centers to encourage needed changes in clinical practices and OMRDD policies. Based on these discussions, as more fully described in Chapter VI, the New York State OMRDD has already initiated many systemic corrective actions targeting concerns raised by the review's findings.

These corrective actions initiated by the sampled centers and the Central Office of the New York State Office of Mental Retardation and Developmental Disabilities are likely to have changed practices since the time of data collection. Thus, the cited deficiencies noted in the report may not still exist or be as widespread.

ORGANIZATION OF THE REPORT

The findings of the study are presented in four chapters. Chapters II, III, and IV provide summaries of the data findings pertaining to the review of 150 sampled resident records. A demographic profile of the resident sample, as well as evaluative comments on the adequacy of annual physical exams and the overall comprehensiveness and orderliness of the resident records are presented in Chapter II. Chapters III and IV present the findings pertinent to the medication prescribing and monitoring practices for psychotherapeutic and anticonvulsant drugs, respectively. The broad issues of safeguarding the administration and security of medications are covered in Chapter V. The study's conclusions and recommendations are presented in Chapter VI.

Appendix A provides definitions of the specific types of psychotherapeutic and anticonvulsant medications referenced in the report. The criteria used for evaluating medication practices at the five centers and the aggregate data scores are presented in Appendix B.

Throughout the course of this review and its planning, the Commission has worked closely with the Office of Mental Retardation and Developmental Disabilities. These cooperative efforts have resulted in many corrective actions by the Office to address significant concerns and deficiencies noted by the Commission. Correspondence from the Office of Mental Retardation and Developmental Disabilities (March 1986 and July 1986) specifying these corrective actions and the Office's formal response to the report's recommendations is included in Appendix C.

CHAPTER II INTRODUCTORY FINDINGS

As a preface to the study's findings regarding psychotherapeutic and anticonvulsant medication practices, it is important to provide a general clinical profile of the sample as well as evaluative comments on the adequacy of annual physical health assessments, and the orderliness and comprehensiveness of record keeping.

The clinical profile is essential for it highlights the physical, medical, and developmental vulnerability of the population studied, and clarifies the need for diligence in supervising all aspects of their care, and particularly the use of medications. It simultaneously reinforces the difficulties of this task for medical and clinical professionals because most of these residents have little ability to articulate their own concerns, needs, or specific symptoms or problems.

Similarly, the physical health assessment is vital to adequate medication practices for this population, whose multiple disabilities often affect both the desired effects and adverse side effects of medications.

Finally, and perhaps most importantly, accurate, comprehensive, and well-organized record keeping is essential to promote continuity of care in a system where the responsibility for care is shared by multiple clinicians. In all

State developmental centers, as in any large health care facility, many clinicians of different specialties are involved in a client's care. In addition, these clinicians work rotating shifts and, unfortunately, turnover rates, especially for physicians, are often quite high. As a result, the record becomes the crucial vehicle for communication among clinicians, continuity of care, and ultimately rational health care and habilitative therapy decision-making for the client over the long term.

DESCRIPTION OF THE SAMPLE

The sample included 80 adult male and 70 adult female residents with a median age of 35. These residents represented a severely mentally disabled and physically frail group of individuals. Eighty-eight (88) percent of the residents were diagnosed as severely or profoundly mentally retarded, and 56 percent were unable to use expressive language. The addition of both acute and chronic physical health problems further compromised the health status of this population. Seventy-three (73) percent of the population suffered at least one serious health condition, and 56 percent suffered from two or more of these conditions. Anemia, pica, ulcers, diabetes, congenital heart disease, spasticity, and circulatory disorders were among the serious health problems common to the sample. Not surprisingly,

given this physical health profile, nearly two-thirds of the residents in the sample were receiving one other prescription drug in addition to psychotherapeutic or anticonvulsant medications. Thirty-two (32) percent were receiving two or more other prescription drugs.

The psychotherapeutic drug regimens of the sample population revealed that 106 of the 150 sample residents were receiving at least one psychotherapeutic drug at the time of the review, and that 18 of these residents were receiving two or more such drugs. Over the 12-month review period, the psychotherapeutic drug regimens of 85 percent of these 106 residents changed at least once, and approximately one-fourth of these residents experienced three or more changes in their medication regimens over the period.

Ninety-eight (98) of the residents were receiving at least one anticonvulsant drug, and 24 were receiving two or more of these drugs at the time of the review. Modifications in anticonvulsant drug regimens occurred in less than one-third of the sample population, and a single medication change, as opposed to multiple changes, accounted for slightly more than half (53 percent) of these regimen changes. Only a small group of sample residents (10), whose seizures were particularly difficult to control, experienced four or more anticonvulsant medication changes during the 12-month period.

PHYSICAL HEALTH ASSESSMENTS

The review revealed that, almost without exception, each resident received an annual physical exam, and in 92 percent of the cases the findings were specified in some detail. Similarly, almost without exception, each case record evidenced implementation of the medical treatment recommendations presented in the annual physical.

Information was also gathered on the number of residents receiving monthly weight and blood pressure checks. Monthly weights were documented for almost 83 percent of the sampled clients. At Brooklyn Developmental Center, however, client weight records were kept in a separate chart on the ward. While ward staff indicated that this procedure eased staff access to weight records, monthly weights should also be documented in a client's individual record, due to the frequency of resident transfers within the facility, to alternate care settings, and to hospitals.

Only 44 percent of the records evidenced monthly blood pressure checks, with rates ranging from 100 percent for sampled residents of West Seneca Developmental Center to 10 percent for Wilton Developmental Center. This finding reflects the absence of a specific OMRDD guideline requiring regular blood pressure monitoring, despite significant

clinical agreement that such checks are an important safeguard for monitoring residents receiving psychotherapeutic and some anticonvulsant drugs.

ORDERLINESS AND COMPREHENSIVENESS OF RECORDS

The review revealed that pertinent medication information was arranged in an orderly and easily accessible fashion in 85 percent of the case records. In these records, medication orders and reviews were relatively easy to locate. Only at one center, Bernard Fineson, and then only at one of the center's three geographically separate units, were resident records, as a general rule, disorganized. Records for residents on this unit evidenced no discernible organizational uniformity, and finding particular information regarding a resident's medications was a difficult and sometimes impossible task for Commission reviewers, as well as unit staff.

The more serious limitations in record keeping, however, related to the comprehensiveness and appropriateness of record notations pertaining to medication decisions. The preponderance of problems clustered around physician documentation as required by the OMRDD guidelines. These deficiencies, which will be discussed in greater detail in the subsequent chapters on psychotherapeutic and anticonvulsant drugs, involved such basic issues as failure

to provide specific diagnoses justifying the drugs prescribed, failure to order and monitor side effects checks, and failure to provide specific justifying rationales for prescribing practices which were contraindicated by the guidelines promulgated by the New York State OMRDD.

Although the review of the 150 resident records surfaced only isolated cases where medication decision-making by the physicians was apparently inappropriate, this absence of physician documentation signaled a grave concern. In some instances, this absence of physician documentation was compensated for by notes by other members of the clinical team which documented the behavioral indications for the medication therapy, side effects checks, and justifications for unusual prescribing practices. Unfortunately, however, this was frequently not the case, and more often, the record charted only medication decisions, but provided little information regarding why specific decisions were made. This deficiency was particularly troublesome since on many wards changes in members of the clinical team were not infrequent, and historical information about prior medication decisions was at high risk of being lost or forgotten.

The limitations in physician documentation also raised concerns, particularly at some centers, of the overall significance of the physician's role in medication decision-making. While the multidisciplinary clinical team model has

recognized benefits, the limited physician notes in some records suggested that physicians served primarily as prescription dispensing agents. Their diagnostic assessment of the resident or even their comprehensive understanding of the specific behaviors/conditions which, in the opinion of other clinical team members, warranted psychotherapeutic or anticonvulsant medication therapy was frequently not apparent.

