

**REPORT OF
AN INVESTIGATION INTO THE DEATH OF
ROY DEAN LEVESQUE
AT SUTTER-YUBA BI-COUNTY MENTAL HEALTH
SERVICES PSYCHIATRIC HEALTH FACILITY**

**Pattern of Inadequate Care Culminates
in Death from Ignored Medication Reaction**

Note: When this report was originally published, we were known as Protection & Advocacy, Inc. (PAI). In October 2008, we changed our name from PAI to Disability Rights California.

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TABLE OF CONTENTS

I.	INTRODUCTION	7
II.	EXECUTIVE SUMMARY	10
-	INAPPROPRIATE CLINICAL PRACTICES, INCLUDING INADEQUATE MEDICATION PRESCRIBING AND MONITORING PRACTICES	10
-	PATTERN AND PRACTICE OF INAPPROPRIATE AND EXCESSIVE USE OF SECLUSION AND RESTRAINT AND UNJUSTIFIED DENIALS OF OTHER BASIC CIVIL AND CONSTITUTIONAL RIGHTS	11
-	INEFFECTIVE OVERSIGHT BY LOCAL AND STATE AUTHORITIES	12
	<u>RECOMMENDATIONS</u>	13
-	IMPLEMENTING EFFECTIVE STRATEGIES FOR IMPROVING CLINICAL PRACTICES, INCLUDING MEDICATION PRESCRIBING AND MONITORING PRACTICES	14
-	IMPROVING LOCAL OVERSIGHT AND REGULATORY ENFORCEMENT	15
III.	BACKGROUND	17
A.	ROY DEAN LEVESQUE.....	17
B.	SUTTER-YUBA BI-COUNTY MENTAL HEALTH SERVICES PSYCHIATRIC HEALTH FACILITY	18
C.	DEPARTMENT OF MENTAL HEALTH.....	20
D.	ANTIPSYCHOTIC MEDICATIONS	21
-	NEUROLEPTIC MEDICATIONS	22
-	NEUROLEPTIC-INDUCED PARKINSONISM.....	22
-	NEUROLEPTIC MALIGNANT SYNDROME	23
-	ANTICHOLINERGIC MEDICATIONS	24

- ANTIANXIETY MEDICATIONS	24
- MOOD STABILIZING MEDICATIONS	25
E. SECLUSION, RESTRAINT, AND THE MISUSE OF POSTURAL SUPPORTS.....	25
IV. INVESTIGATION INTO THE CIRCUMSTANCES SURROUNDING THE DEATH OF ROY DEAN LEVESQUE	27
A. SEQUENCE OF EVENTS	27
- EVENTS LEADING UP TO SYMH/PHF INPATIENT ADMISSION	27
- SYMH/PHF PHYSICAL ASSESSMENT UPON ADMISSION TO INPATIENT SERVICES	28
- COURSE OF LEVESQUE'S TREATMENT DURING INPATIENT ADMISSION AT SYMH/PHF	31
- EVENTS PRECEDING DEATH ON MARCH 15, 1994	32
B. CARE AND TREATMENT ISSUES	35
- SYMH/PHF'S USE OF "SECURITY" AND RESTRAINT ON LEVESQUE	35
- MEDICATIONS PRESCRIBED AND ADMINISTERED TO LEVESQUE	37
- SYMH/PHF'S FAILURE TO RESPOND TO SYMPTOMS CONSISTENT WITH ADVERSE REACTION TO PSYCHIATRIC MEDICATIONS	40
- SUBSTANDARD DOCUMENTATION PRACTICES	45
- LEVEL OF MEDICAL CARE PROVIDED	47
- SYMH/PHF RESPONSE TO LEVESQUE'S DEATH	49
C. CORONER'S INVESTIGATION.....	50
D. DMH'S INVESTIGATION.....	54

V.	INVESTIGATION INTO CARE AND TREATMENT PRACTICES AT SUTTER-YUBA BI-COUNTY MENTAL HEALTH SERVICES PSYCHIATRIC HEALTH FACILITY	55
A.	HISTORY OF DMH's REGULATORY ACTIVITIES.....	55
-	STAFF TRAINING	62
-	COMMUNICATION AND MANAGEMENT ISSUES.....	63
B.	PATTERN OF PATIENTS' RIGHTS VIOLATIONS	64
-	SYM/PHF PATIENTS' RIGHTS ADVOCACY PROGRAM.....	65
-	INAPPROPRIATE AND EXCESSIVE SECLUSION AND RESTRAINT	65
-	INFORMED CONSENT	68
-	CLOTHING.....	69
-	VISITORS.....	71
C.	HISTORY OF COMMUNITY CONCERN.....	71
VI.	FINDINGS AND CONCLUSIONS.....	73
-	SYM/PHF STAFF'S FAILURE TO RESPOND TO SYMPTOMS OF A SEVERE ADVERSE REACTION TO MEDICATIONS CONSTITUTED NEGLIGENCE WHICH LIKELY CAUSED LEVESQUE'S DEATH.	73
-	CONSISTENT WITH A LONG-STANDING PATTERN OF PRACTICE, LEVESQUE WAS SUBJECTED TO THE INAPPROPRIATE AND EXCESSIVE USE OF SECLUSION AND RESTRAINT.....	74
-	THE FACILITY'S DOCUMENTATION PRACTICES ARE GROSSLY SUBSTANDARD AND ADVERSELY AFFECT PATIENT CARE.	74
-	THERE ARE LONG-STANDING PATTERNS OF IDENTIFIED BUT UNCORRECTED DEFICIENCIES INVOLVING	

SUBSTANDARD CARE AND TREATMENT AT SYMH/PHF WHICH RAISE SERIOUS QUESTIONS ABOUT THE ADEQUACY OF EXISTING REGULATORY ENFORCEMENT MECHANISMS.75

VII. RECOMMENDATIONS77

- IN ORDER TO PREVENT FUTURE UNNECESSARY MEDICATION-RELATED HARM, THE DIRECTOR OF SUTTER-YUBA MENTAL HEALTH SERVICES SHOULD IMMEDIATELY IMPLEMENT EFFECTIVE SYSTEMIC STRATEGIES TO SUBSTANTIALLY IMPROVE MEDICATION PRESCRIBING AND MONITORING PRACTICES ON SYMH/PHF'S INPATIENT UNIT.77
- AS THE PRIMARY LOCAL GOVERNING AUTHORITY, THE SUTTER BOARD OF SUPERVISORS SHOULD PROVIDE MORE EFFECTIVE OVERSIGHT OF SYMH/PHF TO ENSURE THAT MENTAL HEALTH SERVICES ARE DELIVERED IN A SAFE, HUMANE, AND CONSTITUTIONALLY SUFFICIENT MANNER.....79
- THE FACILITY SHOULD IMMEDIATELY IMPLEMENT AN EFFECTIVE PLAN TO ENSURE ADEQUATE PATIENT CARE DOCUMENTATION PRACTICES.....80
- THE DEPARTMENT OF MENTAL HEALTH (DMH) SHOULD TAKE ACTION TO PROMULGATE APPROPRIATE REGULATORY ENFORCEMENT PENALTIES.82

I. INTRODUCTION

This report presents Protection and Advocacy, Incorporated's (PAI's) investigation into the circumstances surrounding the death of Roy Dean Levesque at Sutter-Yuba Bi-County Mental Health Services Psychiatric Health Facility (SYMH/PHF) in Yuba City, California, on March 15, 1994.

PAI is an independent, private, nonprofit agency which protects and advocates for the rights of persons with disabilities. Under federal and state law, PAI has the authority to investigate incidents of abuse and neglect of persons with mental or developmental disabilities. 42 United States Code (U.S.C.) §§ 6000 and 10801, et seq.; California Welfare & Institutions Code (WIC) § 4900, et seq.

On February 26, 1994, after becoming progressively and uncharacteristically confused, Levesque was seen at Sutter-Yuba Mental Health Outpatient Services. The outpatient psychiatrist prescribed Haldol, a psychiatric medication, and Levesque returned home after reportedly taking one milligram, as prescribed. Later that evening, Levesque experienced a dramatic change in his behavior and was escorted by local police to SYMH/PHF for crisis evaluation, accompanied by his father. He was put on a 72-hour involuntary hold pursuant to WIC § 5150, et seq., for further evaluation and inpatient hospitalization. During the course of his inpatient hospitalization, his family and friends, as well as SYMH/PHF staff, observed uncharacteristic and disturbing changes in Levesque's physical condition. After receiving care and treatment at SYMH/PHF for 17 days, Levesque was found dead on the morning of March 15, 1994.

PAI investigators determined that SYMH/PHF failed to diagnose and treat (or transfer Levesque to a facility capable of providing diagnosis and treatment) a series of persistent symptoms consistent with a serious adverse reaction to psychiatric medications. Although the cause of Levesque's death remains classified as "undetermined" by the Coroner, PAI investigators note that the ability to more definitively determine the cause of death was compromised by the facility's substandard documentation practices.

During the course of this investigation, PAI investigators also found long-standing patterns of significant, uncorrected care and treatment regulatory deficiencies at SYMH/PHF, as well as violations of fundamental patients' rights laws and regulations.

PAI's investigation, which was initiated in September of 1994, included:

Reviewing Levesque's outpatient and inpatient clinical records from SYMH/PHF.

Reviewing available relevant administrative and patient care policies, procedures, and directives from SYMH/PHF.

Reviewing California Department of Mental Health's (DMH's) Psychiatric Health Facility Regulations and Interpretive Guidelines, annual relicensure audits and reviews, and licensing-related correspondence pertaining to SYMH/PHF for the years 1989 through January 1995; and interviewing the DMH Psychiatric Health Facility (PHF) Licensing Evaluator, Delores Spahnn, Ph.D.

Interviewing over 30 other people, including SYMH/PHF licensed and unlicensed direct care, professional, medical, and administrative staff; local mental health consumers; family members and advocates; as well as Edmund C. Smith, the Director of Sutter-Yuba Mental Health Services at the time of Levesque's death, and the recently appointed Director of Sutter-Yuba Mental Health Services, DeLores E. Coggeshall.

Reviewing Sutter County Sheriff-Coroner's reports and evidence regarding Levesque's death, including physical and microscopic autopsy, investigation reports, photographs, certificate of death and related toxicological reports; and interviewing D.M. Henrikson, M.D., the pathologist who conducted the autopsy upon Levesque's body.

Consulting with Richard C. Unger, M.D., Ph.D., a board-certified psychiatrist and molecular biologist with over 16 years of experience in evaluating and treating persons with mental disabilities.

Consulting with William G. Ellis, neuropathologist, U.C. Davis Medical Center, Pathology Department.

Reviewing numerous other documents, correspondence, newspaper articles, and reports regarding SYMH/PHF inpatient and outpatient mental health services, including a 1993-1994 Sutter County Grand Jury Report.

- Reviewing current sudden-death and neuroleptic malignant syndrome (NMS) research articles, especially as they pertain to at-risk individuals with preexisting brain damage or mental retardation, such as Levesque.

- Conducting a preliminary review of all DMH licensing documents pertaining to PHFs throughout California from 1989 to the present.

II. EXECUTIVE SUMMARY

On February 26, 1994, when Roy Dean Levesque entered SYMH/PHF for the first inpatient psychiatric hospitalization of his life, he was a physically healthy 18-year-old man looking forward to his high school graduation. Although he was developmentally disabled, he had maintained a "B" average and was planning to go to trade school. Seventeen days later, in the early morning hours of March 15, 1994, following a course of treatment which included the misuse of seclusion and restraint, as well as the inappropriate prescribing and inadequate monitoring of psychiatric medications, Levesque died. When Levesque was found dead at approximately 7:00 AM on March 15, 1994, full rigor mortis was present in all of his extremities, and he was reportedly lying in the same position as he had been observed some seven hours earlier after having bumped his head on a nightstand as he fell face first onto his hospital bed.

PAI investigated the circumstances surrounding Levesque's death to identify what facility- based practices, if corrected, could prevent such neglect-related harm from recurring, and what systemic reforms were indicated to ensure the health and safety of persons with disabilities who must continue to receive mental health services at SYMH/PHF.

- INAPPROPRIATE CLINICAL PRACTICES, INCLUDING INADEQUATE MEDICATION PRESCRIBING AND MONITORING PRACTICES

Although the precise cause of Levesque's death remains classified as "undetermined," the evidence indicates that Levesque died from an adverse reaction to psychiatric medications which went undiagnosed and untreated. During his inpatient stay at SYMH/PHF, nursing and medical staff, as well as visitors, observed a number of disturbing symptoms, including, but not limited to: rigidity and muscle spasms, "robotic" posture, shaking, tremors, profuse sweating, flushing of the skin, and difficulty walking, as well as actually falling down. The explanation offered by staff for their ongoing failure to act was that Levesque reminded them of another family member who had also received treatment at SYMH/PHF. However, as pointed out by the physician PAI consulted, unlike his family member, Levesque had many of the known risk factors for developing neuroleptic malignant syndrome (NMS), including the fact that he was young, male, and had preexisting brain damage.

The physician PAI consulted provided this assessment of SYMH/PHF staff's failure to respond to symptoms which, according to the consultant, clearly signaled the possibility of a life-threatening reaction to psychiatric medications:

Although treatment staff observed, discussed and documented symptoms that raised serious issues about adverse reactions to the medications prescribed, including the possibility of neuroleptic malignant syndrome, a potentially fatal disorder which likely culminated in this young man's death, meaningful diagnostic steps were not taken. The fact that the patient in some ways reminded staff of another family member certainly provides no appropriate explanation for ignoring this young man's deteriorating condition.

- PATTERN AND PRACTICE OF INAPPROPRIATE AND EXCESSIVE USE OF SECLUSION AND RESTRAINT AND UNJUSTIFIED DENIALS OF OTHER BASIC CIVIL AND CONSTITUTIONAL RIGHTS

PAI determined that as a part of a long-standing pattern and practice, Levesque was subjected to the inappropriate and excessive use of seclusion and restraint as well as denied a number of other basic rights without just cause, including the right to wear his own clothing and to see visitors of his own choosing.

Levesque was subjected to four and one-half days of seclusion in what staff referred to as "security" or "maximum security," in the absence of any documented or reported aggressive or dangerous behavior, as well as an unknown amount of time restrained to a geri-chair -- a device which the facility was not authorized to use with Levesque because it was not employed for the purpose of increasing Levesque's "mobility and independent functioning" or, as required, "designed and applied . . . under the supervision of a physical or occupational therapist." 22 CCR § 77104(c).

Although facility staff repeatedly stated that providing services in the least restrictive manner is a fundamental principle underlying the delivery of all

care and treatment at SYMH/PHF, and that maintaining an "open," unlocked unit is for the purpose of affirming this principle, staff did not seem to understand that taking away a person's own clothing and isolating that person in "security" (i.e., seclusion) or restraining him or her in a "geri-chair" is far more restrictive and demeaning than locking the door of the facility or putting a fence around its perimeter. A review of licensing documents, as well as numerous statements by staff, further indicate that the improper use of seclusion and restraint is a long-standing practice at the facility.

