

1 MORTON P. COHEN
536 Mission Street
2 San Francisco, CA 94105
(415) 442-7284

3
4 WILLIAM ALSUP
ELLEN BORGERSEN
JACK W. LONDEN
5 LEWIS LAZARUS
MORRISON & FOERSTER
6 One Market Plaza
Spear Street Tower
7 San Francisco, CA 94105

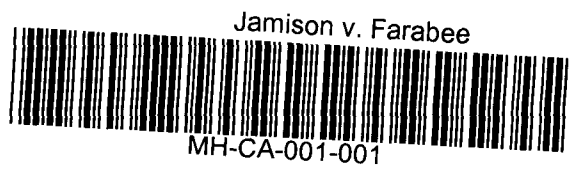
8 MARGARET C. CROSBY
ALAN L. SCHLOSSER
9 AMITAI SCHWARTZ
AMERICAN CIVIL LIBERTIES UNION
10 FOUNDATION OF NORTHERN CALIFORNIA, INC.
1663 Mission Street
11 4th Floor
San Francisco, CA 94105
12 (415) 621-2493

13 Attorneys for Plaintiffs

14

15 UNITED STATES DISTRICT COURT
16 NORTHERN DISTRICT OF CALIFORNIA

17 BARBARA JAMISON, et al.,)
18 Plaintiffs,) NO. C 78 0445 WHO
19 v.) CONSENT DECREE
20 DALE H. FARABEE, et al.,)
21 Defendants.)
22 _____)



23 This action, commenced on February 28, 1978, was
24 brought by the named plaintiffs on behalf of themselves and
25 all others similarly situated, alleging that persons volun-
26 tarily and involuntarily confined as mental patients in
27 California under the Welfare and Institutions Code had
28 been, or in the future would be, administered antipsy-

1 chotic medication without informed consent in violation of
2 their federal constitutional rights to due process. After
3 negotiations resulting in the adoption of regulations concern-
4 ing the rights of voluntary patients to informed consent as
5 to the administration of such medication (Section 850 et seq.
6 of Title 9, California Administrative Code), a dismissal of
7 that portion of the complaint which concerned voluntary
8 patients was entered on February 27, 1981. On May 12, 1981,
9 a Second Amended Complaint was filed and defendants have
10 filed their Answer.

11 The Court has jurisdiction over both the parties
12 and the subject matter of this action. The defendants are
13 Douglas Arnold, as Interim Director of the Department of
14 Mental Health of the State of California; Gary Macomber, as
15 Director of the Department of Developmental Services of the
16 State of California; and David Dawson, as Interim Director of
17 the Department of Health Services of the State of California.

18 The plaintiff class, certified by the Court on
19 May 12, 1981, and amended hereby, consists of adult patients
20 at Napa State Hospital who have been or in the future will be
21 administered antipsychotic medications (as defined in Exhibit A
22 to this Consent Decree) and who belong to one of the following
23 subclasses:

24 (1) all patients detained for 72 hours of
25 evaluation and treatment at Napa pursuant to California
26 Welfare and Institutions Code Section 5150 et. seq.;

27
28

1 (2) all patients certified for 14 days of
2 intensive treatment at Napa pursuant to California
3 Welfare and Institutions Code, Section 5250 et. seq.;

4 (3) all persons committed to Napa by a
5 temporary conservator under a temporary conservatorship
6 established pursuant to California Welfare and Institu-
7 tions Code, Section 5352.1 et. seq.; and

8 (4) all persons committed to Napa by a
9 conservator established pursuant to California Welfare
10 and Institutions Code, Section 5350 et. seq.

11 The parties agree that administration of antipsy-
12 chotic medications to a patient within any of the four
13 plaintiff subclasses without the patient's informed consent
14 implicates a liberty interest protected by the Due Process
15 clause of the Fourteenth Amendment to the United States
16 Constitution. Recognizing this constitutional interest, and
17 for the purpose of avoiding the continuation of difficult,
18 expensive, and protracted litigation, the parties hereby
19 waive a trial of this action, waive findings of fact and
20 conclusions of law, and consent to entry of the order set
21 forth in this Decree.

22 Defendant Interim Director of the Department of
23 Mental Health agrees that this Consent Decree is fully
24 binding on him, each of his officers, agents, employees and
25 successors, and all other persons acting in concert with him
26 who have notice of this Decree. By entering into this
27 Decree, defendants do not admit to any violations of or
28 failure to comply with applicable laws, rules or regulations,

1 nor do defendants admit to any violation of constitutional
2 standards.

3 This Consent Decree is fully binding, to the extent
4 permitted by law, on the named plaintiffs individually and on
5 the plaintiff class. The named plaintiffs shall seek no
6 further relief on the causes of action alleged in the Complaint
7 except to enforce the provisions of this Decree thereby, to
8 the extent permitted by law.

9 If for any reason, after proceedings under Rule 23(e)
10 of Federal Rules of Civil Procedure, the Court does not
11 approve this Consent Decree, the parties' stipulations hereto
12 are null and void for all purposes.

13 NOW THEREFORE IT IS HEREBY ORDERED, ADJUDGED, AND
14 DECREED that:

15 Defendant Interim Director of the Department of
16 Mental Health of the State of California and his officers,
17 agents, servants, employees and others knowingly participat-
18 ing with him or his successors are permanently restrained and
19 enjoined from administering antipsychotic medications (as
20 defined in Exhibit A to this Consent Decree) to persons
21 within any of the four subclasses certified in this action,
22 except in accordance with the following provisions:

23 (1) The Procedures for the Administration of
24 Antipsychotic Medications, attached as Exhibit A to this
25 Consent Decree and incorporated by reference, shall be
26 implemented at Napa State Hospital beginning 60 days
27 after the entry of this Consent Decree, unless otherwise
28 agreed by the parties or ordered by the Court.

1 (2) The Protocol for Selection of Independent
2 Reviewers, attached as Exhibit E to this Consent Decree
3 and incorporated by reference, shall be implemented by
4 the California Department of Mental Health beginning on
5 the date of entry of this Consent Decree.

6 (3) The Napa State Hospital Medical Staff
7 Standards for the Use of Psychotropic Medications,
8 attached as Exhibit C, has been and shall continue to be
9 implemented at Napa State Hospital. On or before
10 July 1, 1983, these standards shall be amended in
11 accordance with Exhibit D to this Consent Decree.

12 (4) Defendants shall, promptly after entry of this
13 Consent Decree, give notice of its existence and contents
14 to all staff members at Napa State Hospital.

15 IMPLEMENTATION

16 The Court shall retain jurisdiction of this matter
17 to monitor defendants' compliance with this Consent Decree.
18 During the first year following implementation of this
19 Consent Decree, plaintiffs may conduct discovery of defendants
20 regarding compliance with it. Such discovery shall be
21 subject to the provisions of the Discovery Order issued by
22 the Court on August 16, 1982. The Director of the Department
23 of Mental Health shall prepare reports regarding compliance
24 with this Decree six months and one year after implementation.
25 The reports shall be served on plaintiffs within thirty days
26 of the close of the reporting period, and filed with the
27 Court (with any agreed modifications) thirty days thereafter.
28

1 Plaintiffs may file a separate statement or report within
2 thirty days after defendants' filing.

3 MODIFICATION

4 The Court retains jurisdiction to modify this
5 Consent Decree upon motion of any party showing good cause
6 for such a modification.

7 Upon the understanding that the provisions of this
8 Consent Decree can be fully performed by the Department of
9 Mental Health of the State of California alone, the claims
10 pleaded in the complaint against defendants Gary Macomber, as
11 Director of the Department of Developmental Services of the
12 State of California, and David Dawson, as Interim Director of
13 the Department of Health Services of the State of California,
14 are hereby dismissed.