Most importantly, the limited physician documentation raised questions about their oversight of and attentiveness to possible adverse effects of the drugs. This concern was most evident in physician inattentiveness to ordering and monitoring side effects checks. Documentation of monthly side effects checks was missing in 43 percent of the records.

Documentation justifying physician prescribing practices was also frequently missing, contrary to OMRDD guidelines. While these exceptional prescribing practices were limited to a minority of the residents in the study's sample, physician rationales justifying these practices were absent in nearly half of the instances where they did occur. In a number of these cases, it was not even clear from physician notes that the physician was aware that the prescription reflected a deviation from New York State OMRDD prescribing guidelines.

In over one-fifth of the resident records, some or all prescribed changes in the residents' psychotherapeutic or anticonvulsant drug regimen initiated over the one year period were not accompanied by a justifying physician rationale. Again, while in some of these instances record notes by other clinicians implied the rationale for these changes, in many no specific rationale could be gleaned from the record.

SUMMARY

As reflected in this chapter, the sample population studied represented a very frail, vulnerable population requiring extreme diligence in overall medical care, as well as in the use of psychotherapeutic and anticonvulsant medications. This diligence was generally demonstrated in the comprehensive annual health assessments of the residents, and prompt implementation of medical treatment recommendations emanating from these assessments, as well as the regular monthly weight monitoring of the residents. Monitoring of other vital signs, and especially blood pressure, was, however, done considerably less universally and generally seemed to be an optional practice, determined by ward nursing staff, or as specifically ordered for individual residents by a physician.

The review also revealed that, with the exception of 15 percent of the cases, resident records provided a clear, ordered road map charting specific medication decisions. Unfortunately, however, this road map sometimes left the rationales for key medication decisions uncharted by the physician team member. As a result, many records fell short of fulfilling their purpose of providing a historical record of the factors considered by physicians in making these decisions. This deficiency particularly impacted on the usefulness of the record to different physicians in making subsequent medication decisions for the residents. It also raised questions about the importance ascribed to the physician's role in medication decision-making and, especially, in overseeing the beneficial and possible adverse effects of medication therapies for the residents.



CHAPTER III
PSYCHOTHERAPEUTIC MEDICATION PRACTICES

Of the 150 residents, 106 were receiving at least one psychotherapeutic medication at the time of the Commission's review. These medications are defined in the New York State OMRDD Manual of Psychotherapeutic and Antiepileptic Drugs as including eight general classes or types of medications: neuroleptics, antidepressants, antianxiety agents, cerebral stimulants, somnifacients, antiparkinson agents, antihistamines, and lithium. (See Appendix A for definitions.)

In reviewing the psychotherapeutic medication practices for these 106 residents, New York State OMRDD guidelines for drug prescribing and monitoring practices were used. These guidelines, incorporated in the above manual, were first disseminated to physicians in State developmental centers in 1978. With no significant exceptions, these guidelines, composed by a committee of expert clinicians convened by the New York State OMRDD, mirror accepted clinical opinion regarding psychotherapeutic medication use as reflected in the current literature. While addressing the clinical issues of polypharmacy, drug dosages, clinical monitoring, side effects checks, and drug free trials, as well as other protocols to avoid the unwarranted long term administration of these drugs, the guidelines do not prohibit clinically

justified exceptional practices. The manual does, however, clearly articulate the expectation that physicians should document specific, explanatory rationales for any prescribing practices which deviate from the guidelines.

The findings of the Commission's assessment are presented in three subsections:

- o Compliance with the Cautious and Limited Use of Psychotherapeutic Medications;
- o Compliance with Specific Prescribing Guidelines; and
- o Compliance with Clinical Monitoring Guidelines.

COMPLIANCE WITH THE CAUTIOUS AND LIMITED USE OF PSYCHOTHERAPEUTIC MEDICATIONS

The OMRDD Manual of Psychotherapeutic and Antiepileptic Drugs cautions physicians treating developmentally disabled persons that mental retardation, per se, is not an indication for the use of psychotherapeutic drugs, and advises them to prescribe these drugs only for diagnosed conditions such as acute psychosis, affective disorders, hyperkinesis, and severe destructive behavior. Recognizing both the potential of these drugs to adversely affect the cognitive functioning of residents and their potential for misuse as agents of chemical restraint, the guidelines advise physicians to consider the drugs' possible adverse effects in the develop-

mentally disabled person. The guidelines also prohibit the use of these drugs as substitutes for programming in the treatment of residents with behavior disorders.

Against this backdrop, it is significant that the Commission's review of 106 records revealed that in 90 percent of the sampled cases, behavioral disorders treated with psychotherapeutic medications were also addressed through specific program initiatives. Indeed, for all sampled residents at Wilton, Bernard Fineson, and West Seneca, a two-pronged attack on behavioral disorders was utilized. Brooklyn Developmental Center provided programming interventions in addition to medication for 17 of its 19 sample residents.

Only at one center, Letchworth Developmental Center, was this critical underpinning of the cautious use of psychotherapeutic medications not assured for many of the sampled residents. At this center, 9 of the 21 sampled residents treated with psychotherapeutic drugs were not currently enrolled in a behavioral program and, therefore, did not benefit from an integrative approach of programming and medication therapy to address their behavioral needs. Significantly, in none of these residents' case records was a clinical justification for the absence of a behavioral program present.

In addition to requiring the concomitant use of behavioral interventions when medications are used in the treatment of behavioral disorders, the OMRDD guidelines also require that, prior to the initiation of psychotherapeutic drug therapy, clinicians first try to treat the disorder with programmatic interventions alone. Systemwide compliance with this guideline averaged 80 percent, with 30 of the 37 cases where psychotherapeutic drugs were introduced during the review period revealing an attempt to manage behavioral disorders initially through a behavior modification program. Notably, there were vast differences among centers in their compliance with this guideline. Wilton Developmental Center showed 100 percent compliance, while Letchworth Village was compliant in only 25 percent of its cases, reflecting the general weakness of the center, as noted above, to provide integrated treatment for residents with behavior disorders.

OMRDD guidelines also require fully documented physician rationales, including a specific diagnosis and description of the behavioral disorder, for the initial prescription of psychotherapeutic medications. Compliance with this guideline was generally poor. Among the 37 sampled residents for whom psychotherapeutic drug therapy was initiated during the review period, physician rationales did not meet the standards in these guidelines for nearly half of the residents. Deficiencies usually included the failure to provide a

psychiatric diagnosis or even a specific description of the resident's behavior warranting the prescription of the drug. This deficiency also extended to the use of lithium carbonate, the drug of choice in the treatment of manic-depressive syndrome and sometimes also useful in reducing severely aggressive behavior. While the low incidence of the use of the drug (seven cases across all five centers) reflected a cautious approach to its use, the absence of an appropriate diagnosis in three of these cases was a signal for concern.

Compliance with guidelines designed to protect residents against the unwarranted long-term use of psychotherapeutic medications was also inconsistent. Whereas all centers demonstrated compliance with the requirement to rewrite medication orders monthly, compliance with the other guidelines designed to discourage the unwarranted long term use of these drugs was poor. Of the 106 case records where the resident was receiving psychotherapeutic medications, only nine contained documentation of a drug-free holiday during the 12-month study period, or a physician rationale justifying the decision not to provide a drug holiday for the resident. In two facilities, Wilton and Bernard Fineson, no sampled records reflected drug-free periods or rationales indicating their appropriateness. Drug-free periods were also not documented in any of the sampled case records at

Brooklyn Developmental Center, although facility staff did present record documentation that drug holidays had been used for other center residents during the one year review period. Letchworth Village offered only 2 of its 21 sampled residents receiving psychotherapeutic medications a drug holiday. The only center which granted drug holidays to a significant number of its sampled residents was West Seneca, where 7 of the 23 residents on psychotherapeutic drugs had had a drug holiday in the past year.