The physician PAI consulted emphasized:

This patient received grossly substandard care which likely culminated in his death. Additionally, the pattern of basic patients' rights violations, especially the misuse of seclusion and restraints upon this young man, is a further indication of serious institutional problems. This death and its attendant circumstances warrant a comprehensive review of the facility's practices.

- INEFFECTIVE OVERSIGHT BY LOCAL AND STATE AUTHORITIES

Pursuant to a joint powers agreement effectuated in 1969, Sutter County has, and continues to assume, "overall administrative responsibility" for the delivery of mental health services "throughout Sutter and Yuba Counties as specified by the Lanterman-Petris-Short Act and local policy." However, there is a long-standing pattern of inadequate care and treatment and denials of other basic civil and constitutional rights of persons who receive inpatient services at SYMH/PHF, including, but not limited to, the inappropriate and excessive use of seclusion, restraint and medications. This indicates that more effective and comprehensive local governmental oversight and intervention is needed if the facility is to become a viable, competent, and trusted provider of mental health services to the mentally disabled citizens of Sutter and Yuba Counties.

In 1990 when the licensing and inspection authority for PHFs was transferred from the California Department of Health Services (DHS) to the California Department of Mental Health (DMH), the Legislature, in part,

stated: "The State Department of Mental Health shall develop and adopt regulations to implement this subdivision." To date, DMH has not promulgated any enforcement regulations and, according to DMH staff, has no plans of doing so. Instead, DMH has chosen to rely on preexisting DHS standards which have proven inadequate.

Despite considerable efforts by the DMH Licensing Evaluator, a review of the licensing documents pertaining to SYMH/PHF revealed a pattern of serious recurring deficiencies that went uncorrected for over five years, including, but not limited to:

- The failure to develop and implement appropriate and individualized interdisciplinary treatment plans.
- The failure to provide independent and adequate levels of treatment, programming, and other mental health services on the inpatient unit.
- The inappropriate and excessive use of seclusion and restraint; and
- The failure to comply with minimum standards governing medical records documentation and the development of patient care policies and procedures.

As pointed out by the DMH Licensing Evaluator, there are no punitive interim sanctions available under DMH's existing regulatory scheme, such as imposing fines or even ordering compliance with plans of correction. If a substandard facility such as SYMH/PHF does not correct serious deficiencies within a reasonable period of time, the only sanctions available are the suspension and/or revocation of the facility's license. These are drastic options which, to date (even given the pattern of serious and persistent health and safety deficiencies preceding Levesque's death), DMH have never pursued.

RECOMMENDATIONS

Based on these major findings, PAI recommends a number of specific actions to be taken by SYMH/PHF staff; the local Mental Health Services Director; the local governing authority, the Sutter Board of Supervisors; and the State Department of Mental Health (DMH).

- IMPLEMENTING EFFECTIVE STRATEGIES FOR IMPROVING CLINICAL PRACTICES, INCLUDING MEDICATION PRESCRIBING AND MONITORING PRACTICES

This facility, as well as the Sutter-Yuba Mental Health Services Division itself, has a history of inadequate management, supervision, and oversight which has adversely affected the quality of basic care and services provided at SYMH/PHF. The facility should overhaul its clinical services, especially its medication prescribing and monitoring practices. This will require inspired leadership, critical self-evaluation, clinical and medical services augmentation, more active supervision at the patient care level, as well as the implementation of effective quality assurance oversight and accountability mechanisms. The physician PAI consulted identified some of the potential institutional barriers to appropriate clinical services reform and expressed his discomfort with the facility's response to Levesque's death:

Particularly disturbing is the facility's apparent failure to understand that they made serious mistakes in the care and treatment of this patient. There appears to be a lack of serious self-evaluation. They do not seem to understand that this somewhat unique case and the grave consequences which ensued [i.e., death likely due to an untreated adverse medication reaction] signal significant institutional failings that need to be addressed. The facility's focusing on the fact that the precise reason for this young man's death hasn't been determined with absolute certainty misses the point. This patient received grossly substandard care which likely culminated in his death.

The recently appointed Sutter-Yuba Mental Health Director should immediately:

- Make whatever organizational, staffing, management, supervision or other changes are necessary to ensure that needed clinical services reforms are implemented, including the provision of adequate medical and nursing care services on a 24-hour basis.

- Ensure that SYMH/PHF is now implementing effective and comprehensive policies, procedures, directives, and in-service training so

that (1) the adverse effects of medications are identified, monitored, and responded to by medical and nursing staff in a timely and appropriate manner; and (2) at-risk individuals, such as Levesque, are identified and properly treated.

- IMPROVING LOCAL OVERSIGHT AND REGULATORY ENFORCEMENT

The Sutter Board of Supervisors should, without delay, exercise its full governmental and oversight authority to:

Develop a long-term corrective action plan in consultation with the Mental Health Advisory Board and consumers (especially present and former recipients of SYMH/PHF services) following an on-the-record hearing which affords the local mental health community, especially consumers, as well as family members, a full and fair opportunity to meaningfully influence the plan, particularly potential outcome performance measures.

Ensure that the newly appointed Mental Health Services Director is provided the unimpeded opportunity, including the vesting of appropriate discretion and decision-making authority, as well as the appropriation of necessary resources and support by the Board, to remedy the significant care, treatment, and patients' rights deficiencies at SYMH/PHF.

Hire appropriate outside clinical or other consultants, and place a "monitor" in the facility to oversee the implementation of institutional and lasting reforms which guarantee constitutionally sufficient levels of care, treatment, and conditions at SYMH/PHF, including the immediate and lasting cessation of the misuse of seclusion and restraint.

As the persistent and significant uncorrected health and safety deficiencies at this facility demonstrate, more effective regulatory enforcement mechanisms are necessary. DMH's reliance on preexisting program standards and its failure to promulgate appropriate enforcement regulations have unnecessarily contributed to placing persons such as Roy Dean Levesque in harm's way. DMH should immediately:

Initiate action to promulgate appropriate enforcement sanctions, which could include, for example, giving notice of violations, imposing fines, and/or putting facilities on probation pending timely compliance with ordered plans of correction.

Exercise its authority to identify specific deficiencies related to the care and treatment of Roy Dean Levesque, and to require further corrective plans as indicated.

Take whatever regulatory action is necessary between now and SYMH/PHF's review in the fall of 1995 to ensure that "incremental" improvements are ongoing and "significant" improvements are forthcoming in a timely enough manner to ensure minimal levels of safety, care, and treatment at SYMH/PHF.

Revoke the facility's license to operate if (1) significant noncompliance with basic care, treatment, and patients' rights requirements are evident during DMH's next comprehensive audit, including the misuse of seclusion and restraint or inadequate medication monitoring practices; and (2) DMH has, by that time, failed to promulgate appropriate enforcement sanctions that, once invoked, would likely result in the timely correction of identified deficiencies.

III. BACKGROUND

A. ROY DEAN LEVESQUE

Roy Dean Levesque was a physically healthy 18-year-old man when he entered Sutter- Yuba Bi-County Mental Health Services Psychiatric Health Facility (SYM/PHF) the evening of February 26, 1994. (This was the first time Levesque had ever received mental health services on an inpatient basis.) Seventeen days later in the early morning hours of March 15, 1994, following a course of treatment which included seclusion, physical restraint, and medications, Levesque was found dead.

Levesque was born on June 11, 1975 in Reno, Nevada, and resided in Yuba City for 17 years. As a child, he was diagnosed as having "attention deficit disorder with hyperactivity" and "developmental articulation disorder." According to his family, Levesque had earned a "B" average, was going to be graduating from Yuba City High School, had recently bought his first car, and was planning to go to trade school. Levesque also enjoyed music and outdoor activities such as boating, fishing and camping, and apparently was well-liked by his peers, school officials as well as staff on SYMH/PHF's inpatient unit.

As expressed by two different SYMH/PHF staff members:

Everybody loved Roy. He was sweet. He would go hug everybody or when you would come on duty, he would come up to you for a hug.

He had fond memories, good memories of the things he had done with his dad. He always talked positive about his school experience. . . . He just had that friendliness, cooperativeness, did what he was told. . . .

An April 24, 1994, article in the Appeal-Democrat, a local newspaper, reported that money had been donated to establish a video learning library in Levesque's honor. (While Levesque had some trouble reading, he reportedly excelled at video learning.) His funeral was well-attended by his peers from Yuba City High School and members of the community. The same article reported that students throughout the high school considered Levesque a positive influence and quoted the head of Yuba City's Special Education Program as saying: "He had a sensible view of the future that you don't often see in someone that age."

**B. SUTTER-YUBA BI-COUNTY MENTAL HEALTH SERVICES
PSYCHIATRIC HEALTH FACILITY**

Sutter and Yuba Counties are primarily agricultural communities located north of Sacramento.

According to SYMH/PHF's policy and procedures manual, as revised in October 1994:

The Sutter-Yuba Bi-County Mental Health Department was created during June of 1969, pursuant to a joint powers agreement between the County of Yuba and County of Sutter. Sutter County is the County which assumes overall administrative responsibility. . . . The Director of Mental Health is the department head for the Department of Mental Health and is directly responsible to the Sutter and Yuba County Administrators and through them to the two County Boards of Supervisors.

SYMH/PHF is located at 1965 Live Oak Boulevard in Yuba City, California. The facility, according to its policy and procedures manual is described as:

[A] psychiatric health facility [PHF] operating under licensure from the State Department of Mental Health. The PHF operates within the standards defined in the Psychiatric Health Facility Regulations and Interpretative Guidelines. Its treatment program operates in accordance with the Welfare and Institutions Code applicable to all . . . community programs in the state of California.

Although some services including screening and referral, placement and personal patient care are provided by unlicensed staff, all treatment services are provided under the direct supervision and orders of licensed mental health professionals. . . .

[B]ecause SYMH/PHF is a non-medical hospital setting, patients who need acute medical care concomitant with psychiatric care cannot be admitted until the patient has been medically evaluated and is declared to be stabilized. SYMH/PHF can only provide services to those individuals whose medical and/or physical problems can be handled on an outpatient level of

care. . . . The presence of an alcohol or a drug problem or developmental disability shall not be the basis for denial of treatment or admission if an acute psychiatric problem also exists. . . .

The range of services provided by SYMH/PHF interdisciplinary staff includes but is not limited to: (1) Crisis intervention/psychosocial assessment/diagnostic services; (2) Individual therapy; (3) Group counseling/education; (4) Medication therapy; (5) Activities therapy; (6) Inpatient psychiatric services.

The interdisciplinary treatment team works with patients to reduce the acute nature of the disorder as quickly as possible in order to return or refer the patient to a less intensive level of care.

Although SYMH/PHF has the capacity for only 18 beds, the facility reports an average census of 16 to 20 persons on the inpatient unit. In the fall of 1994, the inpatient unit was reportedly operating with approximately 12 to 15 regular full-time staff, supplemented by approximately 10 part-time staff. According to the recently appointed Mental Health Services Director, medical, nursing, and other direct care staffing on the inpatient unit is being augmented. Two-thirds to three-quarters of admissions to the inpatient unit are "5150s," or involuntary 72-hour psychiatric detentions. According to SYMH/PHF administrators, 30% to 40% of psychiatric inpatient admissions are due to methamphetamine use.

There are three daily shifts which are each ten hours long: AM shift (8:00 AM to 6:00 PM); PM shift (3:00 PM to 1:00 AM); and NOC shift (the night shift that runs from 11:00 PM to 9:00 AM). During every shift, there is at least one licensed nursing staff who is either a licensed psychiatric technician or licensed vocational nurse (referred to by the facility as the "charge nurse") and two unlicensed staff (referred to by the facility as "psychiatric attendants"). On weekdays, a registered nurse is available from 11:00 AM to 7:00 PM, as well as two regular inpatient psychiatrists.

The inpatient unit is described as an "open unit," meaning that it is unlocked, allowing free ingress and egress from the building. The building, which also houses mental health administrative and outpatient services, is free-standing, surrounded by a parking lot and predominantly unfenced grassy areas. The doors of the inpatient unit are closed and alarmed in the

evenings and on weekends, but never locked. According to the former Mental Health Services Director:

I guess it's a philosophy. . . . For those who need security, we have some of those rooms. We started on a long-term philosophic basis that said we can do this in an unlocked facility and we can treat people in a more -- less hospital and more home-like, more pleasant surroundings. . . . I think it gives the patients a little more respect, a little more self-determination.

See, photograph - Appendix A.

C. DEPARTMENT OF MENTAL HEALTH

The California State Department of Mental Health (DMH) is responsible for inspecting, licensing, and regulating the quality of care provided at psychiatric health facilities (PHFs) such as SYMH/PHF throughout the state. Health & Safety Code (H&S) § 1254.1(a). Pursuant to its licensing and inspection authority, DMH is responsible for assuring compliance with all applicable rules and regulations governing the provision of basic care and services provided by PHFs. Such basic care and services include, but are not limited to: psychiatry, clinical psychology, psychiatric nursing, social work, and drug administration. See, H&S §§ 1250.2(a), 1275.5(c).

In 1990 when the licensing and inspection authority for PHFs was transferred from the California Department of Health Services (DHS) to DMH, the Legislature, in part, stated: "The State Department of Mental Health shall develop and adopt regulations to implement this subdivision." H&S § 1254(e). At the same time, the Legislature also stated, in part:

. . . All regulations relating to the licensing of psychiatric health facilities heretofore adopted by the State Department of Health Services, pursuant to authority now vested in the State Department of Mental Health . . . shall remain in effect and shall be fully enforceable by the State Department of Mental Health with respect to any facility or program required to be licensed as a psychiatric health facility, unless and until

readopted, amended, or repealed by the Director of Mental Health.

H&S § 1275.5(c).

To date, DMH has not promulgated its own enforcement regulations and continues to rely on preexisting program standards established by DHS. According to DMH staff, DMH has no plans to promulgate any PHF regulations.

DMH has a limited range of options to enforce compliance with existing rules and regulations, which include: (1) providing consultative services to assist in the identification or correction of deficiencies or the upgrading of the quality of care; (2) identifying deficiencies and requiring mutually agreed upon plans of correction; and (3) taking action to revoke or suspend the license. Under the existing regulatory scheme, DMH does not have the authority to impose interim punitive sanctions such as placing facilities on probation, levying fines, or ordering timely compliance with required plans of correction. DMH reportedly has never revoked or refused to reissue a PHF license. See, H&S §§ 1280, 1294.

As of March 1995, DMH monitored 13 PHFs. Four additional PHF licenses were in voluntary suspension (a status unrelated to the identification of deficiencies for reasons such as economic inviability). DMH has one full-time evaluator assigned to oversee PHFs throughout the state. This one evaluator's responsibilities include: reviewing initial applications for licensure, conducting annual relicensure audits and surveys, investigating unusual occurrences, responding to complaints, providing consultative services, analyzing pending legislation that may affect PHFs, calculating licensing fees, and preparing an annual report to the Legislature. Prior to July of 1993, these regulatory responsibilities were allocated 1,000 hours (or roughly 25 weeks or six months) per year under a contract position.

D. ANTIPSYCHOTIC MEDICATIONS

Roy Dean Levesque, as do the vast majority of psychiatric inpatients, received antipsychotic medications as part of his ongoing treatment at SYMH/PHF. Antipsychotic or, as they are sometimes called, psychotropic or neuroleptic medications are "customarily used for the treatment of

symptoms of psychoses and other severe mental and emotional disorders." 9 CCR § 856.