15 COSTS AND FEES

16 Plaintiffs' reasonable recoverable costs and
17 reasonable attorneys' fees and other expenses pursuant to
18 42 U.S.C. Section 1988 shall be awarded in such amount as may
19 be agreed to by the parties or determined by the Court.

20 Dated: _____, 1983

21 _____
22 William H. Orrick
23 United States District Judge
24
25
26
27
28

1 Consented to:
DATED: April 15, 1983

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

WILLIAM ALSUP
ELLEN BORGENSEN
JACK W. LONDEN
LEWIS LAZARUS
MORRISON & FOERSTER

MORTON P. COHEN

MARGARET C. CROSBY
ALAN L. SCHLOSSER
AMITAI SCHWARTZ
AMERICAN CIVIL LIBERTIES
UNION FOUNDATION OF
NORTHERN CALIFORNIA

By WPC
Morton P. Cohen
Attorneys for Plaintiffs

Consented to:
DATED: April 26, 1983

JOHN VAN DE CAMP
Attorney General of the
State of California
CHARLTON G. HOLLAND
RALPH M. JOHNSON
Deputy Attorneys General

By Ralph M. Johnson
Ralph M. Johnson
Attorneys for Defendants

PROCEDURES FOR THE ADMINISTRATION
OF ANTIPSYCHOTIC MEDICATION

These procedures are applicable to the administration of antipsychotic medications to adult patients being treated pursuant to the Lanterman-Petris-Short (LPS) Act. None of these procedures shall apply to minor patients.

I. Definitions

- A. "Antipsychotic medication" means any drug customarily used for treatment of symptoms of psychosis and other severe mental and emotional disorders.
- B. "Independent reviewer" means a physician employed and selected by the Department of Mental Health and not otherwise employed at a state hospital.
- C. "Three working days" means three consecutive normal business days. Any act required by this procedure which falls on a weekend or holiday shall be concluded on the next regular business day.
- D. "Necessary Medication" Medication is considered a necessary part of a patient's treatment plan when the patient is incapable, without medication, of participating in any treatment plan available at the hospital that will give the patient a realistic opportunity of improving his/her condition, and administration of medication could be expected to render the patient capable of such participation; and the benefits of the medication outweigh the risks of adverse effects, and the patient's objections, if any, to the medication; and medication is the least restrictive form of treatment reasonably available.
- E. All steps required by these procedures shall be fully documented in the patient's chart.

II. Administration of Antipsychotic Medications

- A. The treating physician shall discuss any proposed medication treatment with the patient as follows:

1.

1. The nature of the patient's mental condition;
2. The reasons for taking such medication, including the likelihood of improving or not improving without such medication;
3. Consent, once given, may be withdrawn at any time by stating such intention to any member of the treating staff;
4. The reasonable alternative treatments available, if any;
5. The type, range of frequency and amount (including use of PRN orders), method (oral or injection), and duration of taking the medication;
6. The probable side effects of these drugs known to commonly occur, and any particular side effects likely to occur with the particular patient;
7. The possible additional side effects which may occur to patients taking such medication beyond three months. The patient shall be advised that such side effects may include persistent involuntary movement of the face or mouth and might at times include similar movement of the hands and feet, and that these symptoms of tardive dyskinesia are potentially irreversible and may appear after medication has been discontinued; and
8. The patient has been informed of his/her rights under these procedures.

B. Requirement of Consent

Antipsychotic medication may be administered to an adult patient treated pursuant to the LPS Act only after the patient has given informed, voluntary consent in writing, except as otherwise provided in these procedures.

1. Consent shall be considered to be informed only after the patient has been provided with the above information by the physician prescribing the medication (in the patient's native language, if possible).

2. The patient shall be asked to sign the consent form utilized in obtaining informed consent from voluntary patients, and this signed consent form shall be included in the legal section of his/her chart. In the event that the patient has been shown the form and communicates consent but does not wish to sign the written consent form, it shall be sufficient for the physician to place the unsigned form in the patient's record together with the notation that while the patient understands the nature and effect of antipsychotic medication and consents to the administration of such medication, the patient does not desire to sign a written consent form.
3. Consent shall be effective for the duration of the patient's stay in the hospital, unless it is revoked by the patient.

C. Revocation of Consent

1. A patient who has consented to medication may refuse a specific medication at any time, by stating or writing that he/she does not wish to take the medication. Medication may not then be given to such a patient, orally or by injection, except as authorized in Section III below.
2. A revocation of consent shall be documented on the consent form by the treating physician and shall then render the consent void.

III. Independent Review of Treatment With Antipsychotic Medication

Antipsychotic medications may be administered to an adult patient treated pursuant to the LPS Act who has not provided informed consent, or who revokes consent, pursuant to the procedures below.

- A. Patients admitted pursuant to Section 5150 and/or 5250 of the LPS Act as gravely disabled.
 1. If a patient admitted pursuant to a 72-hour detention and/or a 14-day certification pursuant to the LPS Act as gravely disabled refuses or revokes consent to the administration of antipsychotic medication, the treating physician shall speak to the patient to

discuss and attempt to respond to the patient's concern about the medication. The physician shall suggest the patient discuss the matter with a person of his/her own choosing, such as a relative, friend, or the patients' rights advocate.

2. If, after the discussion with the patient, the physician believes medication is a necessary part of the patient's treatment plan and (1) the patient still refuses the medication and (2) the physician determines that the patient has the capacity to give informed consent in that the refusal is not a product of the patient's mental illness, then medication shall not be administered, except as provided in Section IV.
 - a. If, however, the physician determines (1) the patient has the capacity to give informed consent, and (2) i. for a patient on medication, withholding medication would result in substantial deterioration; ii. for a patient not on medication, the patient is substantially deteriorating; then the physician may request an independent review. Medication shall not be administered pending the independent review.
 - b. The independent reviewer shall then conduct a personal examination of the patient and a review of the patient's chart within three working days.
 - i. If the independent reviewer determines the patient has the capacity to give informed consent in that the patient's refusal is not a product of the patient's mental illness, medication shall not be administered.
 - ii. If the independent reviewer determines (1) the patient lacks the capacity to give informed consent in that the refusal is a product of the patient's mental illness, and (2) medication is a necessary part of the patient's treatment plan, and (3) i. for a patient on medication, withholding medication would result

in substantial deterioration; ii. for a patient not on medication, the patient is substantially deteriorating, then medication may be administered as part of the patient's treatment plan.

c. Medication may be administered under this section only so long as it is necessary and required to preclude substantial deterioration.

3. If, after a discussion with the patient, the physician believes medication is a necessary part of the patient's treatment plan and the physician determines (1) the patient lacks the capacity to give informed consent in that the refusal is a product of the patient's mental illness and (2) i. for a patient on medication, withholding medication would result in substantial deterioration; ii. for a patient not on medication, the patient is substantially deteriorating; then medication may be administered as part of the patient's treatment plan. However, the physician shall concurrently request an independent review.

a. The independent reviewer shall then conduct a personal examination of the patient and a review of the patient's chart within three working days.

i. If the independent reviewer determines (1) the patient has the capacity to give informed consent in that the refusal is not a product of the patient's mental illness or (2) medication is not a necessary part of the patient's treatment plan, or (3) i. for a patient on medication, withholding medication would not result in substantial deterioration; ii. for a patient not on medication, the patient is not substantially deteriorating, then medication shall not be administered, except as provided in Section IV.

ii. If the independent reviewer determines (1) the patient lacks the capacity to give informed consent in that the refusal is a product of

the patient's mental illness, and
(2) medication is a necessary part
of the patient's treatment plan, and
(3) i. for a patient on medication,
withholding medication would result
in substantial deterioration; ii.
for a patient not on medication the
patient is substantially deterior-
ating, then medication may be admin-
istered as part part of the
patient's treatment plan.

b. Medication may be administered under
this section only so long as it is
necessary and required to preclude sub-
stantial deterioration.