Compliance with guidelines designed to avoid the long term use of antiparkinson drugs and antianxiety agents (Valium and Librium), both of which may have serious adverse side effects when administered for extended periods of time, was also poor. Whereas both drug classes were relatively rarely administered over long periods of time, in these few instances physicians rarely complied with OMRDD protocols. Specifically, antiparkinson agents (Cogentin and Artane) were administered long term to four sample residents. In three of these four cases physicians failed to follow OMRDD's guidelines requiring that antiparkinson agents be employed only as a last resort when the neuroleptic drug cannot be discontinued, changed, or the dosage reduced. In no case was the drug stopped after 90 days, as required by the guidelines, and reinstated only if symptoms recurred and the dosage of the neuroleptic could not be reduced.

Similarly, antianxiety agents were administered to only 13 of the sampled residents for extended periods. However, in none of these instances did notes provide a specific diagnosis and/or a rationale explaining their exceptional use for the extended period. Although at least one instance of the unjustified long term use of antianxiety agents was noted at all five of the centers reviewed, it was most common at Wilton and Brooklyn Developmental Centers where noncompliance was noted for 6 of the 10 and 2 of the 4 residents receiving these drugs, respectively.

COMPLIANCE WITH SPECIFIC PRESCRIBING GUIDELINES

The New York State OMRDD guidelines also regulate prescribing practices in addressing the issues of polypharmacy, drug dosages, and form, frequency and route of drug administration. These prescribing guidelines are not presented as "absolutes" and exceptional practices are permitted, and indeed expected for certain residents as dictated by their clinical needs. Consistent with the overall thesis of the OMRDD medication guidelines, however, physicians are expected to provide justifying rationales for these clinical exceptions.

The review indicated that OMRDD's prescribing guidelines for psychotherapeutic medications, with one exception, were generally respected by the centers' physicians. Simultan-

ously, however, in the relatively few instances where exceptional practices were noted, there was often no physician documentation indicating the reasons behind the unusual prescribing decision or that the possible adverse effects of the medications as prescribed were recognized and being carefully monitored.

Evidence that the physicians as a general rule honored the prescribing guidelines, however, predominated. This compliance was especially evident in physicians' choice of drugs and in their decisions related to appropriate drug preparations and drug dosages. With regard to drug choice, for example, the guideline recommending initial use of only established and well tested drugs listed in OMRDD's drug formulary and the guidelines advising against the use of combined preparations of drugs and sustained release drug preparations, which are generally considered to be less clinically beneficial for developmentally disabled residents, were nearly universally followed. Similarly, there were only four instances where psychotherapeutic drug dosages exceeded the New York State OMRDD guidelines. Use of more than one psychotherapeutic drug to treat a single behavioral disorder or polypharmacy was relatively infrequent and occurred in the medication regimens of only 18 of the 106 sample residents receiving these medications. Compliance with guidelines designed to limit the use of certain non-psychotic

agents, such as antihistamines, cerebral stimulants, lithium carbonate, antiparkinson agents and somnifacients to specific well-defined conditions, was also evident in the low incidence of their use across the five centers.

Notably, however, in those cases where exceptional prescribing practices related to some of these guidelines were observed, it was unusual to find physician justifications for the practice. For example, in 7 of the 18 instances where polypharmacy was noted, and in all 7 instances where sustained release preparations or combination drug preparations were used, no accompanying physician rationale was present. Similarly, physicians did not provide rationales for any of the three residents to whom drugs not listed on the New York State OMRDD formulary were prescribed.

These findings indicate that, while physician prescribing practices are largely consistent with OMRDD guidelines, exceptional prescribing practices are not accorded the careful clinical scrutiny advised by the guidelines. Indeed, in most cases where physician rationales were missing, it was unclear whether the physician was aware that he/she was deviating from the guideline. It was also apparent that there was very limited internal facility oversight to routinely review and evaluate these exceptional practices.

Other New York State OMRDD prescribing guidelines express preference for the oral route of medication administration, the use of tablet versus liquid forms of medications, and the administration of psychotherapeutic medications only once or twice a day. These guidelines are justified both because of their clinical benefits for clients and their benefits in saving staff time and in reducing the possibility of medication errors. When they were introduced in 1978, these guidelines represented perhaps the most widespread change in physician prescribing practices as they had previously existed in State developmental centers.

As such, it was noteworthy that the record reviews evidenced only one instance where psychotherapeutic drugs were administered intramuscularly in a non-emergency situation, and only six instances where these drugs were administered in liquid form, with no record documentation that the residents' clinical needs (i.e., difficulty in swallowing; sequestering medications) warranted the avoidance of tablet medications. Compliance with the guideline advising that psychotherapeutic drugs be administered only once or twice a day was, however, less universal. Among the 106 residents, 35 residents were receiving these drugs more frequently than twice a day and accompanying physician rationales for the more frequent administration were present

for only five of these residents. In fact, none of the relevant case records from Brooklyn and Letchworth Developmental Centers contained a physician rationale for the more frequent administration of these drugs. Based on the findings, it appeared that many physicians were either not aware of, or did not agree with, OMRDD's position that less frequent psychotherapeutic drug administration is advisable.

COMPLIANCE WITH CLINICAL MONITORING GUIDELINES

The Commission's review included several indices for assessing attentiveness to clinical monitoring for the residents receiving psychotherapeutic medications: blood work prior to the initiation of the drug therapy, drug trials, formal medication reviews, and monitoring the drugs' effects, both intended and unintended. All these indices are directly referenced either in the New York State OMRDD Manual of Psychotherapeutic and Antiepileptic Drugs or in New York State OMRDD official policies for medication monitoring.

Three of the centers (Letchworth Village, Bernard Fineson, and West Seneca) provided a complete blood work-up to investigate a resident's metabolic status prior to the initiation of psychotherapeutic drug therapy for all residents sampled. Brooklyn was least successful in this regard, performing blood studies for only two of the seven residents for whom psychotherapeutic drug therapy was

initiated during the review period. Wilton conducted blood studies for 60 percent of its residents who initiated drug therapy during the period.

Letchworth Village, Bernard Fineson, and West Seneca also offered drug trial periods lengthy enough to build serum levels in the therapeutic range for almost all residents sampled. Brooklyn and Wilton were less consistently compliant with this guideline, providing a three-week trial period to test the efficacy of a psychotherapeutic drug regimen for two of the five, and three of the five relevant cases, respectively. (Significantly, in all noted cases where drug regimens were changed prior to a three-week trial, physician justifying rationales were not present.)

The vast majority of the sampled case records (81 percent) also included documentation of monthly medication reviews. Only at one center, Wilton, was such formal documentation of medication reviews not typically available (absent in 43 percent of the relevant cases), but even at this center, progress notes indicated unit staff regular attention to the residents' medication regimen. In most cases, documented reviews also indicated a physician reevaluation of the drug regimen, but, contrary to OMRDD guidelines, they frequently failed to refer specifically to the medication's effects on the residents' daily functioning,

especially in scheduled program activities. Forty-four (44) of the 106 records (59 percent) did not provide such clarification of the drugs' effects. Such specific commentary was absent from the majority of the relevant case records at two centers, Wilton (58 percent) and Letchworth Village (53 percent).

Physicians, as a general rule, also documented rationales for changes in residents' psychotherapeutic drug regimens, although this was not always the case. Changes in the type of psychotherapeutic drug prescribed were accompanied by physician rationales for 22 of the 28 relevant residents, and dosage changes in psychotherapeutic drugs were justified by physician documentation for 48 of the 57 relevant residents.

The most serious deficiency in clinical monitoring practices was the lack of documentation of the routine monitoring of residents for adverse side effects from their psychotherapeutic medications. Of the 106 residents receiving these drugs, quarterly side effects checks were not documented in 45 cases (43 percent). At Letchworth, such checks were not documented for 86 percent of the relevant cases; at Wilton, they were not documented for 67 percent of the relevant cases; and at Brooklyn, they were not documented for 34 percent of the relevant cases. In contrast, such

checks appeared to be standard on most living units at West Seneca, where they were documented in 78 percent of the relevant cases, and on all living units at Bernard Fineson, where they were documented in 90 percent of the relevant cases.