- **NEUROLEPTIC MEDICATIONS**

These medications benefit many individuals by minimizing or eliminating psychotic symptoms such as hallucinations (seeing and hearing things which do not exist) and delusions (grossly inaccurate beliefs which are obviously contrary to fact). They are also intended to reduce excitability, anger, and confusion. Because of their effects on the nervous system, the class of antipsychotic drugs called neuroleptics (e.g., Haldol, which Levesque received) can produce neurological dysfunction, often referred to as extrapyramidal symptoms (EPS). Symptoms of EPS include, but are not limited to, tremors, uncontrollable restlessness (akathisia), painful spasms of the face and neck muscles (dystonia), difficulty swallowing (dysphagia), fidgeting, and shuffling movement of the feet. Neuroleptics have also been associated with heart, breathing, and blood pressure problems; hyperthermia; tardive dyskinesia (repetitive, and sometimes permanent, involuntary movements); and neuroleptic malignant syndrome (a potentially fatal disorder implicated in Levesque's death).

- **NEUROLEPTIC-INDUCED PARKINSONISM**

In addition, according to the physician PAI consulted, Levesque's EPS-related symptoms, as observed by SYMH/PHF staff, family members and friends, were consistent with neuroleptic-induced or "secondary" parkinsonism (as opposed to "primary" Parkinson's disease -- a slowly progressive, degenerative central nervous system disorder whose onset generally is after age 40, with increasing incidence among the elderly). Neuroleptics with the least anticholinergic activity (discussed below), such as Haldol, which Levesque received throughout his hospitalization, produce the greatest incidence of "secondary" parkinsonism.

The diagnostic features of "secondary" or neuroleptic-induced parkinsonism include:

[T]he presence of parkinsonian signs or symptoms (i.e., tremor, muscular rigidity, or akinesia) that develop in association with the use of neuroleptic medication. . . . Parkinsonian tremor is a steady, rhythmic oscillatory movement . . . that is typically slower than other tremors and is apparent at

rest. . . . The tremor can be suppressed, especially when the individual attempts to perform a task with the tremulous limb. . . . Parkinsonian muscular rigidity is defined as excessive firmness and tensing of resting muscles. It may affect all skeletal muscles or it may only involve discrete muscular areas. Two kinds of rigidity occur: continuous ('lead pipe') rigidity and cogwheel rigidity. In lead-pipe rigidity, the limb or joint resists movement and feels locked in place. The rigidity is continuous (i.e., the limb usually does not show moment-to-moment fluctuations). In cogwheel rigidity, as the muscle is stretched around a joint there is a rhythmic, ratchet-like resistance that interrupts the usual smooth motion of the joint. Cogwheel rigidity can be felt by placing the hand over the joint being moved. Cogwheel rigidity occurs when the muscles are passively moved, is most common in the wrists and elbows, and often waxes and wanes. . . . Akinesia is a state of decreased spontaneous motor activity. There is global slowing as well as slowness in initiating and executing movements. Normal everyday behaviors (e.g., grooming) are reduced. Individuals may complain of feeling listless, lacking spontaneity and drive, or oversleeping. Parkinsonian rigidity and akinesia can be manifested as abnormalities in gait or decreases in length of stride, arm swing, or overall spontaneity of walking. Other signs include bent-over neck, stooped shoulders, a staring facial expression, and small shuffling steps.

American Psychiatric Association, Diagnostic and Statistical Manual of Mental Disorders, 4th ed., 1994, p. 736.

- **NEUROLEPTIC MALIGNANT SYNDROME**

Neuroleptic malignant syndrome (NMS), which, according to the physician and neuropathologist PAI consulted, was the most likely cause of Levesque's death, is a relatively uncommon but life-threatening complication from treatment with antipsychotic medications. Its prevalence ranges from as low as 0.5% to as high as 2.4%. NMS is fatal 20% to 30% of the time. Common causes of death include respiratory failure, cardiovascular collapse, and kidney failure. Its core features include mild to extreme elevated body temperature, muscular rigidity, and fluctuating consciousness. The syndrome can occur at any time following the administration of antipsychotic drugs. Its onset is apparently not related to the duration of drug exposure or to toxic overdoses. See, Barry H. Guze, M.D., and Lewis R. Baxter, Jr., M.D., "Medical Intelligence - Current Concepts: Neuroleptic Malignant Syndrome," *The American Journal of*

Psychiatry, 1989, Vol. 313, No. 3, pp. 163-166; Gerard Addonizio, M.D., et al., "Symptoms of Neuroleptic Malignant Syndrome in 82 Consecutive Inpatients," American Journal of Psychiatry, 1986, Vol. 143, No. 12, pp. 1587-1590.

Levesque had many of the predisposing risk factors for developing NMS. These known risk factors included physical exhaustion from agitation, mental retardation, and the fact that Levesque was young and male. Indeed, the known mortality from NMS in individuals such as Levesque, who have preexisting brain damage, is nearly three times greater than in individuals with functional psychoses. Arthur Lazarus, M.D., "Neuroleptic Malignant Syndrome and Preexisting Brain Damage," The Journal of Neuropsychiatry and Clinical Neuroscience, 1992, Vol. 4, pp. 185-187. According to Lazarus:

Further efforts must therefore be directed toward prevention. Individuals with preexisting brain damage and CNS [central nervous system] abnormalities . . . should be recognized as high risk candidates for NMS. Neuroleptics should be used carefully in such individuals, at the lowest possible doses, and only for specific target symptoms.

The treatment for NMS is "prompt discontinuation of neuroleptics and intensive medical and nursing care." Arthur Lazarus, M.D., "Should Neuroleptic Malignant Syndrome be Treated in a Private Psychiatric Hospital or a General Hospital?" General Hospital Psychiatry, 1990, Vol. 12, pp. 245-247.

- **ANTICHOLINERGIC MEDICATIONS**

Antiparkinsonian or antidyskinetics, also known as anticholinergic medications (e.g., Cogentin, which Levesque received), are generally prescribed to reduce extrapyramidal symptoms (EPS). These drugs can also produce their own adverse "anticholinergic" effects. Anticholinergic effects may include sedation, sleepiness, constipation, dizziness, disturbed coordination, tachycardia, fever, heat stroke, and disorientation.

- **ANTI-ANXIETY MEDICATIONS**

Anti-anxiety medications (e.g., Ativan, which Levesque received), also known as minor tranquilizers or minor depressants, are prescribed in an

attempt to control anxiety, nervousness, tension, agitation, and sleep disorders. More frequent adverse effects include sedation, lethargy, dizziness, and problems with balance and walking.

- **MOOD STABILIZING MEDICATIONS**

Examples of these include Lithium, a well-known mood stabilizer, and Tegretol, an anticonvulsant -- commonly prescribed for the treatment of seizures and also for its mood- stabilizing effects. Levesque received both of these medications. Side effects include drowsiness, dizziness, blurred vision, clumsiness, slurred speech, loss of appetite, hallucinations, abnormal heart rhythm, and difficulty swallowing or breathing.

E. SECLUSION, RESTRAINT, AND THE MISUSE OF POSTURAL SUPPORTS

Regulations governing psychiatric health facilities (PHFs) such as SYMH/PHF define both seclusion (which the facility has historically referred to as "security" or "maximum security") and "exclusion time out" as forms of physical or "behavioral" restraint. Seclusion involves isolating the person in a locked area while "exclusion time out" involves removing the person from an activity to another area in the same room or vicinity for purposes of modifying a behavior. See, 22 CCR §§ 77029, 77010. However, seclusion, exclusion time out, as well as behavioral restraint itself (which involves restricting the person's movement through mechanical devices or techniques such as ties or belts), may only be used as a measure to protect the person or others from injury, and only when less restrictive measures are not sufficient to ensure the physical safety of the mental disabled individual or others. In addition, seclusion, exclusion time out, and "behavioral" or physical restraint cannot be used as punishment, for the convenience of staff, or as a less restrictive alternative form of treatment. See, 22 CCR §§ 77101(b), (c); 77103(a); 9 CCR § 865.5. Any form of restraint used for punishment or other improper purposes or periods of time beyond which it was ordered constitutes abuse and must be reported to protective services agencies. See, e.g., WIC §§ 15610.63(f)(1), (2), (3).

Applicable regulations also make it clear that postural supports cannot be used for purposes of behavioral or physical restraint as occurred with Levesque. A postural support is defined as "a method other than

orthopedic braces used to assist patients to achieve proper body position and balance." 22 CCR § 77021.

A "geri-chair" (referring to its origin of use among the "geriatric" or elderly population), which was used improperly upon Levesque, is a chair-like postural support device with a desktop surface that can be locked at the waist. Geri-chairs and other postural supports, such as "posey vests" (i.e., cloth vests with several ties that can be used to help position a person in a chair or bed), are properly used, for example, to assist persons recovering from traumatic injuries, such as a stroke, as part of a rehabilitation plan to help them achieve proper body alignment or a change in positioning. However, the misuse of postural supports as physical or "behavioral" restraint devices, especially upon elderly persons in nursing homes, is well-documented, as is the resultant harm. See, e.g., Steven H. Miles, M.D., and Patrick Irvine, M.D., "Deaths Caused by Physical Restraints," *The Gerontologist*, 1992, Vol. 32, No. 6, pp. 762-766. In an attempt to prevent such misuse and harm upon persons who receive mental health services in psychiatric health facilities, existing regulations require that postural supports, including "geri-chairs," only be "applied . . . [u]nder the supervision of a physical or occupational therapist" for the purpose of "improv[ing] a patient's mobility and independent functioning." See, 22 CCR §§ 77104(a), (b), (c).

IV. INVESTIGATION INTO THE CIRCUMSTANCES SURROUNDING THE DEATH OF ROY DEAN LEVESQUE

A. SEQUENCE OF EVENTS

- EVENTS LEADING UP TO SYMH/PHF INPATIENT ADMISSION

On the evening of Friday, February 25, 1994, Levesque attended a basketball game at Yuba City High School. He began acting uncharacteristically confused, and his father was called to bring him home. Concerned about his son's confused behavior and "incoherent rambling," Levesque's father telephoned SYMH/PHF at 11:23 PM and made plans to take his son to the facility the next day, Saturday, February 26, 1994.

According to his father, Levesque spent the majority of February 26, 1994, waiting to be seen by a psychiatrist. SYMH/PHF records reflect that Levesque was seen in person by various mental health professionals on a "drop-in" crisis basis at 9:45 AM, 6:00 PM, and 11:45 PM. Following the 6:00 PM evaluation, Levesque was given a 30-day outpatient prescription of 1 mg. Haldol tablets, one tablet to be taken at bedtime.

During interviews with PAI Investigators, Levesque's father stated that after he filled the Haldol prescription at Walgreen's Pharmacy, his son took one pill, as directed, and they returned home. Between 9:00 PM and 11:45 PM, there was a dramatic change in Levesque's behavior and he was escorted back to the facility by local police, accompanied by his father.

According to the medical records, as reported by his father, shortly after returning home, Levesque started acting "very restless . . . couldn't decide if he wanted to eat or not" and was standing in his bedroom in his underwear repeatedly counting "1-2-3-4" as he alternately turned away from and towards the bedroom door. Levesque's father also told PAI investigators that he said to his son, "Well, Roy, let's go to bed. I mean, these pills are starting to make you act goofy. Let's get some sleep and you'll feel better tomorrow." Levesque's father further told PAI investigators, "Then I reached out and took his hand. I walked with him towards the bed. He started struggling with me because he didn't want to go to bed." Then, as stated by Levesque's father, as he bent over in the hallway of the family home to pick up their puppy:

Roy then jumped on my back and started hitting me. . . . I called Mental Health and I told the lady on the phone, 'I don't

know what the pill was that you gave my son, but he just attacked me.' And she said, 'What do you mean, "he attacked me"'? I said, 'My son just jumped on me and attacked me and started beating me up.' And she says, 'Well, we'll have to bring him in.' I said, 'Well, okay. I'll bring him in.' She says, 'No, you'll have to have the police bring him in.' . . . And then I told Roy that he had to go to Mental Health and spend the night. . . .

Levesque's father told PAI investigators that this was the first and only time that his son had been aggressive towards him. No other assaultive behavior was reported or documented after this incident.

SYM/PHF staff who observed Levesque during the 6:00 PM contact and again when he was later brought in at 11:45 PM commented to PAI investigators that Levesque had become "considerably less verbal," had developed a "flight posture," and was "rigid" and "shaking." SYMH/PHF staff attributed all of these symptoms to "anger." SYMH/PHF staff also noted that Levesque "would make disconnected statements that [were] unrelated to the questions" and that he had "inappropriate laughter."

Upon admission to SYMH/PHF's inpatient unit at 11:50 PM, Levesque reportedly was oriented to person, time and place, but was "disorganized," "delusional," and "confused." Although Levesque was not assaultive and was even described at that time by staff as "cooperative," he was placed directly into "maximum security" (locked seclusion/isolation). He remained in "security" for the next four and a half days.

- SYMH/PHF PHYSICAL ASSESSMENT UPON ADMISSION TO INPATIENT SERVICES

A member of SYMH/PHF administrative staff explained the process for conducting physical assessments by nursing staff upon admission:

The nursing staff does that [physical assessment] upon admission. The vital signs. It's not a physical examination. It's a nursing physical assessment. Because we don't want to admit somebody that's got an unrecognized serious medical problem, and usually if you check somebody's vital signs and

you check their color and you check their pupillary reactions, you know, you're not going to miss many serious medical problems. I suppose somebody's blood sugar could be sky-high or something. But that's the nursing physical screen to make sure it's appropriate to have him on our non-hospital psychiatric unit.

At 11:50 PM, Levesque's admissions vital signs were recorded as: Temperature 99.4, Blood Pressure 156/114, Pulse 92, Respirations 20.

The Inpatient Admission Physical Assessment noted that Levesque did not appear to be in any physical distress at the time; that he had an accidental bruise on his forehead; that he appeared to have "loose associations" and was "irritable"; that his speech was "pressured"; and that his skin was "warm," "moist" and "flushed."

PAI investigators note that although the above information was gathered by an unlicensed member of nursing staff, it was later co-signed by a licensed member of nursing staff. The date and time is not listed after the signatures, which is misleading since the co-signature by licensed staff, PAI investigators learned, was not obtained until over 24 hours later.

According to the unlicensed staff member who conducted the initial admissions physical assessment:

I went to do his vital signs, he wasn't very cooperative and he gave me a false name. The counselor told me that the read was different. . . . Sometimes when people are in maximum security we're unable to get their vitals because either they're uncooperative or combative. . . .

In discussing Levesque's admissions vital signs with PAI investigators, the licensed staff member who later reviewed and co-signed the physical assessment commented:

That's [referring to 156/114 blood pressure and 92 pulse] a little abnormal, but he was in an agitated state and sometimes when they're agitated -- they retook it and they usually write on the nurses' notes whether it's normal or not. .

. . . But a lot of times the pulse is way up and the blood pressure is way up -- the diastolic is pretty high, 114; 119 is on the border and 140 [systolic].