**B. Patients Admitted Pursuant to Section 5150
and/or 5250 of the LPS Act as a Danger to
Others or a Danger to Self**

1. A patient admitted pursuant to a 72-hour
detention and/or a 14-day certification pur-
suant to the LPS Act as Danger to Others or
Danger to Self and for whom the treating phy-
sician determines medication is necessary for
treatment, may receive medication as part of
the patient's treatment plan.
2. A patient may be treated with medications pur-
suant to this section only so long as the phy-
sician determines medication continues to be
necessary for the preservation of life or the
prevention of serious bodily harm to the
patient or others. Otherwise the provisions
of sections III A or C apply as appropriate.

**C. Patients Admitted Pursuant to
Section 5350 et seq. of the LPS Act**

The procedures of this section apply to a patient
(1) admitted pursuant to conservatorship estab-
lished pursuant to the LPS Act, (2) whose conser-
vator has been granted the power to consent to
treatment, and (3) who refuses or revokes consent
or does not otherwise provide informed consent to
the administration of antipsychotic medication.

1. The treating physician shall speak to the
patient to discuss and attempt to respond to
the patient's concerns, if any, about the
medication. The physician shall suggest the
patient discuss the matter with a person of

his/her own choosing, such as a relative, friend, or the patients' rights advocate.

2. If, after the discussion with the patient, the physician believes medication is a necessary part of the patient's treatment plan and the patient still refuses or has not otherwise provided informed consent to the medication, the physician shall request an independent review. Medication shall not be administered pending the independent review unless the physician determines for a patient on medication, withholding medication would result in substantial deterioration; or for a patient not on medication, the patient is substantially deteriorating.
3. The independent reviewer shall then conduct a personal examination of the patient and a review of the patient's chart within three working days.
 - a. If the independent reviewer determines medication is a necessary form of treatment, medication may be administered as part of the patient's treatment plan.
 - b. If the independent reviewer determines medication is not a necessary form of treatment, medication shall not be administered except as provided in Part IV.
 - c. The independent reviewer shall review every 90 days the treatment program of each patient, who has refused medication or who has not provided informed consent but is receiving medication, to determine:
 - i. Whether the patient is still refusing the medication, or has not provided informed consent; and
 - ii. Whether medication is still a necessary part of the patient's treatment plan; and
 - iii. Whether the other components of the patient's treatment plan are being implemented.
4. Nothing herein, however, affects any rights of conservators pursuant to the LPS Act to give or withhold consent to treatment.

IV. The Emergency Administration of Medication

Nothing in these Procedures is intended to prohibit a physician from taking appropriate action in an emergency. An emergency exists when there is a sudden marked change in the patient's condition so that action is immediately necessary for the preservation of life or the prevention of serious bodily harm to the patient or others, and it is impracticable to first obtain consent. If antipsychotic medication is administered during an emergency, such medication shall be only that which is required to treat the emergency condition and shall be provided in ways that are least restrictive of the personal liberty of the patient.

In the event a patient described herein at Section III A 2, or III C, is administered antipsychotic medications in an emergency, and such emergency condition is likely to last beyond 24 hours, the treating physician shall within that 24 hours request an independent review.

The independent reviewer shall then conduct a personal examination and review of the patient's chart within three working days. In addition to the determinations required above, the independent reviewer shall determine if the emergency condition continues.

V. Patients' Rights Advocate

The patient's rights advocate shall be given notice of each refusal or failure to provide informed consent occurring under sections III or IV herein and written notice of and the opportunity to appear at the examination by the independent reviewer. The patient's rights advocate shall discuss with the patient the patient's objections, if any, to the medication and shall, whether or not present at the review, provide the independent reviewer a written statement of the patient's reason for refusing medication. The patient's rights advocate may request an independent review whenever he/she determines a patient is refusing or has not provided informed consent to medication and an independent review has not been requested.

VI. Information as to Patients Rights

Patients shall be informed in writing of their rights under these procedures prior to the administration of medications, except in an emergency, including for conservatees, their rights of judicial review pursuant to sections 5358.3 and 5364 of the LPS Act.

1 PROTOCOL FOR SELECTION OF INDEPENDENT REVIEWERS

2

- 3 1. The Department of Mental Health shall hire as many
4 Independent Reviewers as are necessary to carry out the
5 functions specified in the Procedures for the Administration
6 of Antipsychotic Medications. The Department shall use
7 its best efforts to fill these positions with part-time
8 consultants.
- 9 2. The Department shall form a committee to select Independ-
10 ent Reviewers. The members of that selection committee
11 shall be:
- 12 a. The Deputy Director of Clinical Services;
 - 13 b. Chief of the Division of State Hospitals or
14 his/her designee; and
 - 15 c. The Chief of the Patient's Rights Office in
16 Sacramento.
- 17 3. The Department of Mental Health shall make available the
18 list of potential independent reviewers to anyone upon
19 request within a reasonable period of time prior to the
20 designation of any persons as Independent Reviewers.
- 21 4. Independent Reviewers shall report to the Department of
22 Mental Health which shall have the authority for pay,
23 supervision and termination decisions.
- 24 5. The Department of Mental Health shall devise a concise
25 form to record data about the performance of Independent
26 Reviewers. This form shall include, but not be limited

27

28

1 to: (1) Number of patients seen; (2) Reason for consul-
2 tation; (3) Decision of Independent Reviewer; and
3 (4) Reasons for decision. The Department shall issue
4 semiannual reports evaluating on a monthly basis the
5 independent reviews. The reports shall be filed with
6 the Court and made available to counsel.

7 6. Nothing in these guidelines precludes counsel from
8 moving the Court, upon a showing of good cause, to
9 compel the release of additional information necessary
10 to evaluate the Independent Reviewers or the process of
11 independent review.

12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

**NAPA STATE HOSPITAL MEDICAL STAFF
STANDARDS FOR THE USE OF PSYCHOTROPIC MEDICATIONS**

We, the medical staff of Napa State Hospital, wishing to outline our scientific rationale and ethical philosophy in the use of psychotropic medications, we have prepared the following expression of the general prescribing policies of our medical staff.

For clarity, we offer the following definitions of terms used in these guidelines:

1) Psychotropic - any CNS-active medication used in the treatment of a mental disorder. This broad class includes essentially all medications discussed in these guidelines.

2) Neuroleptic - any representative of the class of dopamine-blocking agents; viz., the phenothiazines, thioxanthenes, butyrophenones, dibenzoxazepines and dihydroindolones. These agents are primarily indicated in the treatment of schizophrenia. However, they can be useful in other mental disorders, including behavioral and impulse disorders, organic brain syndrome, anxiety states, mania and depression. Therapeutic Review Committee (T.R.C.) may be consulted if the prescribing physician judges the usefulness of a particular agent to be in question.

We are dealing with a select population consisting of those who fail to respond to treatment in the community; those who are obviously beyond community resources such as markedly violent patients/clients; and/or patients/clients from criminal justice. In addition, we care for many severely, developmentally disabled who are unmanageable in the community.

In addition to therapies such as rehabilitative, vocational, group, individual, and milieu, we also have in the neuroleptics a scientifically demonstrated and accepted armamentarium available for use with many of our patients/clients, i.e., the neuroleptic agents (antipsychotics). The misnomer of "tranquilizer" is often applied to these drugs; these agents are not sedatives or "calmatives"; they are a mainstay of therapy in the more severe mental disorders and are responsible for the conversion of our formerly huge mental hospitals from custodial institutions to smaller treatment centers.

Fortunately, the neuroleptics and other psychotropics are among the safest drugs available to the physician. They do, of course, have certain risks and side effects, including the possibility of dyskinesias. These guidelines reflect the approach of the Napa State Hospital medical staff in balancing the risk to benefit ratio of these medications as employed in the treatment of our patients/clients.