The importance of quarterly side effects monitoring for individuals receiving psychotherapeutic drugs is emphasized in OMRDD guidelines, and also reinforced in almost all clinical literature related to the use of these drugs. The literature cites the high incidence of adverse side effects with these drugs, especially with medically frail and developmentally disabled persons. Commonly observed side effects include lethargy, weakness and muscle fatigue, motor restlessness, inappropriate muscle toxicity, and tardive dyskinesia, a serious and persistent disorder involving involuntary movements of the face, mouth, jaw, and tongue, which often cannot be reversed even by the cessation of the drug.

Given this strong clinical concurrence on both the potential for and the seriousness of side effects from these drugs, the absence of documentation of routine side effects checks by a nurse or a physician in so many of the residents' records is a serious concern. The findings suggest that the clinical importance of side effects checks is not universally recognized by physicians in State developmental centers. The

findings also indicate that there was no uniform accountability at any of the centers to reinforce the importance of this practice and the necessity for its careful documentation in residents' records. At three of the five centers, physicians routinely did not order side effects checks or ensure that they were carried out by checking record notes, yet there was no evidence that this omission was criticized or even identified by facility clinical supervisors. While failure to routinely carry out side effects checks was less common at the two other centers, there was also no indication that center oversight practices were in place to identify these exceptions and ensure corrective action.

SUMMARY

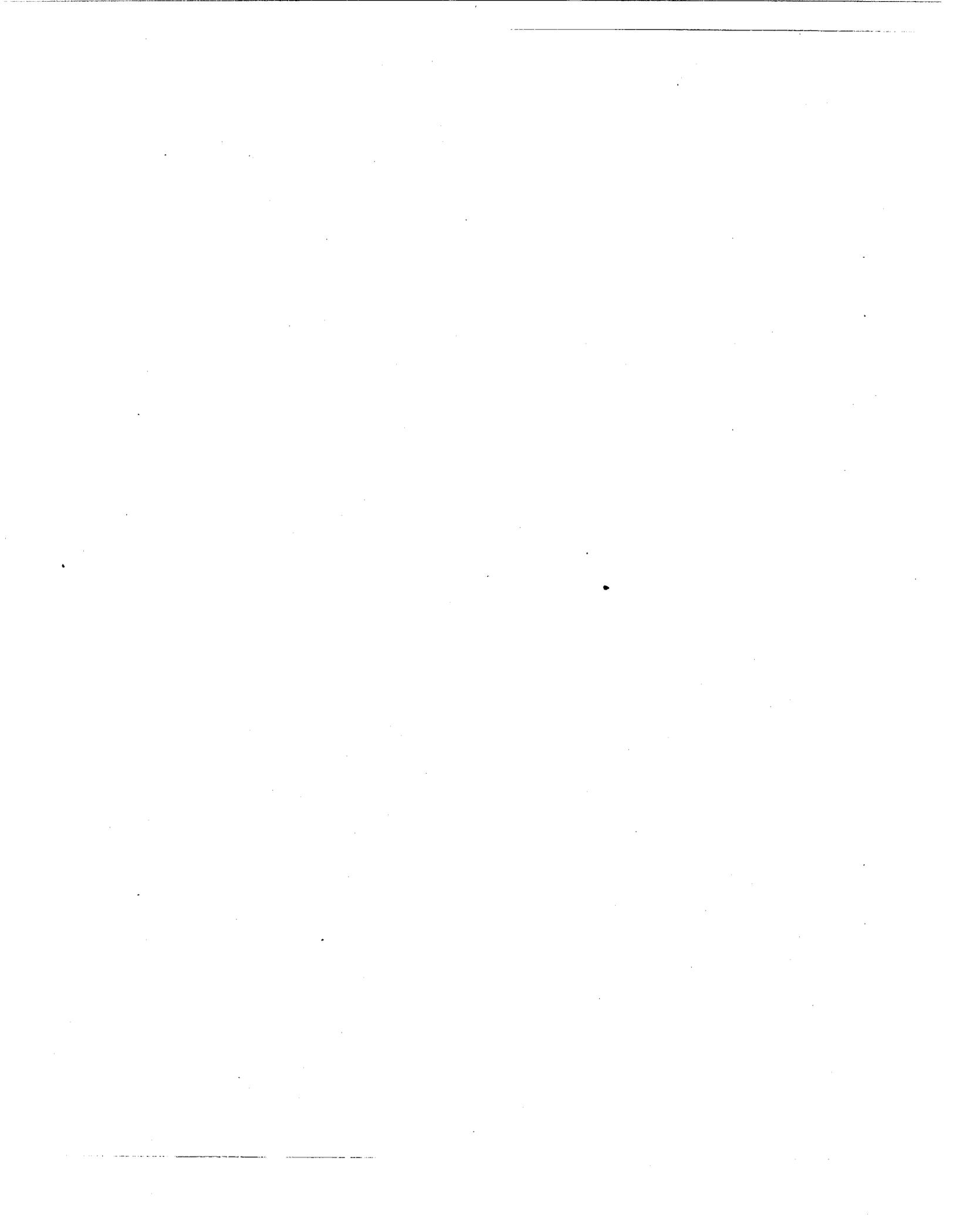
The findings of the Commission's review of psychotherapeutic medication practices across the five developmental centers indicated several significant areas of strong compliance with New York State OMRDD guidelines designed to ensure their safe and appropriate use. Of major significance was the nearly universal attention, exhibited by all but one of the centers, to prescribe psychotherapeutic drugs only when behavioral programming alone proved ineffective and, then, to rely on psychotherapeutic drug therapy only as an adjunct, not a substitute, for behavioral management therapies. Also important was the strong compliance of most

centers' physicians with OMRDD's specific prescribing guidelines for these drugs, and particularly to those guidelines most directly related to promoting their intended clinical benefits and the avoidance of adverse side effects. Finally, the documentation of regular medication reviews for over 80 percent of the sampled residents receiving psychotherapeutic drugs was an indication that the use of these drugs was routinely reviewed by the clinical team.

The review also indicated, however, that the full intent of certain guidelines was not always assured in practice and that some stated guidelines were routinely ignored by physicians. Specifically, physician documentation justifying the initiation of a psychotherapeutic drug therapy was frequently missing from the record and in a smaller, but still significant number of cases, physician justifications for psychotherapeutic drug changes or unusual prescribing practices were lacking. The lack of documentation in medication reviews indicating the integrative assessment of behavioral programs and medication regimens in effecting desired behavioral change was also a signal for concern. These deficiencies were compounded by widespread physician failure at most of the five centers to ensure residents drug-free trials, an important safeguard against the unwarranted long-term use of the medications. Finally, and perhaps most importantly, documentation that residents were

regularly examined for adverse side effects was lacking in more than 40 percent of the sampled records.

Although the reasons behind this paradoxical compliance picture were not fully explored in the review, some appeared fairly evident. It appeared that physicians generally complied with prescribing practices well documented in the literature and, generally, espoused in medical school training. Compliance with other guidelines, specifically tailored by the NYS OMRDD to ensure needed safeguards in long term congregate health care settings for the developmentally disabled, however, was considerably less consistent. Indeed, physician knowledge and training in this area appeared limited in most centers. Copies of the OMRDD Manual of Psychotherapeutic and Antiepileptic Drugs were not available at many of the centers, and many ward clinicians acknowledged never having read the manual. Compounding this problem was the apparent weakness of administrative clinical oversight of medication practices at the centers. Random sample checks of records to note compliance with OMRDD guidelines were not a regular practice at any of the centers. In addition, facility Drug Monitoring Committees typically did not exercise diligent oversight for unusual prescribing practices or for reinforcing the NYS OMRDD clinical monitoring guidelines for psychotherapeutic drugs. As a result, physician non-compliance with specific guidelines often went undetected and uncorrected.



CHAPTER IV ANTICONVULSANT MEDICATION PRACTICES

Among the 150 sample residents, 98 were receiving anticonvulsant medications. Of these residents, 52, or slightly more than half, had been seizure-free during the one year review period, whereas three residents had experienced an episode of status epilepticus during the period. The remaining residents had had at least one documented seizure during the study period, but their seizures most often were controlled with medications.