As with the Physical Assessment nursing document, the first portion of the Physical Examination medical document, labelled "Psychiatric History Summary," had an undated signature by a psychiatrist who was not on the unit until over 24 hours after the time of Levesque's admission. The psychiatrist's signature followed a checked statement which stated: "This person does not appear physically sick, but psychiatric problems warrant admission to the psychiatric inpatient unit; the complete physical examination will be done later by other medical staff."

The actual physical examination which, according to the medical records, occurred on March 2, 1994 (four days after his admission to SYMH/PHF), stated that Levesque was "unable to participate [with] questions for [physical health] history." Upon examination, it was noted that Levesque had a "resting tremor to both legs" and that his neurological condition could not be tested because of his "inability to cooperate." Vital signs at that time were recorded as: Blood Pressure 122/86, Pulse 120, Respirations 20. (The physician who examined Levesque did not document what, if anything, the "resting tremor to both legs" may have indicated about Levesque's physical or neurological condition.)

According to SYMH/PHF staff, a screen for seven different street drugs is usually completed when there are concerns that illicit drugs may be contributing to the person's deterioration. A psychiatrist's note dated March 5, 1994, indicates that a limited drug screen was done: "It is reported that the toxicology was negative on admission from amphetamines, cocaine, and marijuana. It is still possible that a more esoteric substance such as PCP may have been involved, with the events prior to admission, although the patient's family history suggests that a first psychotic break, in fact, is possible." There is no lab report or any further documentary evidence in the chart regarding why or when the drug screen was obtained.

The Unusual Occurrence Report sent to DMH after Levesque's death stated: "His laboratory [findings] and physical examination on admission were unremarkable."

- COURSE OF LEVESQUE'S TREATMENT DURING INPATIENT ADMISSION AT SYMH/PHF

Levesque's diagnoses, as stated by his assigned inpatient psychiatrist, were Organic Mood Disorder with Psychotic Features and Moderate Mental Retardation. However, the physician PAI consulted noted:

The only indication in the records of anything 'organic' about this young man is that he was developmentally disabled which of course does not explain the presence of psychotic behavior. This presumptive diagnosis should have been pursued more closely, but as with the treatment which ensued, almost no further diagnostic inquiry appears to have occurred.

Upon his admission to SYMH/PHF, Levesque exhibited symptoms that were described as "catatonic" by SYMH/PHF staff. Catatonia is a psychiatric condition characterized by excitable or inhibited abnormal body movements and stiff, statue-like posturing. SYMH/PHF staff explained that as Levesque's "catatonic" symptoms subsided and as he became "manageable on the open unit," his condition fluctuated between brief periods of minor improvement and, alternately, medical and mental decompensation.

During the course of his inpatient stay, SYMH/PHF staff, as well as visitors, observed a series of disturbing symptoms relating to Levesque's deteriorating condition: rigidity, stiffness, "spasms," "robotic" posture; "[r]ight shoulder raised awkwardly with head pulled into it"; restlessness, "antsy" and unable to "stay in one place"; poor appetite; difficulty sleeping; tremors and "shaking limbs"; fatigue; constant thirst; profuse and remarkable diaphoresis (sweating); complaints of feeling hot -- "face flushed red at times," and at other times a "pasty pallor," cold and clammy; mouth agape; motor retardation (slow, plodding movement); incontinence of urine; difficulty communicating (mutism, stuttering, stammering); and difficulty with ambulation (unsteady, prodding, "shuffling" gait with a "bizarre" and "striking" posture; reduced arm swing; "stooped" forward listing posture, walking with bent knees and tip-toeing on the balls of feet; "stumbling" and running as if he was falling forward).

Five different SYMH/PHF staff members reported to PAI investigators that they had directly observed or heard Levesque fall on several different occasions, but only one of these falls was documented in his medical record: "Fell down in hallway after being asked to slow down his gait."

In addition, a number of unlicensed SYMH/PHF staff claimed that vital signs were taken almost every shift and that symptoms such as those above were monitored and reported daily on a routine basis to licensed staff. However, Levesque's clinical records, for the most part, do not document this.

An overall synopsis of Levesque's treatment at SYMH/PHF was provided in his Discharge Summary:

Roy had been observed having inappropriate behavior, on/off, since September, but most noticeably at a basketball game 2/25/94. Roy had long-standing developmental disabilities + had been seen in our Children's dept. at an earlier age. M/S [mental status] on admit: mood, anxious, affect labile + inappropriate, [without] logical conversation, [without] insight, delusional, confused, disorganized. MD started Roy on Haldol + Tegretol [with] slow response. Roy was catatonic for several days. . . . With catatonia, he walked [with] a shuffle + bent-over with hands + arms extended, sometimes unsteady, perspiring profusely. At one point he appeared to improve: understandable speech, more appropriate gait, [without] hallucinations. Adjustments of medications continued. . . . Staff assessment was toward Pt experiencing 1st psychotic break since symptoms were identical to Pt's [family member] who is MI [mentally ill] + a Pt here. Medication adjustments made little improvement. . . .

- EVENTS PRECEDING DEATH ON MARCH 15, 1994

On March 14, 1994, at approximately 11:00 PM, staff reported that Levesque fell to the floor in the hallway of the inpatient unit. The Incident Report about this fall stated, in part: ". . . gait was fast, upper body weight leaning forward. Initial staff warning to slow gait, straighten up was to no avail. . . . Fall not observed, though was heard with slumping thud." Later,

at approximately 12:00 AM on March 15, Levesque bumped his head on a nightstand as he fell face first onto his bed. This second incident was not documented in the medical record and no injuries were reported from either of these incidents.

The Unusual Occurrence Report sent to DMH by the facility, dated March 17, 1994, stated this about the events leading to Levesque's death:

The patient was up and about at approximately midnight on the 15th and was assisted back to bed by members of our staff. The patient was in the room with two other patients -- all three were observed hourly during the evening, all three appeared to be sleeping. At the morning medication check, Mr. Levesque was deceased.

According to one SYMH/PHF staff member interviewed by PAI investigators:

. . . [W]e make rounds to see that they're asleep or awake or how they're sleeping once an hour. . . . He probably slept one night out of four -- the night that it happened [referring to Levesque's death]. . . . That [referring to bumping his head on the nightstand] probably happened sometime between 11 and midnight 'cause I was on duty and he got up. I said, 'Roy, you have to go back to bed.' And I sort of turned him around physically by his shoulders and escorted him back to bed. And he just sort of bent over at the waist on the bed and so I picked his legs up and put him in bed and in doing that the bed moved and he just bumped his head. . . . He didn't react at all that I noticed. There was no welt, cut, or bruise or anything noticeable. . . .

This same staff member indicated that Levesque remained in the same position all night after his fall onto the bed and added: "Generally, we don't check to see if they're breathing."

PAI investigators note that when Levesque was found dead in the early morning hours of March 15, 1994, he was reportedly in the same position as he had been observed some seven hours earlier. PAI investigators

further note that the Coroner's photographs reveal what appears to be a rather awkward sleeping position to maintain for over seven hours. These observations alone raise issues as to whether it was reasonable for SYMH/PHF staff not to have checked on Levesque more closely.

In discussing how patients are checked during the night shift, one staff member said: "All we need to see is skin. We don't go in there and shake them and say, 'Are you asleep?' We just check him, he's there. We had no other reason to go in and check him."

The staff member who found Levesque dead in the early hours of the following morning told PAI investigators:

[O]n this night I remember discussing it so vividly with the psych attendant, 'Isn't it good that he's sleeping?' We thought he was asleep because like I told the officers, we don't turn the lights on or anything. We check and see that they're in bed. . . .

I went in the room to give him his medicine and he was face down and I said, 'Roy, you need to wake up and take your medicine for me.' Sometimes it's kind of -- I don't know if he was hard of hearing or just slow to process, and he didn't move so I put my med tray down on the table and kind of rubbed his back. I said, 'Roy, you need to wake up and take your medicine.' And he still, at that time I could feel that he was kind of stiff and I pulled the blanket down and [saw] definite blood pooling on his back -- blue all over. So I went out of the room and called 911 to get an ambulance sent out. We checked the heart and stuff. There was definite rigor mortis set in, like I said the blood was pooling and the paramedics were on the scene. . . . We just thought he was sleeping. We thought he was getting better." [Emphasis added.]

Levesque's medical records reflect that on March 15, 1994, at approximately 7:10 AM, the staff member making medications rounds discovered Levesque lying on his stomach, cyanotic (with a bluish skin color due to lack of oxygen) and without a pulse. A record from Bi-County

Ambulance Service indicates that a paramedic arrived at 7:28 AM and that death was declared at 7:30 AM.

SYM/PHF staff immediately notified the Sutter County Coroner-Sheriff and made arrangements to meet with Levesque's family at his father's home.

B. CARE AND TREATMENT ISSUES

- SYM/PHF'S USE OF "SECURITY" AND RESTRAINT ON LEVESQUE

Seclusion or restraint may only be used when alternative less restrictive measures are not sufficient to ensure the physical safety of the mentally disabled person or others. In addition, seclusion and restraint cannot be used for the convenience of staff, or as a substitute for a less restrictive alternative form of treatment. Nevertheless, Levesque was subjected to four and a half continuous days of seclusion, as well as an unknown amount of time restrained in a "geri-chair" in the absence of any properly documented or reported justification.

According to the medical records and staff accounts, despite the fact that Levesque was characterized as "cooperative" upon admission, he was immediately escorted into the "maximum security" room (i.e., locked seclusion) by staff and police on the rationale that he had been aggressive towards his father prior to hospitalization. He remained in "security" for the next four and a half days -- from the evening of February 26, 1994, until the morning of March 3, 1994. The physician's orders purporting to authorize the ongoing use of seclusion specify no reason whatsoever to justify it and simply say: "Place in security" and "Cont. [continue] in security."

The "maximum security" room, as SYM/PHF staff refer to it, is, in reality, a locked seclusion room used to isolate a patient, much like solitary confinement in a jail setting. A SYM/PHF staff member noted that these rooms are also used to house persons transferred from the jail for mental health treatment, and described the two maximum security rooms as: "locked rooms with steel doors, permanent bunk bolt[ed] down to the floor, grate over the window . . . plaster walls and a toilet in there and a sink. The water is controlled from the outside." See, photograph - Appendix A.

Nursing notes indicate that Levesque was allowed "out of security for a shower" at 10:15 AM on March 3 and then placed "directly into Geri-chair. . . [A]ttempts to climb out of G. chair . . . asked if he had to go to [bathroom] . . . limbs tremors sliding/shuffling gait/tilted forward." SYMH/PHF staff told PAI investigators that Levesque was frequently restrained in the geri-chair although Levesque's records do not reflect the frequency with which this type of restraint was reportedly applied. One staff member recalled: "I remember the leg movements [referring to Levesque's leg tremors] because we have a geri-chair and when he was falling a lot we would put him in that during the day so he could be in a common area. So that he could have interaction with his peers and the staff."

The only other references to this kind of restraint in the records are found in an AM March 7 nursing note which states: "Placed in G. Chair with posey," and a PM March 8 nursing note which states: "He is posied in a w/c [wheelchair] for his own safety."

A frequent visitor to the unit remarked, "I truthfully don't know if he could walk or not. I never saw him out of the geri-chair."

During interviews with PAI investigators, SYMH/PHF staff repeatedly made statements indicating that they did not have a basic understanding of what kind of behavior or situation justifies the use of seclusion and restraint. Frequently cited reasons for secluding persons with mental disabilities (in "security" or "maximum security") included "AWOL risk" (may possibly elope from facility) and "unmanageable on open unit." In fact, one staff member told PAI investigators that Levesque was placed in "security" because he had "rigid posturing like he wanted to get out of there . . . he was an elopement risk, and . . . knowing he was DD [a person with a developmental disability], I certainly didn't want to take any chances of him being an elopement risk 'cause we're an open facility."

SYMH/PHF administrative and direct care staff told PAI investigators that they provide one-to-one direct staff observation, as required, whenever any type of physical restraint, including a geri-chair, is used outside the confines of a seclusion room. As explained by one SYMH/PHF administrator, as was the situation with Levesque, geri-chair restraint is used within ten feet of the nurses' station to "prevent falls" or "if they are confused, wandering, undirectable [and we] don't have the staff to do a 1:1 at the time." This statement evidences a basic lack of understanding about

the purposes of, and standards governing the use of restraint. Existing regulations clearly prohibit the use of physical or "behavioral" restraint because of inadequate staffing or in the absence of dangerousness. Nor can it be credibly asserted that when staff restrained Levesque in the geri-chair and locked the desk-top surface at his waist, thus preventing him from standing or walking, this was being done as a "postural support" for the purpose of improving Levesque's mobility and independent functioning. Moreover, existing regulation only permits postural supports to be "designed and applied . . . under the supervision of a physical or occupational therapist." (PAI investigators note that no physical or occupational therapist was employed by the facility at that time.)

- MEDICATIONS PRESCRIBED AND ADMINISTERED TO LEVESQUE

The following descriptions of the medications that Levesque received during the course of his treatment at SYMH/PHF, including their side effects, are taken from the Physicians' Desk Reference (PDR). For more information concerning the medication dosages, times administered, and symptoms observed, please see Appendix B.

HALDOL (haloperidol) is an antipsychotic medication that can be responsible for many adverse reactions, including the following, which are consistent with observations documented in Levesque's chart: a range of EPS (extrapyramidal symptoms), including rigidity, tremors, shaking, and dystonia (spasms of the shoulder, neck and trunk muscles, often characterized by the arm held in a rotated position and the head drawn back to one side); insomnia; restlessness; anxiety; agitation; drowsiness; depression; lethargy; confusion; exacerbation of psychotic symptoms, including hallucinations and catatonic-like behavioral states which may be responsive to drug withdrawal and/or treatment with anticholinergic drugs; tachycardia (rapid heartbeat); hypertension (high blood pressure); anorexia (loss of appetite); diaphoresis (sweating); and NMS (neuroleptic malignant syndrome). Additionally, per the PDR: "Cases of sudden death and unexpected death have been reported in association with the administration of HALDOL. . . ."

When HALDOL is used in conjunction with LITHIUM, the PDR states that a syndrome "characterized by weakness, lethargy, fever, tremulousness and confusion, extrapyramidal symptoms" and abnormal lab values can

develop. Because of this, "patients receiving combined such therapy should be monitored closely for early evidence of neurological toxicity and treatment discontinued promptly if such signs appear."

COGENTIN (benztropine) is an anticholinergic medication used to control EPS, including neuroleptic-induced or "secondary" parkinsonism. Adverse reactions include the following, which are consistent with observations documented in Levesque's chart: tachycardia, dry mouth to the point of interfering with speaking or eating; confusion, disorientation, exacerbation of psychotic symptoms, nervousness, depression, listlessness, and flushing of the skin.

TEGRETOL (carbamazepine) is normally used to control seizures, though some psychiatrists prescribe it as a mood stabilizer. TEGRETOL, like COGENTIN, may produce anticholinergic side effects. Per the PDR, when TEGRETOL and LITHIUM are taken at the same time, as was the situation with Levesque, this "may increase the risk of neurotoxic side effects." TEGRETOL can be responsible for many adverse reactions, including the following, which are consistent with observations documented in Levesque's chart: drowsiness, unsteadiness; sweating; hypertension; disturbances of coordination, confusion, fatigue, speech disturbances, abnormal involuntary movements, depression with agitation; fever, and chills.