I. Patients/Client's Participation in Therapeutic Decision:

Patients/clients should have an active part in the therapeutic decision-making process. The final decision with regard to recommending medications, however,

must be the responsibility of the treating physician,

Patients/clients should be informed to the fullest extent judged reasonable about any medication they receive. They should ordinarily be informed of its expected beneficial effects, possible side effects, adverse reactions, and long-term hazards. Patients/clients should be informed of any alternative therapies and/or medications.

To further clarify recent legal opinions, the following procedures are to be used in guaranteeing that voluntary patients/clients will not be medicated against their will.

a) Voluntary patients/clients, in the course of their admission procedure and evaluations, will be fully informed of the proposed treatment program. They have the absolute right to refuse any or all aspects of our proposal. They must sign the appropriate consent form affirmatively prior to initiating treatment.

b) If they reject any or all of our proposal, a decision will then be negotiated as to whether there are grounds for continuing with the hospitalization.

c) If it is felt that medication is absolutely essential and that the patient/client is dangerous to self or others and/or gravely disabled, the patient/client shall be switched to involuntary status. As the changing to involuntary of a patient/client who voluntarily comes to Napa State Hospital is a procedure not to be taken lightly, the reasons for same shall be documented thoroughly and also communicated to the program management.

d) If, during the course of a voluntary patient's/client's hospitalization, a crisis occurs which necessitates sudden intervention with treatment procedures likely to be refused by a fully informed voluntary patient/client (e.g., transfer to secure ward, medication, seclusion, restraints, etc.); the patient/client should be fully informed of what is happening and why. If the patient/client 1) accepts the intervention and 2) is deemed capable of giving informed consent, the patient/client may be continued on voluntary status.. In many cases however, status will have to be changed to involuntary. This should be done immediately for the following reason: A voluntary patient/client medicated against his/her will, has well established grounds for both civil and criminal action against those involved in the action of medication (or whatever the procedure imposed).

e) Whatever the course (s) of action taken, the rationale must be thoroughly documented at all levels.

II. Therapeutic Review Committee (T.R.C.):

- a. **Composition:** The Therapeutic Review Committee shall consist of at least five physicians, three of whom shall be appointed by the Executive Committee of the Medical Staff and two by the Executive Director. There shall also be a panel of resource consultants, such as a pharmacist, an internist, and a neurologist, who shall serve in an advisory capacity when requested. A psychiatrist shall serve as chairperson. There shall be two alternates appointed by the Executive Committee to serve in case of extended absence or need of a quorum.
- b. **Duties:** Using a panel of clinical consultants who are on the medical staff of the hospital and who have been specifically credentialed to act as consultants in psychopharmacology, the committee shall:
 - 1) Provide consultation for any member of the medical staff, who so requests, with respect to any clinical problem concerning a patient/client.
 - 2) Develop background information and propose guidelines, as requested, for the medical staff with respect to various treatment modalities. It is not a policy-making body.
- c. **Meetings:** The committee shall meet on call by the chairperson, but at least monthly. It shall maintain a permanent record of its proceedings and activities.

III. Indication and Evaluation:

- A. Psychotropic medications are of primary importance in the treatment of severe mental disorders. When used appropriately and skillfully, the risks they offer are small in relation to their benefits: The dose and duration of administration of these medications should be the least amount necessary to achieve the best results. Psychotropic medications shall not be used for the convenience of the staff or in the control of behavior when it is not an expression of a mental disorder, unless it is an integral part of an approved behavior management program with provisions for its eventual decrease and discontinuation.

Mental disorders are best treated by a multi-dimensional approach. It is incumbent upon the Department of Health and the Legislature to provide the state hospitals with sufficient staffing and funding to make all appropriate evaluation and treatment modalities readily available.

- B. The treatment program, including the use of psychotropic medications for all newly admitted patients/clients, should be reviewed daily by the ward staff. This can be done at daily rand meetings or intershift. The physician shall keep himself/herself informed of the progress of the patient/client and any side effects from the medication. Changes in the treatment program shall be ordered by the appropriate physician in response to changes in the patient/client. As symptoms subside, medications shall be reduced to the lowest effective dosage required to meet the needs of the individual patient/client.

If a single dose of dopamine-blocking or tricyclic antidepressant medication in a 24-hour period is considered to be medically feasible by the physician, and if the patient/client is agreeable, the physician will so order the medication. This reduces the time the nursing staff spends in giving and charting medication and will allow for more time in meeting the other treatment needs of the patient/client.

C. Developmentally Disabled:

Because of the inherent difficulty in evaluating the efficacy of psychotropic medications in non-verbal, severely developmentally disabled patients/clients, special consideration shall be employed in the use of psychotropics in this population. It is suggested that specific target signs be determined and documented for each patient/client and then monitored to provide an objective measurement of response (or non-response) to the agent employed. The use of medication in these patients/clients should be integrated into an appropriate and approved behavior management program. The physician is responsible for ensuring that the behavior management program is proper for the patients/clients psychiatric and medical disorder and is integrated into other aspects of the patient's/client's treatment.

IV. Selection, Dosage and Utilization of Psychotropic Medications:

A. Risk/Benefit Factors:

Recognizing that there are hazards in the long-term use of psychotropic medications, our policy, as stated before, will be to use the smallest dosage necessary to achieve the desired therapeutic effect. For each individual patient/client, the benefits shall be weighed against the risks and medication prescribed accordingly. When there are significant risks involved with a particular patient/client, the risk/benefit considerations shall be documented in adequate detail.

B. Comprehensive Medication History:

Whenever possible, a comprehensive medication history should be obtained to aid in effective treatment. This should include information about previous treatment with psychotropic medications and the response to them. A history should also be obtained of any other significant medical problems the patient/client may have and medications he/she is receiving for them. Whenever possible a family medication history should also be obtained.

C. Maintenance:

With special reference to the maintenance use of psychotropics, it is incumbent upon the physician to determine the least amount of medication required. Periodic attempts to decrease total daily dosage should be utilized towards this end. In regard to the neuroleptics, there is some evidence that the use of the lowest possible dosage may lower the incidence of dyskinesias. Because recent research has suggested that "drug-holidays" may actually contribute to the severity of tardive dyskinesia, we are no longer advocating them.

D. Adverse Drug Reaction:

All ward staff shall be familiar with the potential side effects of psychotropic medication and shall be observant for their occurrence. When these are observed, they shall be reported to the treating physician or the physician on duty and reported in the patient's/client's record.
See appendix.

E. Medication Errors:

Any medication error shall be immediately reported to a physician and recorded in the patient's/client's record and shall be the subject of a Special Incident Report (Form #11 1756-A).

F. Acceptable Upper Limits of Neuroleptic Medications:

1) Adult Psychiatric (age 15 to 65): When it seems necessary to prescribe medications in excess of those amounts listed on pages 13-14, a consultation request shall be sent to the Therapeutic Review Committee. In addition, a note (I.D. or Physician's) recognizing that the limit has been exceeded and stating that a consultation request has been sent shall be written. In the case of acute or exacerbated psychoses, dosage levels of certain specified dopamine-blockers may be exceeded by up to 50% for a maximum period of up to two months.

2) Geriatric (age 65 and over): A consultation request to the Therapeutic Review Committee and a note as above shall be written when it seems necessary to prescribe medications in excess of one-half of the adult psychiatric upper limits (Appendix A) in these patients/clients.

3) Children (age 12 and under): A consultation request to the Therapeutic Review Committee and a note as above shall be written when it seems necessary to prescribe medications in excess of the amounts listed in Appendix B.