Like the Commission's assessment of psychotherapeutic medication practices, the assessment of anticonvulsant medication practices was based on the guidelines contained in New York State OMRDD's Manual of Psychotherapeutic and Antiepileptic Drugs. These guidelines pertaining to antiepileptic, or anticonvulsant drugs, as these drugs are more commonly referred, advise cautious use of the drugs, relate basic prescribing guidelines, and specify certain clinical monitoring practices for all residents receiving these medications. These guidelines are also supplemented by certain sections of the New York State OMRDD policy manual which reinforce and clarify the requirements for certain monitoring practices, especially the conduct of regular medication reviews and maintenance of resident seizure records.

The findings of this aspect of the review are presented in three subsections:

- o Compliance with the Cautious Use of Anticonvulsant Medications;
- o Compliance with Specific Prescribing Guidelines; and
- o Compliance with Clinical Monitoring Guidelines.

COMPLIANCE WITH THE CAUTIOUS USE OF
ANTICONVULSANT MEDICATIONS

OMRDD guidelines state that prescriptions for anti-convulsant medications should be accompanied by "as clear a definition of the seizure disorder, as possible, as well as a comprehensive seizure diagnosis." The New York State OMRDD guidelines also indicate that an electroencephalogram (EEG) "should be done to support clinical impressions" and that EEGs are "frequently useful in establishing a diagnosis."

Against this framework, it was significant that for nearly one-fourth of the residents receiving anticonvulsant drugs, a physician rationale, including a specific seizure diagnosis, was not present in the residents' annual assessments, or other physician notes for the 12-month review period. In addition, record notes for the 46 sampled residents who had had a seizure in the past year often failed to describe the residents' behavior prior to and during seizures. Vital information describing the characteristics

of the residents' seizures, possible triggering events, the duration of seizures, and the residents' behavior after the seizure was also usually absent.

Based on the sample cases, it also appeared that EEGs were rarely performed to support and/or clarify clinical impressions of the residents' seizure conditions or diagnosis. Only 13 percent of the 98 residents receiving anticonvulsant medications had had an EEG within the past year and, more importantly, only slightly more than one-fourth (28 percent) of the residents who had had a seizure in the past year had had an EEG during that period. In part, these findings reflect clinical debate over the usefulness of EEGs. They also derive from the vagueness of OMRDD's guidelines in identifying the specific circumstances where EEGs are strongly recommended. As noted above, the OMRDD guidelines state, in one section, EEGs "should be done to support clinical impressions" and, in another, that EEGs "are frequently useful in establishing a diagnosis." It appeared that most physicians interpreted these guidelines liberally, and ordered EEGs infrequently even for residents who had periodic seizures.

In sum, physician documentation justifying the administration of anticonvulsant medications to many of the sample residents did not meet the standards set forth in the OMRDD manual. Not only were specific seizure diagnoses often

not documented, or sustained by recent EEGs, but more importantly, descriptions of residents' recent seizures were frequently vague and lacking in important aspects. As a result, the clinical record was of little assistance in guiding future anticonvulsant medication decisions, including evaluating the relative risks of drug-free trials for residents who had been seizure free for many years.

The decision to reduce and/or gradually attempt drug-free trials for these residents requires individual resident assessments and extremely careful clinical monitoring and, under any circumstances, cannot be deemed risk-free. At the same time, the decision to maintain these residents long-term on anticonvulsant therapy, which itself has certain known side effects, is also not without risks.* Notably, none of the 98 sampled residents had been afforded a drug-free trial in the one year review period. More critically, only a minority of the clinical records contained sufficient

* The Physicians' Desk Reference documents many side effects of anticonvulsants including reversible lymph node hyperplasia and other hematopoietic complications, osteomalacia, hyperglycemia, dizziness, motor twitching, and headaches. A serious adverse side effect of many of these drugs is gingival hyperplasia which results in an irritation of the gums causing them to swell and retract and which can lead to bleeding of the gums, tooth loss, and severe pain.

information to assist physicians in evaluating the relative risks of continuing or gradually reducing and stopping drug therapy for a trial period.

COMPLIANCE WITH PRESCRIBING GUIDELINES

In accordance with accepted clinical opinion that anticonvulsant drug choice and dosage are largely predicated on the clinical response of the individual to anticonvulsant therapy, as well as the unique characteristics of each resident's seizure activity, the New York State OMRDD's prescribing guidelines for anticonvulsant medications are limited to comments on the administration of multiple anticonvulsant drugs, broad acceptable dosage ranges, and recommended procedures to be followed when altering a resident's anticonvulsant drug regimen. The guidelines also recommend careful monitoring of anticonvulsant drug therapy for those residents who are also receiving certain types of psychotherapeutic drugs, which are known to lower an individual's seizure threshold. As noted below, assessment of the 98 resident records evidenced substantial compliance with the specific prescribing guidelines regarding drug choice, but considerably less universal compliance with physician rationales for specific prescribing decisions.

Specifically, in three of the four cases where anticonvulsant drug therapy was initiated during the review period, therapy began with a single medication, and in 21 of

the 24 cases where residents were receiving multiple anticonvulsant drugs, the drugs were chosen from different drug classes. The review also evidenced only a single instance where a combination preparation of anticonvulsant drugs was prescribed and only a single instance where an anticonvulsant medication not on the official OMRDD formulary was prescribed.

Physician compliance with minimum and maximum drug dosages was also generally found, although scattered exceptions were noted at all but one center (Wilton). Across all centers, 11 of the 98 residents were prescribed anticonvulsant medications at dosages below the established therapeutic range, while 8 residents were prescribed dosages above the established therapeutic range. Physicians were also generally cautious in slowly adjusting the drug dosage to preclude rapid changes in blood serum levels which could threaten a resident's seizure control.

Physician compliance in documenting prescribing decisions for anticonvulsant medications was, however, less consistent. In all of the above instances regarding drug dosages outside the OMRDD guidelines, for example, physician rationales for the unusual decisions were not documented. Physician rationales for changes in anticonvulsant medication regimens were also missing for 14 of 45 cases.

Physician documentation for those residents receiving both anticonvulsant and neuroleptic and/or antidepressant medications was also inadequate in most cases. The New York State OMRDD guidelines indicate that extra caution should be exercised by physicians in these cases. A special justifying rationale for the concomitant drug use is required and extra drug monitoring is advised to protect residents from the possible adverse effect of psychotherapeutics in lowering residents' seizure thresholds. For 18 of the 29 residents receiving both types of drugs, physician documentation failed to meet either of these criteria.

COMPLIANCE WITH CLINICAL MONITORING GUIDELINES

Wide variability in compliance with anticonvulsant clinical monitoring guidelines characterized the study sample. These guidelines require a quarterly review of a resident's anticonvulsant drug regimen, with particular note of the degree of seizure control and of the presence of side effects. Maintenance of an on-going seizure record for each resident receiving anticonvulsant medications is also required. Additionally, periodic monitoring of serum anti-convulsant levels is also recommended, and serum level testing is required when medications are changed, when seizure activity becomes uncontrolled, or when symptoms of toxicity or other adverse side effects are noted.

Across the five sampled facilities, compliance with the guidelines requiring comprehensive anticonvulsant medication reviews was 64 percent. Equally significant, however, was the wide range of scores. Letchworth Village and Wilton Developmental Centers were in compliance in 36 percent and 31 percent of their case records, respectively, whereas at Bernard Fineson, the quarterly review was present in 18 of the 19 sampled case records, representing 94 percent compliance.

Further compromising the value of those medication reviews conducted was the lack of an on-going record of seizure activity in many of the sample case records. These records were not maintained for approximately one-fourth of the sampled residents and, at two centers, Brooklyn and Bernard Fineson, they were not available for more than 60 percent of these residents. Only one center, West Seneca, ensured up-to-date seizure records for all its sampled residents. More importantly, even the maintained seizure records often lacked valuable information related to the seizure itself, clinical impressions as to its cause, and staff descriptions of the duration of the seizure. As a result, these records often did not fulfill their purpose of providing a comprehensive and descriptive record of seizure activity which might be useful in future medical/medication decision-making for the resident.