LITHIUM is an inorganic element that is used to treat mood disorders. In combination with HALDOL, it can produce neurological toxicity. As previously stated, when LITHIUM and TEGRETOL are taken together, the risk of neurotoxic side effects may increase. In addition, according to the PDR, "Decreased tolerance to lithium has been reported to ensue from protracted sweating. . . ."

ATIVAN (lorazepam) is an antianxiety medication. Adverse reactions include the following, which are consistent with observations documented in Levesque's chart: sedation, unsteadiness, disorientation, depression, change in appetite, sleep disturbance, and agitation.

During the course of his treatment at SYMH/PHF, Levesque's medications were frequently adjusted. According to Levesque's father, when he asked SYMH/PHF staff about these adjustments and expressed concern that his son was "getting worse," he was told:

'Well, it isn't balanced today. We're going to try this. He should be better tomorrow.' And then I go in there, 'Oh, yeah, he's having a bad day, but we're dropping this and adding that, and he should be better tomorrow.' Every day it was 'better tomorrow.' . . . From what I understand, I guess, they changed over and tried the Lithium. He got better. And then all of a sudden he was totally out of it. And I asked her -- 'well, we got the levels too high or too low' that he would be 'better tomorrow.' Well 'tomorrow' was the day that I found out my son was dead and he wasn't 'better.'

During interviews with PAI investigators, Levesque's assigned psychiatrist expressed that she had some reluctance about prescribing Lithium to Levesque "because a choice with people who have a lot of organic problems like Roy . . . Lithium is not considered that good a medication as Tegretol. . . ." Despite this reluctance, the psychiatrist did prescribe Lithium in addition to Tegretol, on March 10, 1994, explaining: ". . . [Y]ou see, in medicine we're also taught to give medications which other family members do well on. So I was willing to give it a try for that reason. His [family member] had been stable on it."

In commenting on this medication decision-making process, the physician PAI consulted said:

This is an example of how medication decisions were made in the absence of appropriate diagnostic inquiry. Without reasonable explanation, the Lithium was added before the effectiveness of the Tegretol was evaluated. Tegretol blood levels weren't taken until about two weeks into this patient's stay (this is usually done three to four days into treatment) and the patient's Tegretol level was still subtherapeutic on the day lithium was added. The patient therefore was exposed to the risks of this medication but not the potential therapeutic benefits. And, while it is certainly appropriate to consider that a medication worked for a patient's family member that is only one factor, among many, from all available sources, to be considered.

- SYMH/PHF'S FAILURE TO RESPOND TO SYMPTOMS CONSISTENT WITH ADVERSE REACTION TO PSYCHIATRIC MEDICATIONS

As discussed above, Levesque experienced a series of documented symptoms which should have signaled the possibility of a serious adverse reaction to the medications.

Levesque's grandmother, who reportedly conveyed her concerns about the medications to staff, described the condition of her grandson during one of their visits:

He was in a gorilla stance, all puffed up, he was sweating, his teeth were clenched, and he had a fever. . . . He was just burning up and then when it stopped he got cold and clammy, but he was still sweaty. . . . His face was all swollen -- his eyes almost swollen shut. . . . And he would stand and then he'd sit, and he'd stand and he would walk off here and then he'd come back and sit and then he'd get to another chair and then he'd sit and all this time this stuff was dripping down him. You would wonder what in the name of God that had done that to that kid. Then you'd ask somebody -- 'Well, it's the medication.'

A member of unlicensed direct care staff expressed his frustration about what he perceived to be the lack of appropriate clinical response by professional staff, telling PAI investigators:

. . . [I]t bugged the hell out of me to see someone like that and no change like I said, and nothing was done about it. Whether something was done about it or not, as I reported to the nurses section, 'look at this guy. He looks terrible and these were his vital signs. . . .' When I informed the nurse -- I would run down the symptoms -- 'he's not doing good at all,' and the nurse would say, 'no, he's not' and check the medications he was on. . . . Nothing really came of it.

In responding to questions about the treatment decisions that they made, including why the issue of neuroleptic malignant syndrome and other

serious adverse medication reactions were not more vigorously pursued, SYMH/PHF staff repeatedly stated to PAI investigators that Levesque's overall appearance reminded them of another family member who had also received treatment at the facility. According to one SYMH/PHF staff member, daily treatment team meetings included the following discussions:

. . . [T]hey talked about the sweating, shuffling, taking his vital signs, is he having side effects . . . neuroleptic malignancy came up more than once . . . and then it would come up -- other people have that who have worked here when his [family member] was here. He even looks like his [family member] did when [the family member] was in the hospital. There was some talk about the medicine [the family member] had taken and what worked for [the family member].

PAI investigators note that the same staff members who repeatedly explained their actions and omissions by pointing to the perceived similarity between Levesque and another family member failed to acknowledge the obvious differences between Levesque and that same family member -- including the fact that Levesque was young, male and developmentally disabled. As pointed out by the physician PAI consulted, all of these factors should have been recognized as increasing Levesque's risk of developing neuroleptic malignant syndrome.

In addition, PAI investigators note that not all staff shared the opinion that Levesque's symptoms "were just like his [family member]'s." As explained by one SYMH/PHF staff member:

. . . [S]ome of the older nurses that had worked with [the family member] because his [family member] was like that when [the family member] was ill, but when [the family member] was in last year, I noted that [the family member] had that slow plodding kind of psychomotor retardation, but not the diaphoresis, or any of the other stuff.

The physician PAI consulted made this observation about the lack of diagnostic inquiry and follow-up:

Although treatment staff observed, discussed and documented symptoms that raised serious issues about adverse reactions to the medications prescribed, including the possibility of neuroleptic malignant syndrome, a potentially fatal disorder which likely culminated in this young man's death, meaningful diagnostic steps were not taken. The fact that the patient in some ways reminded staff of another family member certainly provides no appropriate explanation for ignoring this young man's deteriorating condition.

According to the literature and the physician PAI consulted, although diagnostic criteria for NMS remain controversial, available diagnostic tools include:

- A trial period of withholding neuroleptic medications. (Resolution of NMS may take five to ten days after withdrawal of oral neuroleptics.)
- Vigilant monitoring of vital signs (blood pressure, respirations, body temperature, pulse) on a regular basis to identify signs of autonomic instability.
- Vigilant monitoring for other physical indications, such as diaphoresis (sweating), rigidity, and altered consciousness.
- Obtaining a laboratory value of creatinine phosphokinase (CPK), a simple blood test which measures skeletal muscle breakdown. (Elevated levels have been reported in 91% to 95% of NMS cases in which CPK values were obtained.)
- Conducting a complete blood count for leukocytosis (increased white blood cells), which has been reported in approximately 40% of NMS cases.
- Conducting liver function tests, in which elevated enzymes may be present.
- Obtaining an EEG (electroencephalogram). This is not necessarily diagnostic of NMS; in some cases results may be normal or show a diffuse slowing.

- Obtaining electrolyte data to determine if abnormalities exist.

- Urine testing to check for metabolic acidosis and renal failure, which has been associated with some neuroleptic-related fatalities.

See, e.g., Silvia S. Gratz, et al., "The Treatment and Management of Neuroleptic Malignant Syndrome," *Prog. Neuro-Psychopharmacol. & Biol. Psychiat.*, 1992, Vol. 16, pp. 425-443; Richard D. Boyd, "Neuroleptic Malignant Syndrome and Mental Retardation: Review and Analysis of 29 Cases," *American Journal on Mental Retardation*, 1993, Vol. 98, No. 1, pp. 143-155; Vicken Y. Totten, M.D., et al., "Neuroleptic Malignant Syndrome Presenting Without Initial Fever: A Case Report," *The Journal of Emergency Medicine*, 1994, Vol. 12, No. 1, pp. 43-47.

According to the documentation, with the exception of the subtherapeutic levels of Tegretol reported on March 10 and March 14, 1994, the following laboratory tests were conducted, with unremarkable results:

March 1, 1994	Complete blood count, chemistry panel, thyroid panel
March 8, 1994	Complete urinalysis
March 14, 1994	Lithium level

During interviews with PAI investigators, Levesque's assigned psychiatrist stated that the muscular rigidity and stiffness experienced by Levesque appeared to wax and wane and that NMS was ruled out because "he wasn't running [a] high temperature, his body wasn't hot . . . didn't stay rigid like that all the time and he wasn't showing any changes at all. He came in with the kind of behavior and stayed that way, except for a couple of days when he was doing well and then went back." PAI investigators note that, per current NMS literature, the diagnosis of NMS does not require a high temperature. Mohammad S. Jahan, M.D., et al., "Neuroleptic Malignant Syndrome," *Journal of the National Medical Association*, 1992, Vol. 84, No. 11, pp. 966-969. In addition, contrary to the psychiatrist's statement, Levesque's body did appear to feel hot at times (as evidenced by the direct observation of his visitors and SYMH/PHF staff -- the profuse sweating, his face being "flushed red" at times, complaints of "feeling hot" and the stripping off of clothing).

Levesque's assigned psychiatrist also described the remarkable appearance of Levesque's walk as a "dancing doll walk" in which the back of the hands face forward, with arms bent perpendicularly at the elbow, slightly tilted outward, chin jutting forward, buttocks jutting back, and a wide-based gait. This observation led the psychiatrist to believe that "something like Parkinson['s]" (but unrelated to the medications) was the underlying cause of Levesque's bizarre body movements. Huntington's chorea (a progressive and degenerative disease of neurons in the brain, characterized by jerky, sudden involuntary movements after which the resulting posture may be prolonged for a few seconds) was also considered by the psychiatrist but was ruled out because "it's not common in young men."

PAI investigators underscore that, while the precise cause of Levesque's death may never be determined, the evidence strongly suggests that Levesque had an adverse reaction to psychiatric medications that went undiagnosed and untreated. As pointed out by the physician PAI consulted, the failure to respond is particularly disturbing in light of the fact that staff actually discussed and considered the possibility of neuroleptic malignant syndrome but did not even try the simplest of diagnostics -- such as obtaining a CPK level because Levesque "looked like" another family member. Moreover, as explained by the physician PAI consulted:

The severe autonomic and extrapyramidal symptoms evident in this case, which included profuse sweating, flushing of the skin, bizarre body movements including tremors, rigidity, severe muscle spasms, stooped posture, a shuffling listing gait and even falling -- with or without persistent 'lead pipe' rigidity -- signaled the very real possibility of neuroleptic malignant syndrome which required immediate and potentially life-saving clinical attention.

One staff member recalled her discomfort in continuing to administer the medication when NMS had not been ruled out:

I remember telling [another staff] 'I do not feel comfortable giving this Haldol with these symptoms' and he said he had discussed this with the doctor and the other team and they had come to the conclusion, although they could understand

my concern, that they didn't think it was neuroleptic malignant syndrome -- that it was just catatonia and that he should probably have it. I think it should have been ruled out -- there are types of catatonia -- the malignant catatonia, too, but I just think he may, should have had some expert advice. Instead of thinking that's in the past and thinking of [his family member] and thinking it's the same thing, same course.

- SUBSTANDARD DOCUMENTATION PRACTICES

PAI investigators were told that staff discussions about obtaining an MRI (magnetic resonance imaging) or CT (computed tomographic scan) scan reportedly occurred as early as March 4, 1994. SYMH/PHF staff also stated that Medi-Cal refused payment for these proposed tests. However, PAI investigators note that SYMH/PHF could produce no documentation regarding these requests. In addition, as pointed out by the physician PAI consulted, although an MRI or CT scan is an appropriate tool for ruling out certain organic causes of decompensation, such testing is not considered diagnostic -- as is the simple CPK blood test which SYMH/PHF never obtained -- for ruling out the potentially fatal disorder of neuroleptic malignant syndrome.

Although SYMH/PHF staff insisted that Levesque's vital signs were taken daily, perhaps even every shift, his clinical records reflect documentation of complete vital signs (blood pressure, respirations, pulse and temperature) only twice during his entire inpatient hospitalization: when he was admitted on February 26, 1994, at 11:50 PM and on March 8, 1994, at 8:00 PM. PAI investigators could find only six entries pertaining to Levesque's vital signs during his inpatient hospitalization:

- (1) February 26, 1994, 11:50 PM -- Temperature 99.4, Blood Pressure 156/114, Pulse 92, Respirations 20.
- (2) March 2, 1994, time unknown -- Blood Pressure 122/86, Pulse 120, Respirations 20.
- (3) March 5, 1994, between 8:00 AM and 4:00 PM -- "c/o [complaint of] feeling hot - temp was within normal limits."

(4) March 7, 1994, between 8:00 AM and 4:00 PM -- "vitals taken, WNL [within normal limits]."

(5) March 8, 1994, 8:00 PM -- Temperature 99, Blood Pressure 122/82, Pulse 92, Respirations 20.

(6) March 13, 1994, between 8:00 AM and 4:00 PM -- Temperature 95.8.

One nursing staff member who worked four days a week reported taking Levesque's vital signs daily and told PAI investigators: "His temperature never did go over 100 to my knowledge, and that was rectally. . . . His blood pressure didn't fluctuate very much. I can't really say anything abnormal about his respiration. . . ." A family member also reported that on March 6, 1994, Levesque's temperature was taken rectally, with results "somewhere in the 100's . . . slightly elevated."

SYM/PHF staff stated to PAI investigators that vital signs were taken routinely and documented on "cheat sheets," (which are sheets of paper containing significant clinical observations which are later transferred to the permanent medical record as appropriate). As shown above, and especially given Levesque's condition, vital signs were infrequently recorded in the permanent medical record, and, the "cheat sheets" were unavailable to PAI investigators because they had been discarded.

As the physician PAI consulted explained:

The documentation in the clinical record is grossly substandard. Basic information such as the recording of vital signs on a routine basis was not done. Additionally, the process of clinical inference is almost totally missing. The records do not in any meaningful way provide insight into the basis for the treatment decisions made for this patient, including the clinical rationale underlying the adjusting of his medications and the failure to respond to what the record indicates were potentially dangerous side effects that went undiagnosed and untreated. This presents an even greater problem whereas, in this facility, a patient may be treated by different physicians whose primary means of communication is the patient's medical record. In such circum- stances good

documentation becomes even more important if appropriate medical care is to be delivered.

- LEVEL OF MEDICAL CARE PROVIDED

Although SYMH/PHF is licensed as a psychiatric health facility (PHF) -- a non-hospital facility intended to provide a low-cost alternative to acute inpatient psychiatric hospitalization -- it must still "[a]ssure that all services including care and treatment provided to patients, is adequate and safe at all times." 22 CCR § 77081(a). California regulations governing PHFs further require that "[a] facility shall accept and retain only those patients for whom it can provide adequate care." 22 CCR § 77113(b). Additionally, "[a] physician shall be on-call at all times for the provision of physical health care and those services which can only be provided by a physician. . . . Patients requiring general acute physical health care shall be diverted from admission or transferred to a general acute hospital." 22 CCR § 77061(d); emphasis added.