G. Drug Combinations (Polypharmacy):

Polypharmacy shall be defined as: the regular use of more than one drug or agent for the treatment of a single problem or condition. Generally, only one psychotropic drug should be prescribed at one time. There is little evidence to support the use of psychotropic drug combinations under most circumstances. Such a practice hinders identification of the offending drug if side effects occur. Drug consultations with the Therapeutic Review Committee may be indicated when combined medications are used. There are important exceptions to the suggestion of prescribing only one psychotropic at a time, some of which are:

1) The combination of an antidepressant such as Amitriptyline with a neuroleptic such as Perphenazine (Etrafon, Triavil) may increase the therapeutic effect in affective illnesses. If such a fixed-combination is to be used, the appropriate dosage ratio of the two drugs should initially be determined by titrating the two drugs separately. Generally the neuroleptic should be discontinued as soon as possible after the psychosis of a psychotic depression abates.

2) Severe mania may benefit from a combination of lithium and a neuroleptic since optimal response to lithium may not occur for six to ten days. This combination may result in organic brain syndrome, particularly when the dosage of neuroleptic is not reduced as the lithium becomes effective. Every attempt shall be made to withdraw the neuroleptic as soon as possible and the early signs of ONS observed for. Continued use of the two without demonstrated need constitutes undesirable polypharmacy.

3) Occasionally it is in the patient's/client's best interests to take advantage of the side effects of two different classes of neuroleptics (e.g., a more potent, non-sedating piperazine phenothiazine such as trifluoperazine (Stelazine) during the day with a more sedating aliphatic phenothiazine such as chlorpromazine (Thorazine) at bedtime). The reasons for this shall be adequately documented.

II. Neuroleptic and Sedative P.R.N. Orders:

P.R.N. orders are an essential component of treatment in psychiatry just as they are in the rest of medicine. In general, with our population, neuroleptics are the most appropriate drug class for use on an "as needed" basis to alleviate psychotically generated anxiety or agitation. The use of p.r.n.'s can usually be minimal after the first two to three weeks of hospitalization. Continued need for frequent p.r.n.'s suggests that the patient's/client's routine regimen is insufficient. However, even well-stabilized patients/clients may need p.r.n. medication during times of stress. The judicious use of p.r.n.'s in these instances minimizes the total amount of medication administered. In the acute treatment phase it is usually best to have the p.r.n. the same as the neuroleptic regularly administered to permit proper titration.

P.R.N. orders after the acute phase of illness shall have a corresponding physician's note. If a physician allows more than two p.r.n. doses in 24 hours, a note should explain the reasons for this. The prescribing physician shall seek consultation with the Therapeutic Review Committee in any cases of continued need for frequent p.r.n. medications which occur past the phase of acute illness. After the patient/client has been stabilized, anything in excess of two p.r.n.'s in a 24-hour period should be considered frequent. After a patient/client has been stabilized on medications, the additive use of p.r.n.'s plus the regular medication shall not exceed the acceptable upper limits set forth on pages 14 & 15.

In summary:

1. The physician's routine order shall permit no more than two p.r.n.'s per 24 hours, and the frequency shall be specified.
 2. The order shall be specific as to whether the IM or the oral route is to be used and under what circumstances.
 3. Orders that permit oral or IM should reflect the fact that the same dosage given by the IM route is usually two to two and one-half times more potent than when given by the oral route.
 4. Only one psychoactive p.r.n. medication should be available at a time and when a neuroleptic, it should generally be the same as the neuroleptic being used on a regular basis.
- The same dosage of Loxitane may have a similar potency when given IM or orally, although the amounts of the major-action metabolites vary according to the route of the administration.

5. If the combined sum of the p.r.n.'s ordered plus the dosage regularly administered exceeds the Guidelines, a T.R.C. consult shall be requested.
6. Any deviations from the above shall have thorough documentation of their necessity and shall also be accompanied by a request for a T.R.C. consult.

I. Parenteral Short-Acting Neuroleptic Drugs, Acute Use:

Short-acting IM (intramuscular) neuroleptic medications may be used in appropriate situations. The physician must be aware that IM neuroleptic medications are generally at least twice as potent as the oral route of administration. Generally no more than one-third the upper oral dose should be given IM in a 24-hour period. When using IM medications, the patient/client shall be carefully monitored for acute side effects such as hypotension and dystonias. Appropriate situations include (1) refusal to take medication by mouth and/or (2) the necessity to control an acutely agitated and assaultive patient/client.

J. Parenteral Neuroleptic Drugs, Depot-Type:

When long-acting fluphenazine is indicated, the physician shall justify its usage and reasons for the decision in the patient's/client's chart. The physician will use the medical history of the patient/client, as obtained from the patient/client and other available sources, in arriving at such a decision. As in the use of all medications, the dose of long-acting fluphenazine shall be reduced to the lowest effective dose as the patient/client responds to treatment. Usually only documented difficulty with absorption or documented non-compliance are the only indications.

K. Anti-Parkinsonian Drugs:

Although the prophylactic use of an anti-parkinsonian agent with neuroleptic is held by some drug experts to be justified, routine use should be discouraged because of possible side effects. Anti-parkinsonian drugs are generally regarded as ineffective prophylactically in preventing extrapyramidal effects and may cause toxic psychosis. It is also important to know that there is good evidence that anti-parkinsonian drugs may substantially reduce blood levels of phenothiazines. Also, these medications are widely abused "on the street" for their apparent euphoric effect. This should not discourage their usage where akathisia or akinesia may be a significant factor in behavior, particularly non-compliance. Physicians should also be aware of the unusual conditions such as laryngeal-pharyngeal dystonias and treat them promptly and adequately.

Based on the above considerations, anti-parkinsonian agents will generally be used only upon the appearance of extrapyramidal side effects. Exceptions should have an explanatory physician's note. After a maximum of two months, consideration should be given to decreasing anti-parkinsonian drugs to determine if the patient/client continues to be in need of them. If it is not possible to withdraw the patient/client from anti-parkinsonian drugs, consideration should be given to substituting a neuroleptic with a lower incidence of extrapyramidal side effects. Exceptions should, again, have an explanatory physician's note.

L. Use of Minor Tranquillizers or Anxiolytic Agents:

A certain amount of anxiety is both normal and necessary to promote adaptive change. However, whenever anxiety increases to the point of interfering significantly with performance, intervention is indicated. The potential for abuse of these drugs can be minimized by good patient/client selection, and making appropriate use of the various drugs' different half-lives and side effects. The anxiolytic agents should generally be employed only for the duration of the stressful period and, in the case of the benzodiazepines, decreased and discontinued gradually at high dosages and/or when used longer than a month, to prevent the occurrence of withdrawal seizures. In addition to marked or overwhelming anxiety they are indicated adjunctively or as the primary pharmacologic agent for acute alcohol withdrawal; impending or acute delirium tremens; (in cases where hepatic insufficiency may be present, there should be caution in the use of chlorthalidone in the higher ranges for any period greater than a week); organic hallucinosis, and as adjuncts in the treatment of skeletal muscle spasm; convulsive disorders and various other neurological disorders. In the absence of such concurrent organic factors, minor tranquilizers should not generally be utilized in the treatment of psychotic disorders. Other usages appropriate to Mapa State Hospital might include: helping alleviate excessive stress in D.D. patients/clients in approved behavior modification programs; M.D. patients/clients in whom the diagnosis is unclear and other medications might confuse the issue; in the management of agitated assaultive patients/clients while one medication is clearing the system prior to beginning another; in treatment-resistant akathisia from dopamine-blocking drugs or tricyclic antidepressants, etc.