There was a similarly widespread lack of compliance with guidelines requiring documented checks of side effects from anticonvulsant drug therapy. Overall, side effects checks were not documented in 36 percent of the sampled cases. Documentation of such checks was especially poor at Wilton and Letchworth Village Developmental Centers. At both centers routine side effects checks were not documented in more than 60 percent of the relevant case records. In contrast, at Bernard Fineson, side effects checks for residents receiving anticonvulsant drugs appeared routine and were present in all but one of the sampled residents' records. (As the reader will recall, this center also stood out in its documented monitoring efforts regarding side effects from psychotherapeutic drugs.)

Monitoring anticonvulsant serum levels provides another important clinical safeguard for residents with seizure disorders. By monitoring anticonvulsant serum levels, physicians can more reliably measure the residents' individual effective dosage rate. Serum levels can also be helpful in safeguarding against toxic and/or non-therapeutic dosage levels for residents who may metabolize anticonvulsant drugs more or less rapidly than established norms.

Guidelines require that serum levels be done whenever anticonvulsant medication regimens are changed or symptoms of toxicity appear. They also recommend routine periodic serum

levels to monitor drug dosages. Facilities varied widely in their compliance with these guidelines. Whereas required blood levels were conducted in 66 percent of the relevant cases across the five sample sites, West Seneca's case records revealed that required blood serum levels were done in 84 percent of the relevant cases, while Bernard Fineson was in compliance in only 28 percent of the relevant case records. Among the sample cases from Wilton, Brooklyn and Letchworth Village Developmental Centers, compliance ratings ranged from 57 to 75 percent. Conduct of periodic serum levels was less routine, especially for residents who had been seizure free. Most facilities' clinicians viewed such routine testing for these residents as a waste of resources. This view is generally supported by clinical experts, although many support annual serum testing to prevent seizures due to changes in metabolism resulting from aging, illness, change in activity, etc.

SUMMARY

The review of anticonvulsant medication practices across the five centers indicated more variability and less consistent compliance with New York State OMRDD's guidelines than was evident in the centers' psychotherapeutic medication practices. The review indicated generally strong compliance

with OMRDD guidelines pertaining to multiple drug therapy, drug dosages, and drug choice, but significant non-compliance with other important clinical practices.

Heading the list of problems was the lack of physician documentation of specific seizure diagnoses or even comprehensive descriptions of the residents' seizures in many records. In addition, up-to-date seizure records were missing for over one-fourth of the sampled residents and, even when available, these records were usually only date/time logs and provided little information about the duration of the seizure, its effect on the resident, or its surrounding circumstances.

Physician documentation was also lacking in other areas. Physician rationales for changes in anticonvulsant medications and exceptional prescribing practices were missing in a significant minority of the relevant case records. Further concerns included the variable clinical monitoring practices for residents receiving anticonvulsant drugs. Other anticonvulsant medication reviews and side effects checks were not conducted for over one-third of the sample residents receiving these drugs. In addition, it appeared physicians made limited use of EEGs to clarify seizure diagnoses or serum levels to regulate and periodically monitor drug dosages.

Several facilities reported that one factor behind the noted problems was that available neurologist or neurological consultant services were insufficient for the many residents receiving anticonvulsant medications. There also seemed to be considerable debate as well as limited awareness among the facilities' physicians regarding New York State OMRDD guidelines for anticonvulsant medications. Even the necessity for such basics as documentation of specific seizure diagnoses, clear and comprehensive clinical descriptions of a resident's past seizures in the records, and regular medication reviews and side effects checks seemed to be unrecognized by many physicians. Physician awareness of other clinical monitoring practices, subject to more debate in the clinical literature, including routine neurological exams, blood serum levels, and EEG testing, were even less evident. When combined with the limited availability of board-certified neurologists, this lack of clinical consensus seemed to lead to variable and, in some cases, weak clinical practices and monitoring for residents receiving anticonvulsant medications.

CHAPTER V
MEDICATION ADMINISTRATION
AND SECURITY

The Commission's review of medication practices also sought to evaluate facility procedures related to the secure storage of medications and their safe, hygienic, and humane administration to residents. Facility practices related to medication security were assessed through inspections of the centers' pharmacies, as well as medication storage areas on four randomly selected wards. Actual on-unit medication administration to residents was also observed on the four randomly selected wards during unannounced visits. In addition, a one-month sample of medication error incident reports was reviewed from all 20 of the State's developmental centers. While this review focused on evaluating the facilities' handling and review of these errors, it also sought empirical data regarding the number and nature of reported errors.

The findings of these aspects of the review are presented in four subsections:

- o Medication Security on Resident Living Units;
- o Pharmacy Security;
- o On-Unit Medication Administration Practices; and
- o Oversight and Follow-up on Medication Errors.

MEDICATION SECURITY ON RESIDENT
LIVING UNITS

The review of security measures for medication storage and administration on the living units at the five centers revealed substantial compliance with OMRDD policies and procedures. Indeed, one center, Wilton Developmental Center, was in total compliance with all review criteria. Many examples of strong compliance were also noted across centers. For example, on all wards visited, poisons were stored separately from drugs, and all drugs used externally were stored separately from drugs used internally. Drugs requiring refrigeration were clearly labeled and kept in a separate refrigerator compartment from non-medicine items. Security for controlled substances and for syringes and needles was equally tight. On all sample wards, the nurse counted all controlled substances at the beginning and end of all shifts and recorded the counts on the required OMRDD form (Form 209 MED). On all sample wards, syringes and needles were also stored in a locked stationary cabinet, and daily counts of syringes were documented.

The medication areas of 19 of the 20 wards at the five facilities were observed to be clean and properly lit and, on all wards visited, all drugs were stored in containers labeled and filled by the pharmacy. In addition, the review revealed no instances of medications with worn, illegible,

incomplete, or missing labels. Finally, on 18 of the 20 wards visited, keys to the medication rooms were kept on the person authorized to control the medication station.

Exceptions to this practice included one living unit at Letchworth where keys were sometimes placed in a drawer in the medication room, and one ward at West Seneca, where keys were observed lying on a counter.

Only at one center, Brooklyn, were significant deficiencies in living unit drug security noted and, even here, there were only isolated areas of concern. For example, on one ward, Commission staff observed the preparation of an open medication cart three hours in advance of administration time. This fully stocked cart was also stored in an unlocked office seriously compromising the security of the prepared drugs, as well as resident safety. The Commission also questioned the common practice at this center in using open medication carts which have no sides or guardrails, and offered no protection against the spilling of medication cups should the cart be jostled.

PHARMACY SECURITY

The main pharmacy at each of the five centers was visited to ascertain compliance with OMRDD policies for drug security/storage. Again, substantial compliance characterized each of the centers. All pharmacies were

locked at the time of the Commission's unannounced visit, and could be unlocked only with the pharmacy keys, rather than the grand master keys. Only at Wilton Developmental Center, however, were pharmacy keys stamped "Do Not Duplicate," as required by OMRDD policy. With the exception of the Glen Oaks site of Bernard Fineson Developmental Center, pharmacists also completed and documented their monthly inspections of ward medication stations and controlled substance substations, as required by OMRDD policies.

OMRDD policies also require oversight of pharmacists, through mandated monitoring responsibilities assigned to the Business Officer and the Deputy Director for Administration (DDIA) of the center. Spot-checks by the Business Officer to verify shelf count with inventory figures were conducted at least monthly at four of the five centers. At Brooklyn Developmental Center, these spot-checks were conducted, but only quarterly, contrary to OMRDD policy. Compliance in ensuring quarterly inspections of pharmacy security precautions by the DDIA was less consistent among the centers, and occurred regularly at only two of the five centers (Letchworth and Wilton). At the three other centers (Brooklyn, Bernard Fineson, and West Seneca), there was no evidence that the DDIA regularly conducted these inspections.