DMH's Interpretive Guidelines regarding this latter regulation state:

The basic principle is that a PHF admission is appropriate if a patient's medical condition can be managed on an outpatient basis. A PHF admission is not appropriate if a particular patient's condition cannot be managed by the PHF for any reason. If the PHF does not have the resources with which to provide needed medical care to a prospective patient, the patient may not be admitted to the PHF.

Several SYMH/PHF staff members expressed their perspectives regarding the level of medical care provided at the facility:

We don't do output and intake. This is a non-hospital facility, but we do watch to see how much they're drinking anyway. . .

There wasn't good follow up. . . . No good back-up for getting medical evaluations.

In my opinion, I thought he [Levesque] should have at least been sent to a medical hospital.

[W]e're not a medical facility -- we're just a PHF . . . we get a lot of folks here that are not appropriate for being here . . . it takes a lot of staff to care for a client like [Levesque] and we have two psych. attendants and a nurse for eighteen patients and then you . . . get somebody with medical problems and we're just not really set up for it, and I think sometimes that we can keep patients that are inappropriate to be here.

. . . [I]t seemed to me that there should have been something more we could have done. . . . I think we should have gotten more consultations of some sort. Neurological, whatever. . . . It wasn't that he didn't have a lot of care from the staff and the [psychiatric] attendants. He had a lot of attention, but I just don't know if he had enough professional care.

Levesque's assigned psychiatrist at SYMH/PHF stated that the treatment team did not consider transfer to a medically oriented facility because:

I would have considered after he was stable because nobody was going to accept him the way he was for medical evaluation. He was on Medi-Cal and it's almost impossible to get them admitted anywhere. Literally, we have to beg people here when we want the non-psychiatrists to take them in a car and take them into the hospital, keep them there to be evaluated. . . . There are only two neurologists [in the area]. One doesn't take Medi-Cal. The other one does. He just came in. He does take Medi-Cal but he takes one Medi-Cal a week. . . .

The physician PAI consulted provided this overall assessment of the medical care provided Levesque:

The most basic level of diagnostic inquiry and follow up did not occur. They talk about MRI's and CT scans and even the possibility of neuroleptic malignant syndrome and then drop the issues without explanation. The monitoring of this

patient's response to treatment was far below acceptable standards. Medical staff did not even order the close monitoring of vital signs or the drawing of a CPK -- simple tasks that could have and should have been done given this patient's symptoms and ongoing level of distress and deterioration.

- SYMH/PHF RESPONSE TO LEVESQUE'S DEATH

Following Levesque's death, a small group of psychiatrists who work at SYMH/PHF, including the assigned psychiatrist, participated in a death review meeting. PAI investigators were told that this mortality review did not include a review of the Coroner's report by the assigned psychiatrist and that no minutes or other record of the meeting were kept.

As stated by the former Mental Health Services Director concerning the cause of Levesque's death:

Whether catatonia was responsible for his death or neuroleptic syndrome, a person can still argue about those kinds of things. I suspect we're never going to know. Various people are going to speculate as to what they think or what they might feel or what they think this might [go] together or whatever. But the reality is that this young man died in a psychiatric facility on a low dosage of medication, after [having] been here a fairly lengthy time. . . . I think we're stuck with an unexplained death -- medically unexplained. . . . I'm not sure anything we would have done with Roy would have made a difference. I think the medical care he got from the staff was as good as he would have gotten anywhere. . . . But the reality is this young man died probably the best I can tell because of an act of God. I don't know. It was not because he got too much medication or too little medication or he wasn't taken care of. The medical evidence is relatively clear about that as best as I can tell. . . .

Other than the meeting described above, PAI investigators could find no evidence of remedial action taken by SYMH/PHF specifically in response to Levesque's death.

The physician PAI consulted expressed his discomfort with the facility's lack of critical analysis of the clinical circumstances surrounding Levesque's death, stating:

Particularly disturbing is the facility's apparent failure to understand that they made serious mistakes in the care and treatment of this patient. There appears to be a lack of serious self-evaluation. They do not seem to understand that this somewhat unique case and the grave consequences which ensued [i.e., death likely due to an untreated adverse medication reaction] signal significant institutional failings that need to be addressed. The facility's focusing on the fact that the precise reason for this young man's death hasn't been determined with absolute certainty misses the point. This patient received grossly substandard care which likely culminated in his death. Additionally, the pattern of basic patients' rights violations, especially the misuse of seclusion and restraints upon this young man, is a further indication of serious institutional problems. This death and its attendant circumstances warrant a comprehensive review of the facility's practices.

C. CORONER'S INVESTIGATION

After receiving a call from SYMH/PHF staff at 7:37 AM, March 15, 1994, the Chief Deputy Coroner of Sutter County Sheriff/Coroner's Office responded to the scene, arriving at 8:00 AM. The Coroner was briefed by a Sutter County Sheriff Deputy who had begun interviewing SYMH/PHF staff witnesses. A detective from the Yuba City Police Department joined the Coroner, and photographs and a videotape of the scene were taken. Levesque's Certificate of Death indicates that death was officially pronounced at 7:47 AM.

According to the Coroner's report of investigation, red/pink lividity (settling of blood into body parts after death, due to gravity) was observed "all along the lower chest, legs, face and neck, indicating that the victim was possibly laying face down, at time of death." Also, full rigor mortis was documented as present in all of Levesque's extremities, from the neck to the feet. PAI investigators note that these findings indicate that Levesque had been

dead for at least two hours, if not more, as lividity usually becomes visible two hours after death and rigor mortis usually sets in within two to four hours, becoming fully established after twelve hours. PAI investigators again note that Levesque was found dead in the same position as he was last seen alive over seven hours earlier.

Additionally, a small amount of blood was observed under Levesque's nose, inside his mouth, on the pillowcase under his face, and on the bed sheet beneath his pillow. The Coroner did not see any injury to Levesque's head, and "no sign of foul play was observed at the scene."

An autopsy was conducted at 7:00 AM the following day on March 16, 1994. No signs of external head trauma were noted. It was noted that there was a "slight amount of gray- brown soil" on the bottom of Levesque's feet. The Coroner's photographs indicate that the heels of Levesque's feet were clean, which is consistent with SYMH/PHF staff's observations that Levesque was shuffling on the balls of his feet. Specimens gathered for toxicology included blood drawn from a thigh artery and from the heart, stomach contents, urine, bile, and eye fluid. A microscopic examination of various body tissue samples was conducted on March 31, 1994.

Autopsy findings included:

- An involuted thymus (a lymph gland at the base of the neck) with rare petechial hemorrhages (bleeding underneath the membrane).
- Erosion of the esophagus (tube leading from the mouth to the stomach).
- Some thinning of the stomach lining with focalized red spots due to distended capillaries (small blood vessels).
- Moderate to marked congestion and edema in focalized areas of the lungs.
- Small deposits of cholesterol on the gallbladder.
- Slight bleeding on both sides of the mastoid (tissue located under the scalp behind the ear).

□ Hypopigmentation (loss of pigment) of neurons (nerve cells) bilaterally (on both sides) of the substantia nigra (a subportion of the cerebellum, the part of brain responsible for voluntary muscle tone, balance and coordination), as well as evidence of mild lack of oxygen noted in the cerebellum. (A search of the NMS- related literature identified a case study where, as in Levesque's autopsy, one of the findings was hypopigmentation of the substantia nigra, which the authors noted may be yet another central nervous system-related risk factor for developing NMS. See, H.J. Gertz and L.G. Schmidt, "Low Melanin Content of Substantia Nigra in a Case of Neuroleptic Malignant Syndrome," *Psychopharmacopsychiatry*, 1991, Vol. 24, pp. 93-95.

The toxicology reports noted that the Lithium and Tegretol were slightly under therapeutic levels. Levels of Haldol were never tested, but according to the forensic pathologist interviewed by PAI investigators, the neuropathologist PAI conferred with, as well as the physician PAI consulted, Levesque's pre-death symptoms were not consistent with those one would expect to see from toxic levels of Haldol. They all agreed that Levesque's pre- death symptoms, including those consistent with extreme neuroleptic-induced parkinsonism, likely signaled the development of neuroleptic malignant syndrome.

The autopsy report included these statements by the forensic pathologist:

In general, sudden unexpected death in young adults who have a psychiatric illness result from one of three or four causes: single or combined drug toxicities, water intoxication, neuroleptic malignant syndrome, and adverse drug reactions (especially cardiac dysrhythmia). Postmortem toxicologic studies have ruled out drug toxicities in this case, and vitreous electrolyte studies exclude the possibility of water intoxication, as well as electrolyte abnormalities caused by lithium and hyperglycemia.

Neuroleptic malignant syndrome, which is seen in patients treated with major tranquilizers (including haloperidol) is a rare fatal reaction, which does not appear to be related to the dose of the tranquilizer administered, which is characterized by muscular rigidity, hyperthermia (high fever), and evidence

of instability of the autonomic nervous system (manifested by irregular pulse or blood pressure), tachycardia, diaphoresis (sweating), and cardiac dysrhythmias. The only physical finding in this case which would suggest neuroleptic malignant syndrome is a description in a progress note (dated March 8, 1994) that the patient was 'sweating a lot,' but there is no evidence that a temperature was taken to confirm or disprove high fever.

PAI investigators note that the forensic pathologist relied on the inadequate documentation in Levesque's medical records from SYMH/PHF. Also, as noted previously, current literature indicates that a highly elevated body temperature is not required for a diagnosis of NMS.

The forensic pathologist continued:

A variety of adverse drug reactions are possible in this case, the most serious of which is an encephalopathic syndrome which has been reported in patients who are receiving a combination of neuroleptic medications (major tranquilizers), including haloperidol, and lithium carbonate (used to treat manic episodes of manic-depressive disorders). . . . There is no evidence in this case . . . to suggest this disorder, however. Much more likely adverse drug reactions relate to the cardiovascular system, since many of the drugs prescribed in this case, alone or in combination, can produce serious, potentially lethal, effects on the heart, especially hypotension and hypertension, tachycardia, bradycardia, and cardiac dysrhythmias (including heart block). These adverse effects on the heart (particularly dysrhythmias) are especially compatible with the apparent sudden death which occurred in this case.

There have been reports of individuals with psychiatric illness, especially schizophrenia, who die suddenly and unexpectedly, and in whom no anatomic cause of death can be found. Most of these individuals, however, were not taking major tranquilizers at the time of their deaths. Furthermore, while a number of these deaths have been recorded in

catatonic schizophrenics, resulting in a syndrome sometimes called 'lethal catatonia,' it is not clear how many of these deaths were actually the result of the neuroleptic malignant syndrome.

Finally, I cannot completely exclude a subtle natural cause for this unfortunate young man's demise, especially an undiagnosed cardiac dysrhythmia. There is, however, no premortem EKG evidence to support the possibility of an underlying dysrhythmia.

Consequently, while I cannot unequivocally establish a cause of death in this case, I believe it is possible, even likely, that the death resulted from one of the known complications of major tranquilizer therapy including especially the neuroleptic malignant syndrome or a rhythm disturbance of the heart. . . . [Emphasis added.]

Cause of death was listed as and remains "undetermined."

D. DMH'S INVESTIGATION

To date, DMH has not issued any written findings identifying any specific deficiencies relating to Levesque's death, care or treatment at SYMH/PHF. The DMH evaluator did tell PAI investigators that two DMH psychiatrists reviewed Levesque's records and concluded:

The only thing that we could really nail the facility on or pinpoint them on is the lack of documentation regarding what they did to this young man, how they followed him with regard to the nursing services, the taking of vitals and the charting of that . . . they had not documented as well as they should have....

However, as discussed in the following pages, the facility was reviewed twice during 1994, and additional consultative services following Levesque's death have been provided by the DMH evaluator as recently as March 20, 1995.

V. INVESTIGATION INTO CARE AND TREATMENT PRACTICES AT SUTTER-YUBA BI-COUNTY MENTAL HEALTH SERVICES PSYCHIATRIC HEALTH FACILITY

A. HISTORY OF DMH's REGULATORY ACTIVITIES

As stated previously, DMH is the only agency that monitors program compliance at SYMH/PHF. Since the end of 1989, five audits and/or reviews have been completed by DMH.

- (1) Annual relicensure audit conducted December 4, 1989; report regarding audit dated February 20, 1990; no facility response on file.
- (2) Annual relicensure audit conducted November 29, 1990; report regarding audit dated February 6, 1991; facility response dated March 27, 1991.
- (3) Consultative review requested by facility, conducted by DMH on November 29 and 30, 1993; report regarding survey dated December 21, 1993.
- (4) Annual relicensure audit conducted March 14, 1994 (the last day Levesque was alive); report dated July 21, 1994; facility response dated August 24, 1994.
- (5) Audit conducted November 16 and 17, 1994; undated report received by facility on December 30, 1994; facility response dated January 25, 1995.

A review of licensing documents reveals a long-standing pattern of recurring deficiencies, many of which raised some of the same significant care and treatment issues identified during the course of PAI's investigation into the circumstances surrounding Levesque's death, including:

- The failure to develop and implement appropriate and individualized interdisciplinary treatment plans.
- The failure to provide independent and adequate levels of treatment, programming, and other services on the inpatient unit.
- The inappropriate and excessive use of seclusion and restraint.

The failure to comply with minimum standards governing medical records documentation and the development of patient care policies and procedures.

The failure to provide required clinical oversight of the psychiatric and medical care delivered on the inpatient unit, including the failure to ensure that appropriate medication prescribing and monitoring practices were followed.

The 1989 audit identified four areas of deficiencies:

- (1) Authorizations allowing flexibility to SYMH/PHF's program were not posted.
- (2) Interdisciplinary plans failed to clearly identify patients' problems and therapeutic goals.
- (3) Inadequate quality assurance review by the Clinical Services Director and failure by the pharmacist to report prescribing irregularities.
- (4) Two fires went unreported as unusual occurrences.

In emphasizing the facility's need to insist on quality reports from the pharmacist, DMH said:

When pharmacy reports contain no detail, no discussion of clinical/ pharmaceutical issues and the clinical director does not read the reports, one is left with the impression that the facility is satisfied with status quo. The reality is that a facility cannot stand still with regard to the standard of practice it provides. Invariably, the quality of care will slide and patients will suffer. [Emphasis added.]

There is no SYMH/PHF response to the 1989 deficiencies on record. SYMH/PHF's 1990 annual relicensure audit identified five areas of deficiencies:

- (1) Failure to formulate specialized nursing care plans for inpatients requiring them (compare with treatment planning problem identified in 1989).
- (2) Inappropriate use of seclusion and restraint.
- (3) Failure to maintain clearance from the State Fire Marshal (compare with 1989 audit in which two fires were not reported to DMH as unusual occurrences).
- (4) Inconsistent documentation regarding the application and duration of seclusion and restraint.
- (5) Pattern of inadequate documentation regarding diagnostic formulation, patient progress and treatment rationale, as well as questions about insufficient contact with patients by physicians.

Noteworthy narratives regarding DMH's findings from the 1990 SYMH/PHF audit included:

With the exception of one part-time psychiatrist, there is a marked lack of physician documentation with regard to diagnostic formulation, patient progress, treatment rationale, etc. in the patient record. . . . In chart number 02-09-04, the patient was admitted 11/21/90 and the only psychiatric note was dated 11/29/90. Such frequency of physician contact is clearly insufficient for treatment of patients with acute psychiatric disorders.