We also recognize that in some instances other medical considerations would militate against the use of dopamine-blocking agents in particular. The minor tranquilizers would seem to have a role here. This might include: Those patients/clients suffering from organic brain syndrome, the "burned-out schizophrenic" not responsive to dopamine-blocking agents, those with severe or worsening tardive dyskinesia, parkinsonism and certain medical disorders, etc. In other cases very low doses of the high potency dopamine-blocking drugs such as Halldol or Navane might prove more effective. While the benzodiazepines might be used to help alleviate or prevent "catastrophic reactions" in the neurologically impaired, care must be taken to not further impair such individuals' already limited adaptive capabilities. Paradoxical responses to these drugs are not rare here and must also be observed for. As with all medications the risk-benefit ratio should be documented, as should the continued need for the drug, particularly after the third month. In the majority of the patients/clients in the above categories, the risk of abuse and/or dependency is at worst minimal, but those cases in which it might be a factor there should be documentation that the issue is and has been considered and evaluated. In cases of doubt the Therapeutic Review Committee may be consulted.

M. Use of Lithium Carbonate:

1) Indications: Lithium carbonate is effective in most cases of acute mania in bipolar manic-depressive disease. It significantly reduces recurrences of manic episodes when given as maintenance medication (usually at lower dosage). There is increasing evidence that lithium is effective in managing the depressions of bipolar disease, in other depressive illness, in alcoholism,

in impulsive violence, in "schizo-affective" schizophrenia, in other idiosyncratic "schizophrenias", etc. Hence, it is not necessary to change a diagnosis in order to institute lithium. If there is any question as to the appropriateness of lithium therapy consult the Therapeutic Review Committee.

2) Contraindications: In general, significant renal and/or cardiovascular and/or neurological disease and pregnancy (especially the first trimester) are contraindications. However, if a patient/client is deteriorating, in an unmanageable manic state, and not responding to other measures, lithium should be considered as well as electroconvulsive therapy. One must weigh the risk/benefit ratio in these conditions, and other conditions significantly involving, for instance; electrolyte balance and/or thyroid function. The Therapeutic Review Committee should be consulted when considering lithium therapy for patients/clients with significant medical, surgical problems and the risk/benefit considerations documented. Diuretics are not a contraindication, but require careful monitoring of blood levels and the patients/clients.

3) Pretreatment Baselines and Subsequent Monitoring: The initial workup of all lithium candidates should be reviewed to assure that it is in order. Within the 30 days previous to initiating lithium, baseline levels should be obtained, and evaluated, for: CBC; electrolytes, including calcium; pregnancy test; urinalysis with specific gravity; creatinine, BUN and thyroid function (current procedure: T-3, T-4 and palpation of gland). If neurological disease is extant or suspected, a baseline EEG should be done. If clients are known to be in good physical health and have been on lithium without difficulty by history, lithium may be resumed STAT. Appropriate orders for pretreatment workup should be written at the same time. A serum lithium level should be obtained prior to administration of general and spinal anesthesia for surgery.

The physical condition of long term lithium clients should be periodically evaluated with above items in mind. The T-3, T-4 levels should be repeated annually and more frequently in those patients/clients in which imbalance might be more likely (e.g., lithium-induced diabetes insipidus, sodium chloride restriction for hypertension, etc.) A routine monitoring of the pulse will disclose bradycardia, the most common (and reversible) side effect. An EKG should be performed when clinically indicated. A CBC should be done annually. A basic neurological evaluation for toxicity should be carried out whenever clinically indicated by routine observations.

4) Initiating Therapy: Patients/clients can be started on a normal dose, or they can be "loaded" the first day. Serum lithium levels should be drawn in the a.m. after abstinence from lithium for twelve hours and should be checked frequently (twice weekly, occasionally three times weekly) until stabilized. Weekly levels are indicated for the remainder of the first month. Levels can then be reduced to monthly and less frequently as indicated. Lithium should be given at least t.i.d. until steady state is established (about two weeks). It then should be given at least b.i.d. (preferably with or after meals). Half life is twenty-four hours. Therefore, serum lithium

levels halve in twenty-four hour hours following cessation of lithium (assuming reasonable renal function).

5) Lithium Toxicity: The therapeutic range for lithium is relatively narrow: the serum lithium level should generally be at least 0.8 mEq/l in the young and should usually not exceed 1.5 mEq/l, although in the acute treatment phase higher levels (up to 2.0 mEq/l) are usually tolerated and may be briefly required. In the elderly, and occasionally even in younger individuals, good therapeutic results may occur at levels less than 0.8 mEq/l. The serum level can be lowered to a maintenance level (usually above 0.8 mEq/l to prevent depression) when the acute phase subsides.

On commencing therapy there is, occasionally, some initial sluggishness and/or nausea and/or vomiting and/or diarrhea and/or mild tremor. (This may be due to the serum level rising too rapidly, and usually passes without treatment; it should not be confused with the toxicity resulting from excessive lithium levels). Toxicity frequently presents with a picture of more serious nausea and/or vomiting and/or diarrhea; drowsiness; and most often, coarse tremor (a good method for evaluating is to monitor patient's/client's capacity to perform the fine movements required to feed themselves). As toxicity becomes more severe, a picture of progressive neurological impairment becomes obvious. There are other less common manifestations of toxicity with which everyone prescribing or taking lithium should acquaint themselves. Be aware also of the appropriate treatment for managing lithium toxicity, which requires more than simple withdrawal of the drug. An early internal medicine and/or neurological consultation should be sought whenever degree of toxicity merits same.

Watch electrolytes in physically compromised patients/clients. Watch for dehydration in secluded clients, patients/clients sweating excessively during the summer, or not eating properly. Be aware of fluctuating sodium intake.

When a patient/client, either responsive to lithium by history and/or a prime candidate for lithium, refuses serial lithium levels, lithium therapy may nevertheless be initiated. Initial dosage should be conservative. Each dosage change should document that the patient/client is being monitored for early signs of toxicity. The patient/client, and not the serum level, is the best indicator of impending toxicity. On rare occasions "idiosyncratic low-level lithium toxicity" may occur. The most common cause of serum lithium fluctuation is probably a change in the patient's/client's eating and drinking habits without the physician's knowledge.

N. Use of Antidepressants:

These medications are useful in the treatment of psychotic and nonpsychotic depressions. Most of their side effects are due to their anticholinergic activity; the physician should bear in mind that these effects are additive with the anticholinergic effects of other medications such as neuroleptics and anti-parkinsonian agents. Patients/clients with cardiac disease should be closely monitored for the possibility of adverse cardiac effects. Especially in patients/clients with cardiovascular/cerebrovascular disease, the possibility of orthostatic hypotension should be borne in mind. Based on the above, the following are recommended:

1) Patients/clients with a history of cardiac disease, especially coronary artery disease, should have a baseline EKG prior to the institution of tricyclic treatment. Furthermore, patients/clients over 40 should have a baseline EKG even in the absence of known cardiac disturbance, and a baseline EKG is recommended (but not mandated) for all patients/clients.

2. Use of antidepressants in patients/clients with significant EKG abnormalities, or other evidence of notable cardiovascular disease, should be accompanied by documentation of risk/benefit considerations and serial followup of cardiac function.

Failure of response to antidepressants can often be attributed to inadequate dosage/duration or lack of trial of a different class of antidepressant. Therefore, the following are recommended:

1) Adequate dosages should be employed, e.g., at least 150 mg. daily of amitriptyline or its equivalent for four to six weeks.

2) Nortriptyline probably has a "therapeutic window", and therefore a reduction rather than an increase may be beneficial.

3) Trial of a different class (amitriptyline vs imipramine) of tricyclic, if depression fails to respond to the first antidepressant employed. Family history is very useful in determining the class likely to be useful.