ON-UNIT MEDICATION ADMINISTRATION

Across the 20 living units visited, most residents received their medications in a safe, hygienic, and humane fashion. At all five centers, only staff authorized to administer medication (physicians, nurses, and trained mental hygiene therapy aides) were doing so.* Medications were also always poured/prepared by the person administering them, except in those centers using the unit dose drug dispensing system, where these tasks are appropriately done by the pharmacist. Most residents also received their medications by personnel following standard medication administration practices. Staff were following procedures to ensure that the "Rule of Six Rights"--right patient, right drug, right dosage, right form, right route, and right time--was observed.

Commission staff also observed, however, a number of isolated practices which compromised the hygienic and humane administration of medications. Generally accepted medication administration practices concerning cleanliness were violated at West Seneca, Letchworth Village, and Bernard Fineson. At these three facilities, personnel were observed administering

*New York State law provides that non-nursing personnel may administer medications in State-operated mental hygiene facilities, if they have completed a required training program and passed a certification examination.

medications without washing their hands between dispensing medicine to residents. At Bernard Fineson and Letchworth Village Developmental Centers, Commission staff also observed the routine practice of using tongue blades inserted far into residents' mouths to administer medications.

At three centers (Bernard Fineson, Letchworth and Brooklyn), it was also routine practice for staff to crush tablets before administering them to some residents. This practice, absent a resident-specific physician rationale, is forbidden in OMRDD's medication policies because the crushing of certain tablets can interfere with their proper digestive absorption. Further compounding this deficiency was the unsafe practice, noted at Bernard Fineson and Letchworth Village Developmental Centers, of using the same mortar and pestle for crushing different medications for multiple residents without cleaning these implements between medications. We were also concerned about the dental hygiene implications of Brooklyn Developmental Center's standard practice of administering crushed medications in gobs of jelly or apple butter, which could promote tooth decay. While ward staff indicated that this practice was instituted to ease medication administration, the use of unsweetened applesauce or other pureed unsweetened fruits, employed by other facilities, seemed equally effective and yet did not contribute to tooth decay.

Most disturbing, however, were the practices observed on selected wards of three of the five centers which violated residents' privacy and their humane treatment. For example, on wards of two centers (West Seneca and Letchworth) we observed staff administering medications to some residents while the residents were using the toilet. We also observed medications being administered to some residents just exiting showers and standing naked at Letchworth and Brooklyn Developmental Centers.

Although these deficiencies related to the safe, humane, and hygienic administration of medications to residents occurred only on selected wards, together they raise serious concerns which need to be addressed through staff supervision and training. It is also noteworthy that, while in some instances non-nursing personnel were involved in the noted deficient practices, in an equal number of instances nursing staff were involved.

OVERSIGHT OF MEDICATION ADMINISTRATION ERRORS

Recent media headlines have alerted the general public to the frequent incidence of medication administration errors in all health care settings. To address this problem, health care facilities, including State developmental centers, have developed a variety of systems to identify medication errors and to ensure appropriate corrective action. Within develop-

mental centers, this mechanism is the incident reporting and review system, which requires that errors be reported in writing to the clinical supervisor and reviewed by the Special Review Committee.

Since there were no existing data on medication errors in the State's developmental center system, the Commission requested copies of all medication error reports from each of the State's 20 developmental centers for the month of September 1984. Additional documents relating information about the investigation and subsequent corrective/preventive actions regarding the error reports were also requested. In addition, the chairpersons of the Special Review Committees completed a written survey, eliciting their opinions of the centers' practices for reporting, investigating, and preventing medication errors.

The data revealed that a total of 166 medication errors were reported by the 20 developmental centers during September 1984. Although many different types of errors were documented among the reports, three types, omitted dose, wrong dose, and procedural errors such as miscounting medications, failure to sign for medications, and failure to maintain medication station key security, accounted for nearly 60 percent of the error reports. Failure to give a resident a dose of prescribed medications (omitted dose) led the ranking, and accounted for 38 percent of the reports.

Transcription errors accounted for 9 percent of the medication errors, while medication administration to the wrong resident, administration of an extra dose of medication, and administration at the wrong time, each accounted for approximately 5 percent of the medication errors. (See Table 3.)

Review of the error reports themselves indicated that they were almost always legible and comprehensive. Additionally, all of the reports were prepared during the same shift that the incident occurred or was discovered.

Nearly three-fourths of the reported errors also generated a concrete corrective action. Significantly, for over half of the incidents (56 percent), the corrective action was directed at the individual who committed the error, and usually took the form of employee counseling, although one facility had a standard practice of mandating retraining and recertification for medication administration for all mental hygiene therapy aides who committed a medication error. Other administrative actions included issuing new facility or ward policies for medication administration, and removing persons from supervisory responsibilities in the administration of medications. Only in one incident was specific employee disciplinary action proposed. In this case, the center alleged that the employee had willfully not administered medications to 21 residents on one afternoon.

TABLE 3. FREQUENCY OF TYPES OF MEDICATION
 ERRORS REPORTED DURING SEPTEMBER 1984
 IN 20 STATE DEVELOPMENTAL CENTERS

<u>Type of Error</u>	<u>Number of Incidents</u>	<u>Percent</u> *
Omitted dose	63	(38)
Procedural	30	(18)
Wrong dose	24	(14)
Transcribing error	15	(9)
Extra dose	10	(6)
Wrong time	9	(5)
Wrong resident	8	(5)
Wrong drug	5	(3)
Other	12	(7)

*Percent exceeds 100 since some incidents involve more than one type of error.

Systemic corrective actions, designed to prevent similar errors across the centers' living units, were instituted in relation to less than 15 percent of the incidents across the 20 centers. These actions focused on policy changes and staff retraining. Eleven (11) instances of specific policy or procedural changes were noted, and 13 references to staff memoranda or group meetings/discussions to reinforce specific aspects of existing policies or procedures were noted in the review of the 166 reports.

The most significant finding of the review of the errors reported by facilities was the overall low reported medication error rates of the facilities. Although specific error rates for each center could not be calculated because calculating rates requires precise data on the number of dosages of medications administered over a defined time period, the Commission calculated rates using the most conservative assumption of one dose of medication per day per every two center residents. (See Table 4.) Actual dosages based on our sample would be at least six times this estimate. Even using this conservative assumption, only five centers (O.D. Heck, Monroe, Syracuse, Newark, and Wilton) came close to the national norm of 3 to 5 percent error rates.*

* Neil M. Davis and Michel R. Cohen, Medication Errors: Causes and Prevention; Philadelphia; George F. Stickney Co., 1981, p. 4.

TABLE 4. NUMBER OF REPORTED MEDICATION ERRORS AND
PERCENT MEDICATION ERROR RATES
BY DEVELOPMENTAL CENTERS
FOR SEPTEMBER 1984

Facility	Number of Reported Errors	Resident Census	Percent Error Rate* Per 100 Clients
TOTAL	166	12,335	0.10
Westchester	0	176	0.00
Manhattan	0	190	0.00
Sunmount	0	256	0.00
Bernard Fineson	0	448	0.00
Brooklyn	0	613	0.00
Staten Island	1	782	0.01
Long Island	2	1,280	0.01
Wassaic	4	1,413	0.02
Rome	3	730	0.03
Bronx	1	224	0.03
Letchworth	26	2,315	0.07
J.N. Adams	3	264	0.08
West Seneca	13	962	0.09
Craig	2	119	1.10
Broome	10	462	1.44
O.D. Heck	12	348	2.30
Monroe	16	407	2.60
Syracuse	18	456	2.60
Newark	24	516	3.10
Wilton	31	374	5.50

*Assumes one dose of medication per every two residents per day. It should be noted that this is a very conservative estimate and that actual dosage rates per resident are likely three or four times higher. As a result, it is likely that medication error rates reported in this table (medication errors divided by total daily dosages of medications) are substantially inflated.