In commenting on one chart from the 1990 audit which referred to a person who, similar to the situation with Levesque, was secluded and restrained for being "unmanageable on open unit" and "disruptive on unit," DMH said:

These are inappropriate indications for restraining and/or secluding a patient. Prior to seclusion and restraint, a patient must represent imminent dangerousness; that is, unless restrained, the patient will physically harm himself or others. Being unmanageable or disruptive on the unit is not the same as dangerousness from which the patient or others must be

protected. This same chart contained the 15 minute check documentation, usually at the beginning of the shift progress notes. Consequently, several hours worth of 15 minute check documentation were grouped together leaving the reviewer to wonder about the consistency with which the checks were actually done.

SYM/PHF's response to this finding was: "Treatment staff have been advised at regular staff meetings and through written instructions regarding more specific documentation for the justification of restraint in seclusion have been given to all staff."

Included within the 1990 audit recommendations is the following statement by DMH:

The reviewer acknowledges the difficulty the facility has had in recruiting a medical director and maintaining its psychiatric staff. Nevertheless, a minimum standard of care must be maintained in the treatment of psychiatric inpatients. The facility and local government is in a position of public trust; as such, they must insist in the strongest possible manner on professionalism from its psychiatric staff with regard to the assessment, diagnosis, treatment and ongoing monitoring of PHF patients. [Emphasis added.]

No audit for 1992 is on record.

In 1993, SYM/PHF requested and DMH conducted a consultative review which addressed the following: admission criteria, client access to services, involuntary admissions, follow-up care, staff training, discharges, and an overall assessment of SYM/PHF's program in comparison to other licensed PHF programs.

DMH sent two nurses and one physician, who reported: (1) that SYM/PHF staff needed to better document the specific behaviors which justified the decision to involuntarily detain; and (2) that "[t]he facility should develop a formalized staff training program and an organized inservice record keeping system" as "the reviewers were not able to evaluate the quality of inservice training provided to staff because the program content

of the classes offered was not well documented." Despite the DMH Licensing Evaluator's prior findings (who did not participate in this consultative review) and even though the DMH consultants admittedly "did not conduct an in-depth survey," they provided this overall assessment of the facility:

The focus of the review was only on those specific areas requested. . . . Consequently, the reviewers did not conduct an in-depth survey of the program. In general, however, the reviewers found the Sutter/Yuba PHF program to be in compliance with the standards and regulations governing PHFs. Treatment services were appropriate to the population served. There are over 20 PHFs located throughout California. Although demographic characteristics, available resources, and bed capacities vary among these facilities, making objective comparisons with other PHFs very difficult, the Sutter/Yuba PHF program appears to be operating within an acceptable range of performance.

The March 14, 1994, relicensure audit identified six areas of deficiencies, five of which had been identified during previous audits:

- (1) Consumer information not posted or out of date (compare with 1989 audit).
- (2) No appropriate clinical director (compare with statement from 1990 audit).
- (3) That SYMH/PHF "relies heavily on the county Day Treatment Program to provide a treatment program for its inpatients and does not provide its own recreation program. . . . Further, there is no evidence that the patients' level of functioning is considered prior to their inclusion in the Day Treatment Program and that the inclusion of PHF patients in the Day Treatment Program is a matter of facility convenience rather than an individually considered therapeutic intervention."
- (4) Interdisciplinary treatment plans (ITPs) "are ill-defined and missing major components" (compare with 1989 and 1990

audits) and "[t]he treatment plans failed to specify specific goals of treatment, what interventions and methods would be made to reach those goals nor what the measurable objectives were. Further, the ITPs did not consistently identify who or what discipline was responsible for carrying out the various components of the ITP. The ITPs were not consistently reviewed and modified in a timely way consistent with regulations."

- (5) No clearance from the State Fire Marshal (compare with 1989 and 1990 audits).
- (6) Non-utilitarian policies and procedures manual, which had also been mentioned, though not officially cited as a deficiency in DMH's 1989 audit report: "The facility does not have a useful policy and procedure manual and has made very little progress in developing one since it was first cited as a deficiency in 1989. Although it must be noted that some work has been done in the past year to put a manual together, it must also be noted that progress has languished for months. The lack of progress is unacceptable."

In commenting on the ongoing care and treatment deficiencies identified during DMH's November 1994, audit of the facility, the DMH evaluator said: "They have the information they require right now to be a top-notch PHF [psychiatric health facility]. Nothing that I've said to them . . . should come as a surprise because they have heard it all before." That audit identified six areas of deficiencies, the most significant involving the misuse of seclusion and restraint:

- (1) Rehabilitation services -- program developing but still in the beginning stage. The evaluator commented:

The facility [has] made an effort to update its therapeutic program and not rely on the adjoining day-treatment program to provide daily activities. However . . . the facility is advised to consider incorporating the following:

- Offer a range of therapeutic groups and activities which are geared toward addressing the different clinical needs of patients.

- Draw on the expertise of existing staff to provide therapeutic groups; e.g., nurses to provide medication education for patients.
 - In addition to providing the ADL [activities of daily living] cart, offer basic hygiene and grooming information.
 - Offer instruction for gravely disabled patients on basic grocery shopping, meal planning and budgets.
 - In formulating the global treatment program, consider the purpose and goal of each group; that is, what therapeutic gain does the facility wish to gain for its patients by offering the particular treatment.
- (2) Interdisciplinary treatment plans (compare with 1989, 1990, and earlier 1994 audits) fail to identify who or which discipline was responsible for each treatment, and are still not utilitarian, cluttered with information better- suited elsewhere in chart.
- (3&4) Types of restraint and behavioral restraint (compare with 1990 audit) -- "The facility employs a seclusion system it has termed 'security'. . . . No specific orders are required, by facility policy, to place a patient in security, nor are 15 minute checks done. . . . Any restriction of a patient's freedom to enter and leave his/her room or to move around the facility is to be considered seclusion. . . . The facility is to immediately discontinue the practice of 'security' and conform its practices and procedures to the regulation governing seclusion and restraint. It is recommended that the facility employ standard nomenclature when referring to placing a patient in a locked room and refrain from employing the term 'security.'" [Emphasis added.]
- (5) Postural supports -- *"The facility does not employ a physical or occupational therapist and it utilizes soft-tie restraints as an alternative to seclusion and/or restraint. This is an inappropriate use of geri-chair and posey restraint and the facility is instructed to cease the practice immediately, inform all relevant staff as to the change in policy and practice and formulate appropriate policy for inclusion in policies and procedures manual."* [Emphasis added.]
- (PAI investigators understand that geri-chair misuse has been a long-standing practice which should have been cited previously.)
- (6) Inadequate and bulky unit health record system.

The policies and procedures manual received commendation in DMH's recent SYMH/PHF audit: "The facility has dramatically improved the quality of its policy and procedure manual which is now a relevant resource and reference tool."

PAI investigators note that SYMH/PHF's revised policy and procedures manual is indeed a vast improvement over the previous manual (which had policies dating back as far as 1977, many of which had been revised only once since 1987). However, the revised version still contains many problems, too numerous to mention in this report (e.g., inadequate patients' rights and seclusion and restraint policies and procedures).

- STAFF TRAINING

PAI investigators reviewed SYMH/PHF's staff training records dating back to October 1992 and could not find any clear evidence that direct care staff were provided with inservice education regarding neuroleptics and/or the potential adverse effects of psychiatric medications. Trainings included: a one-hour tape of an Oprah show regarding "parents who institutionalize their kids"; a segment from 48 Hours on "schizophrenia"; a one-hour session described as, "Fat or Fitness in the '90's"; a two-hour meeting regarding the linen closet; and a two-hour meeting regarding the application of "posey restraints," a type of postural support that SYMH/PHF was not authorized to use.

For instance, one unlicensed staff described the manner in which instruction regarding the taking of vital signs was given:

[A]// I got was 'well, here's a stethoscope, here's a blood pressure cuff. You put this on. You pump it. The 'scope goes here,' that type of thing and they tell you what you're listening for and describe it. Again, you know, people who came from picking fruit in the fields to coming into mental health, taking blood pressures are two different jobs -- extremes.

According to the DMH evaluator, an unlicensed but "organized and motivated" member of staff has recently been designated the new In-service Coordinator and is in the process of implementing a new system which will record the subject matter, date, and amount of training and

education provided, as well as track and monitor the accrual of individual staff member participation in such in-service activities.

- COMMUNICATION AND MANAGEMENT ISSUES

In addition to receiving inadequate training about the adverse effects of psychiatric medications, another unlicensed member of SYMH/PHF direct care staff stated that staff in her position don't even receive information regarding a change in a client's medication: "[W]e don't know any of the medication changes. That goes on between the nurses, the RN and the doctors and the social workers. . . ." Yet, these very staff are responsible for delivering most patient care and for documenting client progress: "We just write down the observations -- what we felt."

One main concern expressed to PAI investigators was that, as was the situation with Levesque, some of the psychiatrists' prescribing practices appear inconsistent and uncoordinated, often resulting in multiple, unexplained changes in patients' medication regimens. As one observer noted: "The doctors are very disorganized in prescribing medications and they don't seem to have the same protocol like they do in . . . some of the other 24 hour care facilities." One member of professional staff commented that this problem underscored the need for a Clinical Services Director. A part-time Clinical Services Director (who was a physician) was hired in November 1994, thus satisfying this regulatory staffing requirement for the first time in several years. On April 20, 1995, another physician began serving as the Clinical Services Director and recruitment for a permanent Medical Director has begun.

Consumers and other members of the mental health community conveyed a number of observations about the overall management of the facility, most of which involved their impressions that the facility's structure was too "loose," lacked consistency and organization, and failed to clearly identify supervisory roles and responsibilities. One person said:

. . . [A] lot of it has to do with philosophy and focus. I'm often concerned with what is the goal. There are a lot of repeat hospitalizations and without a clinical director who's responsible for the actual level of care, we have that scattered-type feeling.

One mental health consumer described the problem this way: ". . . [S]eems like a lack of control over what's going on the unit that it's just chaos a lot of times because of the lack of help and the lack of doctors."

B. PATTERN OF PATIENTS' RIGHTS VIOLATIONS

Persons with mental and developmental disabilities have the same legal rights and responsibilities guaranteed all other persons by the Federal Constitution and laws, and the constitution and laws of the state of California, unless specifically limited by federal or state law or regulations. [WIC §§ 4502, 5325.1.] As citizens, they do not lose their rights by being hospitalized or receiving services. During the course of this investigation, PAI investigators discovered numerous violations of basic patients' rights and mental health laws and regulations which had been left uncorrected for over five years.

The evidence indicates that, as part of a long-standing pattern and practice, Levesque was denied the following fundamental rights which, under California law, may never be denied:

- *The right to treatment services which promote the potential of the person to function independently. Treatment should be provided in ways that are least restrictive of the personal liberty of the individual.*
- *The right to dignity, privacy, and humane care.*
- *The right to be free from harm, including unnecessary or excessive physical restraint, isolation, medication, abuse, or neglect. Medication may not be used as punishment, for the convenience of staff, as a substitute for -- or in quantities that interfere with -- the treatment program.*
- *The right to prompt medical care and treatment.*
- *The right to be free from hazardous procedures.*

WIC § 5325.1.

- SYMH/PHF PATIENTS' RIGHTS ADVOCACY PROGRAM

Sutter Yuba Mental Health Services employs one Patients' Rights Advocate who is an independent contractor for 1,600 hours per year. This translates into three-quarters of a full-time position. Additionally, there is money for 200 hours of "backup" advocacy services.

The legally prescribed duties of county patients' right advocates include:

- Assisting staff in ensuring that patients' rights information is posted in all mental health facilities and that persons receiving mental health services are informed of their rights, including the right to contact the local advocate and the statewide Office of Patients' Rights.
- Investigating and resolving complaints from persons with mental disabilities about violations or abuse of their rights.
- Monitoring facilities and training staff to ensure compliance with patients' rights, laws, regulations, and policies.
- Advocating for persons with mental disabilities who are unable or afraid to register a complaint on their own behalf.

Until the last quarter of 1994, persons wishing to receive services from the patients' advocate could not do so directly and had to leave a message for the advocate at SYMH/PHF's main phone number.

- INAPPROPRIATE AND EXCESSIVE SECLUSION AND RESTRAINT

As discussed earlier, Levesque was subjected to four and a half days of seclusion and an unknown amount of time restrained in a geri-chair without justification. Although, as of January 1995, SYMH/PHF administration, in written correspondence to DMH, continued to characterize the seclusion and restraint deficiencies identified by DMH as a "misunderstanding and miscommunication," statements obtained during PAI's investigation indicate that the facility has a long-standing pattern and practice of using seclusion and restraint when it is not appropriate.

In describing his understanding of the justification for using "security" (or seclusion), one staff member said:

When somebody is really disoriented and they're so confused that they would wander off sometimes off the unit, we have them stay -- we have them stay in a room for their own protection. We are an open unit here. So often times people will become so confused and so disoriented and they will just walk through the double doors and go out and not just go into another part of the building, but they would actually go out on the street. So we try to protect them, as well as the other patients for confusion like that or [if] they're highly assaultive in any kind of way.

Another licensed staff member said:

Usually they're assaultive to others or if they can't be managed on an open unit. Well, if they're actively hallucinating and acting out or so disorganized that we can't have them on the open unit 'cause our units are open, it's not locked. So you know like if they were to like stick something in the microwave that shouldn't -- something that could be a danger to them.

Per the DMH Licensing Evaluator:

One of the [things] that has been frustrating for me in terms of talking about these issues is that I hear[d] them saying the words 'less restrictive' a long time ago, but they are not implementing them in a manner that is really least restrictive. If someone is an AWOL risk, they'll put them in security, they'll take away their clothing, walk them out in pajamas.

The former Mental Health Services Director wrote this about the issue of the "open unit" as it pertains to restrictive measures such as seclusion and restraint:

I don't know if the cost will be prohibitive in terms of installing sprinkler systems and other fire safety items. I also don't

know if you have considered the fact that, while a locked inpatient unit may have some impact on restraint or seclusion for patient who have a tendency to wander throughout the building, these same patients will wander throughout the unit and be intrusive in patient's rooms and other areas, and may still have to be confined or secured in some way. In addition, by locking the inpatient unit, you make all other patients prisoners, and we try very diligently to indicate to patients in this program that they have an illness, they are not criminal[s], they do not need to be locked up, and they can control their behavior most of the time. By locking the inpatient unit, you will restrict the mobility of those patients who do not need their mobility restricted. They will not be able to do their laundry, go get a Pepsi, or do things like that without staff assistance, both to get out of the unit and to get back on. I am not sure we shouldn't consider the rights and benefits of the vast majority of patients when considering this particular item. [Emphasis added.]

SYM/PHF's practices undermine and are antithetical to their "open unit" philosophy. Though administrators feel an unlocked door allows clients more respect and self-determination, there is nothing empowering or respectful about being stripped of one's clothing and/or being locked in an isolation room or restrained in a locked chair-like device. As for the concern regarding clients' access to the Pepsi machine or laundering facilities, PAI investigators note that access to these amenities is surely impeded when one is isolated and/or restrained. A less restrictive measure, such as moving these amenities to the unit, would address this concern.