4) The new tetracyclic antidepressants are available as another possibility. Dysthymic disorder (DSM II Depressive neurosis), "atypical depression", and depressions not responsive to tricyclic antidepressants may respond to an MAOI inhibitor. Generally, if a tricyclic antidepressant has been used, the MAOI should usually not be started until two weeks after cessation of the tricyclic. No other MAOI, TCA, Reserpine, any psychostimulant, any drug containing epinephrine or its congeners, or anticholinergic antiparkinsonian drug should be used concurrently. The patient/client and staff should be fully informed of the importance of adhering to a tyramine-free diet (no wine, cheese, etc.). The same preliminary lab work as with TCAs should be done with MAOIs. An MAOI diet is available at Napa State Hospital.

0. Use of Hypnotics:

1) Insomnia: Sleep research literature extensively documents the ineffectiveness and counter-productiveness of almost all hypnotics after one week of administration. Flurazepam (Dalmane) is an exception, and is judged clinically effective up to three weeks. The following guidelines are offered:

a) Use of hypnotic, other than flurazepam shall be limited to no more than seven consecutive days, up to a total of 15 days per month. Additionally, commonly recognized dosage limits (e.g., PDR) shall be followed (e.g., 2 grams chloral hydrate in 24 hours, 200 mg. Seconal).

b) Insomnia is a symptom requiring treatment of the underlying cause when possible. When hypnotics are required more than 50% of the time after the first month of hospitalization, T.R.C. should be consulted.

- c) True insomnia is relatively rare in comparison to the "complaint of insomnia". A thorough history usually reveals the cause and ; probably a simple solution, e.g., adjusting the bedtime schedule.

2) Sedation: Hypnotics may be quite appropriate in cases of marked agitation/combativeness, particularly in the early phases of treatment. Such usage can ordinarily be minimized as the underlying mental disorder is identified and begins to respond to specific treatment. The general rules under Section II (PRN Order) of these Guidelines are applicable. In addition, the following principles are offered:

- a) When using sedatives, one should bear in mind the possible potentiation of sedative effects by concurrently administered medication.
- b) Where physical habituation is judged present, the offending hypnotic will be gradually withdrawn rather than abruptly discontinued.
- c) The use of these agents for sedation ordinarily will be limited to emergency situations in which IM administration is preferable to the oral route.

P. Psychostimulant Medication:

In children (and occasionally in adults) suffering from attention deficit disorder, especially with hyperactivity, there is a positive (paradoxical) response to the psychostimulants such as dextroamphetamine (Dexedrine)methylphenidate (Ritalin), or pemoline (Cylert). Indeed, these drugs are believed by some investigators to be the drugs of choice. The target symptoms of inattentiveness, distractability, and hyperactivity as well as the risk/benefit ratio should be documented. The response, positive or negative, should be documented.

Q. Use of Megadoses of Water-soluble Vitamins:

The use of megadoses of water-soluble vitamins as part of the treatment program for various disorders, including schizophrenia, is controversial. Advocates stress the uniqueness of the individual and state that some may have vitamin dependent conditions, i.e., a relative deficiency, probably of genetic origin; therefore, the uniqueness of the individual determines the optimum requirement. Also mentioned are the number of steps lying between the vitamins' ingestion and their delivery to the cells of the body. (1)

There is no clear indication in the literature at present as to the dosage level at which the term "mega" is appropriately applied. Operationally, therefore, we define as a megadose any amount which exceeds 100 times the daily dietary allowance. It is noted that the daily dietary "allowance levels are intended to cover individual variations among most normal persons as they live in the United States under usual environmental stresses". (2)

Before a megadose is prescribed, a consultation should be requested through the Therapeutic Review Committee. Megadoses probably should not be given to patients/clients with diabetes mellitus, gout, duodenal ulcer or liver disease; nor patients/clients with sickle-cell disease or G6PD deficiency, since deaths have been reported in patients/clients with these conditions, when given megadoses of vitamin C.

Accordingly, liver function studies, a uric acid level, a CBC, BUN, creatinine, T-3, T-4, and urinalysis are recommended prior to instituting megadoses. It is also recommended that a behavioral rating scale and an assessment of perceptual dysfunction be employed to aid in the evaluation of the efficacy, or lack thereof, of the treatment regimen.

Vitamin	Daily Dietary Allowance (2)	Megadose
B-3 (niacin)	13 mg. equiv. (females) 18 mg. equiv. (males)	1500 mg. equiv. (1.5 gms.) 1800 mg. equiv. (1.8 gms.)
B-6	2 mg.	200 mg.
C (ascorbic acid)	60 mg.	6000 mg. (6 gms.)

V. Documentation:

Since the State uses the Problem Oriented Record, all orders shall be keyed to the Problem List. When a physician writes an order changing the medication regimen there should be a corresponding explanatory note recorded in the chart. Orders on new patients/clients and monthly orders need not be individually explained in the I.D. Notes, as there are corresponding psychiatric evaluations and progress notes in the chart.

VI. The Medical Director shall keep himself or herself knowledgeable of the Department of Health Policy and practice in the administration of psychotropic medications. He or she shall be responsible for keeping the Therapeutic Review Committee informed of such policy and changes thereto.

VII. Any practices contemplated by the individual physician in the administration of psychotropic medications which are not in general use within the hospital shall be submitted to the Therapeutic Review Committee for prior approval.

VIII. Investigational Use of Marketable Drugs:

The use of any non-FDA approved drug shall be submitted for review and prior approval by the Therapeutic Review Committee and the Napa State Hospital Protection of Human Subjects Committee. This is not to be construed with the use of FDA-approved drugs for non-FDA-approved uses, when said usage is supported by the current literature but not yet acted upon by the FDA (e.g., lithium in depression or schizophrenia). In such cases the physician shall address the risk/benefit ratio, including "line of reasoning" for prescribing the drug. In cases of doubt, consult the Therapeutic Review Committee. Efficacy or lack of same should always be documented.

IX. These guidelines on the use of psychotropic medications will be reviewed and revised at least annually and more often if indicated as new scientific advances are made in the fields of mental disorder and psychopharmacology.

Guidelines Review and Revision, June, 1981.


Thomas E. Laskay, M.D.
Chairman, T.R.C.

**ACCEPTABLE UPPER LIMITS OF NEUROLEPTIC MEDICATIONS
FOR PSYCHIATRIC ADULTS**

NAME	GENERIC NAME	ACCEPTABLE UPPER LIMIT	FDA APPROVED UPPER LIMIT	REF. FOR DOSAGE	DOPAMINE-BLOCKING RATE **
<u>ALIPHATIC PHENOTHIAZINES</u>					
Thorazine	Chlorpromazine	1600mg/day *	2000mg/day	1,2,3	1
Vesprin	Triflupromazine	200mg/day		1,2	4
<u>PIPERIDINE PHENOTHIAZINES</u>					
Mellaril	Thioridazine	800mg/day	300mg/day	1,2,3,4	1
Serenil	Mesoridazine	400mg/day		1,2,3,4	2
Quide	Piperacetazine	160mg/day		1,2,3,4	10
<u>PIPERAZINE PHENOTHIAZINES</u>					
Tindal	Acetophenazine	400mg/day	20mg/day	4,4	5
Prolixin HCL	Fluphenazine	45mg/day		1,3	50
Prolixin Decanoate	Fluphenazine Decanoate	50mg/week 2cc		4,9	165 approx.
Prolixin "E"	Fluphenazine Enanthate	50mg/week 2cc		4,9	165 approx.
Trilafon	Perphenazine	64mg/day		2,3,4,5	10
Dartal	Thiopropazine	150mg/day	2	10	
Stelazine	Trifluoperazine	40mg/day *	40mg/day	1,3,4,5	20
Repose	Butaperazine	100mg/day		1,2,3,4	10
<u>BUTYROPHENONES</u>					
Maldol	Haloperidol	100mg/day	100mg/day	3,5	50
<u>THIOXANTHINES</u>					
Navane	Thiothixene	60mg/day *	60mg/day	1,2,3,4,5	25
Taractan	Chlorprothixene	600mg/day		1,2,4,5	1
<u>DIBENZOXAZEPINES</u>					
Loxitane	Loxapine	250mg/day		5	5-10
<u>DIHYDROINDOLE</u>					
Moban	Molindone	225mg/day		3,5	7-10

REFERENCES FOR EQUIVALENTS: 2,6,7,8, & 9,10.