Significantly, only Newark and Wilton Developmental Centers, with reported error rates of 3 and 5 percent using this assumption, fell within the national norm range. In contrast, five centers, including one facility with a census of 600 residents reported no errors for the one month period and five others had error rates of less than 1 percent.

These findings raised concerns about the probable underreporting of medication errors among the centers. A recognized concern of all hospitals and health care facilities, the underreporting of medication errors is difficult to confirm in the best of circumstances. Unfortunately, staffing levels, as well as the antiquated pharmacy dispensing systems of many developmental centers, make this issue even more problematic for these facilities. Staffing levels usually require that medication administration at the centers be an independent task of a single staff person. Thus, error detection and reporting frequently relies on self-reports. Since the most prevalent consequence (corrective action) emanating from an error report, as noted above, is directed to the individual committing the error, the incentive to report errors is not great. Compounding this problem is the fact that many centers at the time of the data collection still dispense many of the most commonly prescribed drugs (including many psychotherapeutic and anticonvulsant medications) from large stock supplies kept on

the wards. A dispensing system long abandoned by most hospitals due to its poor accountability for medications, this stock drug dispensing system can allow many instances of omitted or wrong dosages to go undetected by the staff person administering medications and/or supervisory clinical staff on the wards.

Thus, although data collected in the Commission's review cannot confirm the underreporting of errors, the reported error rates, as well as the circumstances surrounding medication administration at most of the centers, support its likely probability. This probability of significant underreporting was reinforced by the considerably higher reporting rates of Newark and Wilton Developmental Centers, both of which have abandoned the stock drug dispensing system in favor of the unit dose system, whereby drugs are dispensed to the wards by the pharmacy in individualized dosages for each resident. Due to its tightening of accountability for each dose of medication to be administered, this system is strongly advocated in the clinical literature as the most effective vehicle to both prevent errors and to ensure their detection. In contrast, none of the five centers reporting no errors was using this system at the time of the Commission's reviews.

The probability of significant underreporting was also suggested by the comments of the chairperson of the centers' Special Review Committees. These committees are charged with

the task of reviewing all reported incidents at the center, including medication errors. While the chairpersons nearly unanimously gave their centers high marks for handling medication errors, they also raised concerns about certain weaknesses of the system. On the positive side, the chairpersons identified as the major strengths of the system: fairness, timeliness, review of reported errors by a variety of professionals, and ability to identify systemic problems. On the negative side, most chairpersons cited excessive paperwork and senior staff time associated with the administrative oversight and investigation of medication errors, and some noted that corrective actions were inadequate to prevent the recurrence of some medication errors. Leading the list of the chairpersons' concerns, however, was the system's overall limited accountability for medication administration, including limited staff supervision and the ultimate reliance on staff self-reporting for most errors. Although only a few chairpersons frankly acknowledged significant underreporting of medication errors at their centers due to this limited accountability, almost all were quick to cite the unit dose drug dispensing systems and its benefits as the most needed improvement in OMRDD's overall medication practices.

As noted above, the clinical literature sustains this view of the chairpersons. Davis and Cohen, in their recent work, Medication Errors: Causes and Prevention, cite

published studies reporting approximately 80 percent fewer medication errors in hospitals using a unit dose system compared to hospitals using a traditional drug distribution system. Other citations in this work and other literature on the unit dose system reference its immediate benefits in enhancing accountability of medications and ensuring that medication errors are detected and reported.*

Another needed improvement noted by several chairpersons was the reduced utilization of non-nursing personnel in the administration of medications.** These chairpersons indicated that primary reliance of nursing personnel would increase the professional skills of staff involved, prevent medication errors, and also enhance the likelihood that errors would be reported. This study did not examine this issue, and it was not possible, given the strong likelihood of underreporting, to confirm or deny these premises from the 166 error reports reviewed. At the same time, the

* Neil M. Davis and Michael R. Cohen, Medication Errors: Causes and Prevention; Philadelphia; George F. Stickney Co., 1981, p. 4.

** While New York State law allows only nursing personnel to administer medications in health care facilities, State-operated and -licensed mental hygiene facilities are exempted from this provision, and may use therapy aides or other non-nursing personnel to administer medications if they have completed a 30-hour training course and passed a certification exam.

clinical literature is unequivocal on this issue, strongly advocating the clinical advisability of vesting the important task of medication administration -- especially to vulnerable patient populations -- only with nursing personnel.

Summary

Overall, the review of the security of medication storage, as well as the administration of medications to residents, revealed many strong practices. Among the five centers visited, medication security on the living units, as well as in the pharmacy, was rarely compromised at the times of the Commission's observations. The only deficiency which appeared to affect more than half of the five centers was the failure of DDIA's to conduct their quarterly inspections of center pharmacies.

Appropriate practices to ensure the safe, hygienic, and humane administration of medications to residents were also observed on a majority of the wards visited, although deficient practices noted on a number of wards were serious and clearly mandate correction. These deficiencies seemed to call for both more supervisory and staff instruction regarding these medication administration issues.

With regard to the vigilant reporting of medication administration errors, there appeared to be a strong probability that many errors were not reported. While those

errors which were reported were generally documented appropriately and also usually resulted in some corrective action, the likely underreporting of medication errors is believed to be a significant problem at many, if not nearly all of the centers. Center staff agreed with experts in the field that systemwide implementation of the unit dose drug dispensing system is the most promising strategy to resolve this critical deficiency in safeguarding drug administration to residents. Another strategy suggested by facility staff and also echoed in the literature is to reduce the reliance on non-nursing personnel in the administration of medications.

Finally, the Commission's review indicated that the most prevalent corrective action emanating from reported medication errors was directed toward the individual committing the error. While this type of corrective action may be appropriate, it was also noteworthy that little corrective action attention was directed toward administrative or supervisory staff, or general staff training. This finding, coupled with several chairpersons' concerns that such corrective actions are not always adequate, suggests that more attention to systemic corrective action may result in more effective prevention of medication

errors. More emphasis on this type of corrective action may also have a positive impact in promoting the reporting of medication errors, for employees will respect the acknowledgment of shared responsibility of center administration for the circumstances surrounding some errors.



CHAPTER VI
CONCLUSIONS AND RECOMMENDATIONS

This review of medication practices revealed many strong practices to ensure residents' health and the appropriate use of medications in promoting their habilitation. With the exception of one center, psychotherapeutic drugs were used to modify resident behavior only in conjunction with structured behavioral management programs, and there was no evidence that these drugs were used excessively as forms of chemical restraint. Psychotherapeutic drug dosages were usually well below the recommended maximum dosages in the OMRDD guidelines, and very few instances of "PRN" or "Stat" psychotherapeutic drug administration were noted over the year review period.

Similarly, physician practices in anticonvulsant drug choice and dosage levels were almost universally in accord with OMRDD guidelines. Compliance with other OMRDD prescribing guidelines for psychotherapeutic and anticonvulsant drugs relating to the preference for oral tablet (versus liquid) administration, for the use of long-established (versus newer) medications, and for the limited use of certain drug classes (i.e., antiparkinson, somnifacient, antianxiety, and cerebral stimulant drugs) was also generally noted across all the five centers. Finally, medication security was safeguarded, consistent with

OMRDD policies and procedures, on almost all living units, and in all pharmacies, during the times of the Commission's unannounced visits.

Equally important, almost all of the randomly sampled residents had had a complete physical exam within the past year, and treatment recommendations emanating from the exams had been implemented. With the exception of one unit of one of the five centers, the residents' case records were also reasonably organized, and medication order sheets, medication review notations, and progress notes were easy to find and review. Physicians also exercised care to renew medication orders at least every 30 days, as required by OMRDD policies.

Together, these findings are heartening and highlight the success of the New York State OMRDD in implementing major systemic change to correct many of the more egregious deficiencies in medication practices that were alleged to have plagued the State's institutions prior to the Willowbrook Consent Decree. Given that the centers reviewed collectively serve nearly 4,000 severely developmentally disabled individuals, and that over 5,000 direct care and clinical staff personnel are involved in the care and treatment of these individuals, these accomplishments are impressive.