* Up to 50% higher dosage may be used for the acute treatment phase or for acute exacerbations, but not to exceed two months without consultation.

** Approximate relative dopamine-blocking activity using CPZ as a standard.

GENERIC	TRADE	DOSAGE RANGE	
		AGE 12-65	UNDER 12 OVER 65
TRICYCLIC ANTIDEPRESSANTS:			
Amitriptyline	Elavil	100-300 mg.	25-150 mg.
Desipramine	Norpramin, Pertofrane	100-300 mg.	25-150 mg.
Doxepin	Adapin, Sinequan	100-300 mg.	25-150 mg.
Imipramine	Primine, Imfranil	100-300 mg.	25-150 mg.
Nortriptyline	Aventyl, Pamelor	50-150 mg.	10-75 mg.
Protriptyline	Triptil, Vivactil	20-60 mg.	5-30 mg.
MONOAMINE OXIDASE INHIBITORS:			
<u>AGE 16-65</u>			
Phenelzine	Nardil	30-90 mg.	•
Isocarboxazid	Marplan	50-150 mg.	•
Tranycypromine	Parnate	30-90 mg.	•
MINOR TRANQUILIZERS OR ANXIOLYTIC AGENTS:			
Chlordiazepoxide	Librium	20-100 mg.	10-40 mg.
Diacepan	Valium	10-40 mg.	2.5-20 mg.
Oxazepam	Serax	25-120 mg.	10-60 mg.
Chlorthalidate	Tranzone	25-60 mg.	7.5-30 mg.
Praxapam	Vertran	20-60 mg.	10-30 mg.
Lorazepam	Ativan	1-30 mg.	0.5-5 mg.
Meprobamate	Equanil, Miltown	400-1600 mg.	200-600 mg.
Hydroxyzine	Vistaril	75-400 mg.	25-200 mg.
PSYCHOSTIMULANTS:			
<u>AGE 5-18</u>			
Dextroamphetamine	Dexedrine	•	5-80 mg.
Methylphenidate	Ritalin	•	5-16 mg.
Propylamine	Cylert	•	37.5-150 mg.
SEDATIVES, HYPNOTICS:			
Chloral hydrate	Noctec, Aquachloral	1500 mg.	
Secobarbital	Seconal	200 mg.	
Amobarbital •	Amytal, Suesec	50 mg. ••	
Flurazepam	Dalmane	15-30 mg.	

• Usually not employed in this age group. If any doubts obtain an appropriate consultation.

•• 1.0 gm. per day on D.D. side.

REFERENCES CITED:

1. BIT II - Freedman, Kaplan & Sackoff - P. 1927
2. Clinical Use of Psychopharmacologic Drugs - Hallister - P. 33
3. Drug Treatment - G.S. Avery (Editor) - P. 208
4. AMA Drug Evaluations - Second Edition - Chapter 29
5. FDI - 1977
6. Schizophrenia Bulletin - Summer, 1975 - P. 30
7. Manual of Psychiatric Therapeutics - Shader (Editor) - P. 86
8. Psychiatric Annals - January 1976 Article by Durin - P. 85
9. Schizophrenia Bulletin - Volume 2, #4 - P. 506 & 507

ADDITIONAL REFERENCES:

1. Chemotherapy in Psychiatry - Baldessarini, Ross - 1977
2. Psychopharmacology: From Theory to Practice - Barchas, Jack, et al (Editors) - 1977
3. Clinical Handbook of Psychopharmacology - DiMascio, Albert and Shader, Richard (Editors) - 1976
4. Psychopharmacology: A Generation of Progress - Lytton, Morris, DiMascio, Albert and Millan, Keith (Editors) - 1976
5. Dorsey, R. et al., Psychopharmacological Screening Criteria Development Project.
Journal of the American Medical Association 241: 1021-1031, 1979.
6. Jefferson, J. and Greist, J.; Primer of Lithium Therapy. Baltimore, The Williams and Wilkins Company, 1977.

T.R.C. CONSULTANTS

Dr. John Baker
Dictates (c.c.)

Program II - 201 (Q-1) \$370
Not all day Wed, or Thurs.
P.M.

Dr. Richard Brenner
Dictates

Program IX (T-R) \$502 or 5342
not here Fridays

Dr. E. Perry Benbow
Dictates?

Program III - 330 (Q-7) \$254 or 5330

Dr. Samuel Paul
(no Dr. Neil consults)
Dictates (c.c.)

Program VII (A-4) Ext. 5393

Dr. C. Palmer
Dictates

Program II - 201 (Q-1) Ext. 5609 or 5301

Dr. Lawrence Post
Hand-write (c.c.)

Program III (0768) Ext. 5330
Unit 330-331

Dr. Herb McGrew
Dictates

Program IV (Asst. Pro. Dir.) Ext. 5584 - 5555
or have operator
locate

Dr. Else Ross
Handwrites

Program IX (T-4) \$334

Dr. Jeffrey Zwerin
Dictates

Program V (S-6) \$382

Dr. Richard Drury
Dictates

...
(Wickie's office) 2nd and 4th Fridays
Mendocino County Mental
Health (707-468-4303)

Dr. R. Wagner

Rosemary's office

Dr. Elaine Knutsen

Prog. Ed. \$436 or 5661

T.R.C. RESOURCE CONSULTANTS

Dr. Howard Mahon-Haft
Dictates (Internal Medicine)

Route thru
Chart Study Room

(Call Operator
BY 5434)

Box-175

Dr. Gerhard Nellhaus
Dictates (Neurology)

Neuro-Assessment Clinic

Ext 5674

Dr. Rothman (Part time)
Neurologist
Tardive Dyskinesia
Handwritings

c/o Vickie

T.R.C. COMMITTEE MEMBERS

Dr. Thomas E. Laskay, Chairperson

Dr. Peter Van Arman

Program II (S-1)

Ext. 5620 and 5372

Dr. Chang (Enille)

Program II - 942 (T-8)

Ext. 5342

Dr. Ross (Eise)

Program IX (T-4)

Ext. 5334

Dr. Paul

Program VII (A-4)

Ext. 5393

John Banducci, Pharmacist. Invite to all meetings.

Distribution of T.R.C. Minutes

To all Committee Members

Plus

- 1) Dr. O'Connor
- 2) Vickie (N.P.R.)
- 3) Dr. Swenson, Secretary of the Medical Staff (Program VIII A-2)
- 4) Dr. Brannick, President of the Medical Staff (Prof. Ed.)
- 5) Kathryn Milne, Medical Staff secretary
- 6) John Banducci, Pharmacist
- 7) The original copy goes to Sharon Hosler's office.
- 8) Dr. Donoviel
- 9) A copy goes in our T.R.C. "Minutes File"

M 05601

1 The Napa State Hospital Medical Staff Standards for the Use
2 of Psychotropic Medications shall be amended as follows:

3 1. Part II, subsection (c) shall read:
4 Consultations: Consultations to the Thera-
5 peutic Review Committee are mandatory if:
6 (1) the Patient has been diagnosed as suffer-
7 ing from tardive dyskinesa; or (2) the patient
8 is pregnant. Consultations to the Therapeutic
9 Review Committee are recommended if: (1) the
10 prescribed dosage of neuroleptic medications
11 exceeds 1200 milligrams per day in Thorazine
12 equivalent.

13 2. The former Part II, subsection (c) regarding
14 "Meetings" shall be renumbered Part II,
15 subsection (d).
16
17
18
19
20
21
22
23
24
25
26
27
28