PAI investigators further note that per the facility's own statistics from 1994 regarding denial of rights on the inpatient unit, which is 18 beds, seclusion use was as high as 63 people for a three-month period. Moreover, according to the Licensing Evaluator, as recently as March 20, 1995, SYM/PHF program administration remained "confused" about the basic regulations governing the use of seclusion and restraint.

- INFORMED CONSENT

Involuntarily detained persons, such as Levesque, retain their fundamental right to accept or refuse treatment with antipsychotic medications, except in a statutorily defined emergency and/or when there has been a legal finding of incapacity in a hearing conducted for that purpose. WIC § 5332; Riese v. St. Mary's Hospital and Medical Center, 209 Cal. App. 3d 1303 (1987). Often referred to as "the right to know," informed consent means that patients, after being provided adequate information about their condition and proposed treatment, knowingly and intelligently, without duress or coercion, clearly and explicitly give their consent to the proposed treatment. Cobbs v. Grant, 8 Cal.3d 229 (1972). In Levesque's case, there is a question whether he actually made a knowing and voluntary decision regarding his medications.

PAI investigators note that some information pertaining to the medication side effects detailed in the forms used by SYMH/PHF to obtain informed consent is incomplete or inaccurate. (For example, both tardive dyskinesia and neuroleptic malignant syndrome (NMS) are inaccurately portrayed as risks which occur only after neuroleptic medications are taken for more than three months.) And, even though Levesque received five different psychiatric medications, consent forms for only three of these (Haldol, Cogentin, and Tegretol) were located in his SYMH/PHF medical records. Furthermore, none of the forms indicated the mode, frequency or dosage range of the medications prescribed to Levesque. Nor were any specific risks relating to him (such as NMS) identified. In addition, there is some suggestion that Levesque may have been attempting to refuse the medications or felt coerced into taking them, but that medical staff failed to pursue the issue. A March 2, 1994, psychiatrist's progress note states, in part: "He is hesitant about taking the meds, but it is not clear whether this is true reluctance for the medication or psychomotor retardation and bewilderment."

One SYMH/PHF administrator said that when a consumer exercises his or her right to refuse consent:

What we do . . . is have the doctor order the medication and three or four times a day and the nurse offer it to the patient and do the patient education thing: 'Now this is the medication that the doctor talked to you about, and we think

it's in your . . .' and so they get that lecture, information, education, three or four times a day, and oftentimes after a day or two or three or four days, they'll say 'Oh, alright, I guess I'll try it. . . .'

Per the facility's Medication Monitoring Subcommittee Quarterly Report for April through June 1994:

. . . [F]ocus areas for improvement continued to be similar to those in past quarters. For example, suggestions for further lab monitoring, completeness of informed consent documentation, and clarification of allergy data or dosages prescribed.

- CLOTHING

Levesque was not allowed to wear his own clothing for eleven days because he was considered an "elopement risk." This practice is not in keeping with the "good cause" standard which requires that:

- The exercise of the specific right would be injurious to the patient; or
- There is evidence that the specific right, if exercised, would seriously infringe on the rights of others; or
- The institution or facility would suffer serious damage if the specific right is not denied; AND
- There is no less restrictive way of protecting the above interests.

9 CCR § 865.2; emphasis added.

Here is one representative statement of SYMH/PHF's practice:

Just as soon as we feel like a patient can function on the open unit, we'll take them out [of 'security'] and, of course, the first step is almost always to deny their clothing for the first step. 'Cause that's sort of, especially when they're a high elopement risk that will often deter elopement just because they have to wear pajamas. They're not as inclined to streak

through the parking lot with pajamas as much as they would in their own clothes. So that's usually a very common step with a high elopement patient.

Per a frequent visitor to the inpatient unit:

. . . [I]n order to maintain some of the necessary safeguards for some of the patients, you see a lot of patients wandering in their pajamas all over the facility and it doesn't -- it doesn't look good for the clients because they're -- one reason is 'why are they wandering around in a public facility in their pajamas?' but it seems to have a bad mix between what is required for the security and confidentiality of the patient and what's required for the daily functioning of what is actually a large county department. . . . I think they take clothes away because people are 'AWOL risks' and so that's why so many of the clients wander around in their pajamas and even go to the grocery store in their pajamas and all these sort of inappropriate things. . . . It doesn't really keep people from going AWOL. It just compounds. . . . It's demeaning to see these people wandering around [in their pajamas]. It's very demeaning. It's also stigmatizing.

One mental health consumer said this about the practice: ". . . [T]hey stripped me and they give you paper clothing. . . ." This same consumer stated that a staff member told her: "'If you'll take your clothes off and put this on, I won't have to bring in the man.' That's [a] horribly humiliating experience. . . . I don't think a man ought to be undressing the women in there." According to the DMH Licensing Evaluator, as of March 20, 1995, the facility agreed to no longer use the paper "fiber type see-through" gowns apparently referred to by the consumer quoted above.

PAI investigators note that according to the facility's own records, during one three-month period in 1994 as many as 48 people were denied the right to wear their own clothing. PAI investigators further note that for the year 1994, denial of rights reports indicate that SYMH/PHF's denial of the person's right to wear his or her clothing constituted 43% of the total of all rights denied by the facility, compared to the statewide average of 3%.

- VISITORS

According to SYMH/PHF policy, persons in "security" (which may not always be for good cause, as required) cannot have visitors.

Levesque's family stated that they were not allowed to visit him until three days after his admission at SYMH/PHF. The reason given by SYMH/PHF staff was that Levesque was "too catatonic, too disturbed" to receive visitors. This stated rationale did not meet the good cause and other related standards which, among other things, require that the reason for denying the right have some clear relationship to the right denied. 9 CCR § 865.2. In denying Levesque his right to visit with his family, SYMH/PHF needed to demonstrate that allowing the visits would have posed a danger to himself, to others or to the facility, and that there was no less restrictive way of protecting those interests. However, there is no evidence to support any of the requisite findings.

When Levesque's family was allowed to visit, their first view of him was through the reinforced glass of the maximum security cell. Per Levesque's family, he was standing about eighteen inches away from the door with his hand outstretched toward the doorknob.

(PAI investigators note that although required to report denials of the right to see visitors to DMH on a quarterly basis, SYMH/PHF failed to report any denials of visitation rights during 1994.)

C. HISTORY OF COMMUNITY CONCERN

During this investigation, PAI investigators learned that SYMH/PHF has been the source of controversy and concern among the local mental health community for a long time. Complaints of breaches of confidentiality, poor documentation practices, disorganized management, inconsistent medication prescribing practices, inadequate training of staff, lack of a real inpatient treatment program and appropriate clinical oversight, and poor discharge practices from the inpatient unit echoed throughout interviews conducted by PAI investigators.

In October of 1992, according to a local newspaper article in the Appeal-Democrat, a \$25,000 settlement was granted to a SYMH/PHF client who

had filed a suit in Sutter County Superior Court. The client had reportedly received services from October 4 to October 20, 1990, and was "obviously very ill and was suffering neurological deficits such as disorientation and difficulty walking and talking . . . these problems were related to overmedication with Lithium. There was also a question of inappropriate use of Clozaril and Lithium combined." The client, according to his attorney, "appeared in the beginning of the episode to have suffered serious mental and neurological injuries; however, after appropriate treatment his disorientation, affected gait and all other mental and neurological deficits completely resolved within six months of the incident." According to the Appeal-Democrat article, SYMH/PHF "agreed to settle the lawsuit without admitting liability. The doctors were dismissed as defendants."

A 1993-1994 County of Sutter Grand Jury was convened in response to complaints concerning Sutter-Yuba Mental Bi-County Mental Health Services. Among the issues reviewed by the Grand Jury were: appointment of representatives to the Mental Health Advisory Board; lack of a Mental Health Program Chief for three years; facility overcrowding; the misuse of "extra help" employees; concerns about the adequacy of medical consultative services on a 24-hour basis, and insufficient funding.

Said one person regarding the overall sentiment among the mental health community concerning SYMH/PHF:

*. . . [Y]ears and years of not correcting problems and I would simply like to see audits corrected . . . more accountability. . .
. I would just like to see what needs to be done corrected and not pussy footing around anymore. . . . The clients deserve it. For professionalism, they deserve to have a well-run facility that lives by the rules like the rest of us.*

VI. FINDINGS AND CONCLUSIONS

- SYMH/PHF STAFF'S FAILURE TO RESPOND TO SYMPTOMS OF A SEVERE ADVERSE REACTION TO MEDICATIONS CONSTITUTED NEGLIGENCE WHICH LIKELY CAUSED LEVESQUE'S DEATH.

Although the precise cause of Levesque's death remains classified as "undetermined," the evidence indicates that Levesque died from an adverse reaction to psychiatric medications which went undiagnosed and untreated. During his inpatient stay at SYMH/PHF, nursing and medical staff, as well as visitors, observed a number of disturbing symptoms consistent with an adverse reaction to the medications, including, but not limited to: rigidity and muscle spasms, "robotic" posture, shaking, tremors, profuse sweating, flushing of the skin, and difficulty walking, as well as actually falling down. The explanation offered by staff for this ongoing failure to act was that Levesque reminded them of another family member who had also received treatment at SYMH/PHF. However, as pointed out by the physician PAI consulted, unlike his family member, Levesque had many of the known risk factors for developing NMS, including the fact that he was young, male, and had a developmental disability. Additionally, as stated by the physician PAI consulted:

Although treatment staff observed, discussed and documented symptoms that raised serious issues about adverse reactions to the medications prescribed, including the possibility of neuroleptic malignant syndrome, a potentially fatal disorder which likely culminated in this young man's death, meaningful diagnostic steps were not taken. The fact that the patient in some ways reminded staff of another family member certainly provides no appropriate explanation for ignoring this young man's deteriorating condition.

. . . The facility's focusing on the fact that the precise reason for this young man's death hasn't been determined with absolute certainty misses the point. This patient received grossly substandard care which likely culminated in his death. . . . This death warrants a comprehensive review of the facility's treatment practices.

- CONSISTENT WITH A LONG-STANDING PATTERN OF PRACTICE, LEVESQUE WAS SUBJECTED TO THE INAPPROPRIATE AND EXCESSIVE USE OF SECLUSION AND RESTRAINT.

The evidence indicates that Levesque was improperly denied a number of his basic statutory and constitutional rights, including, but not limited to, his rights to reasonably safe conditions and not to be subjected to seclusion and restraint without adequate justification or in a manner not consistent with appropriate clinical standards governing the use of such restrictive interventions. See, WIC § 5325.1 and *Youngberg v. Romeo*, 457 U.S.307 (1982). Levesque was subjected to four and one-half days of seclusion in what staff referred to as "security" or "maximum security," in the absence of any documented or reported aggressive or dangerous behavior at SYMH/PHF, as well as an unknown amount of time restrained to a geri-chair -- a device which the facility was not authorized to use upon Levesque because it was not employed for the purpose of increasing Levesque's "mobility and independent functioning" or, as required, "designed and applied . . . under the supervision of a physical or occupational therapist." Title 22 CCR § 77104(c).

Although facility staff stated repeatedly that providing services in the least restrictive manner is a fundamental principle underlying the delivery of all care and treatment at SYMH/PHF, and that maintaining an "open," unlocked unit is for the purpose of affirming this principle, staff did not seem to understand that taking away a person's own clothing and isolating that person in "security" (i.e., seclusion) or restraining him or her in a "geri-chair" is far more restrictive and demeaning than locking the door of the facility or putting a fence around its perimeter. A review of licensing documents, as well as numerous statements by staff, further indicate that the improper use of seclusion and restraint without just cause is a long-standing practice at the facility. (A copy of this report has been forwarded to the U.S. Department of Justice pursuant to the Civil Rights of Institutionalized Persons Act (CRIPA), 42 U.S.C. § 1997; and to the Bureau of Medi-Cal Fraud & Patient Abuse, Office of the Attorney General, State of California.)

- THE FACILITY'S DOCUMENTATION PRACTICES ARE GROSSLY SUBSTANDARD AND ADVERSELY AFFECT PATIENT CARE.

The physician PAI consulted explained:

The documentation in the clinical record is grossly substandard. Basic information such as the recording of vital signs on a routine basis was not done. Additionally, the process of clinical inference is almost totally missing. The records do not in any meaningful way provide insight into the basis for the treatment decisions made for this patient, including the clinical rationale underlying the adjusting of his medications and the failure to respond to what the record indicates were potentially dangerous side effects that went undiagnosed and untreated. This presents an even greater problem whereas, in this facility, a patient may be treated by different physicians whose primary means of communication is the patient's medical record. In such circumstances good documentation becomes even more important if appropriate medical care is to be delivered.

- THERE ARE LONG-STANDING PATTERNS OF IDENTIFIED BUT UNCORRECTED DEFICIENCIES INVOLVING SUBSTANDARD CARE AND TREATMENT AT SYMH/PHF WHICH RAISE SERIOUS QUESTIONS ABOUT THE ADEQUACY OF EXISTING REGULATORY ENFORCEMENT MECHANISMS.

A review of the licensing documents from the Department of Mental Health (DMH) revealed a pattern of serious recurring deficiencies that went uncorrected for over five years, including, but not limited to:

- The failure to develop and implement appropriate and individualized interdisciplinary treatment plans.
- The failure to provide independent and adequate levels of treatment, programming, and other mental health services to persons on the inpatient unit;
- The inappropriate and excessive use of seclusion and restraint; and
- The failure to comply with minimum standards governing medical records documentation and the development of patient care policies and procedures.

In 1990 when the licensing and inspection authority for PHFs was transferred from the California Department of Health Services (DHS) to DMH, the Legislature, in part, stated: "The State Department of Mental Health shall develop and adopt regulations to implement this subdivision." To date, DMH has chosen not to promulgate its own enforcement regulations, instead relying on preexisting standards established by DHS which have proven inadequate. According to DMH staff, DMH has no plans to promulgate any PHF regulations.

As pointed out by the DMH evaluator, there are no interim sanctions available under DMH's existing regulatory scheme, such as imposing fines or even ordering timely compliance with a plan of correction. If a substandard facility such as SYMH/PHF does not correct serious deficiencies within a reasonable period of time, the only punitive sanctions available are the suspension and/or revocation of the facility's license. These are drastic options which, to date (even given the pattern of serious and persistent health and safety deficiencies preceding Levesque's death), DMH has never pursued. (PAI's preliminary review of DMH licensing documents involving PHFs throughout California indicates that other facilities -- and the persons with mental disabilities they serve -- would also benefit from the promulgation of appropriate interim enforcement mechanisms.)

VII. RECOMMENDATIONS

- IN ORDER TO PREVENT FUTURE UNNECESSARY MEDICATION-RELATED HARM, THE DIRECTOR OF SUTTER-YUBA MENTAL HEALTH SERVICES SHOULD IMMEDIATELY IMPLEMENT EFFECTIVE SYSTEMIC STRATEGIES TO SUBSTANTIALLY IMPROVE MEDICATION PRESCRIBING AND MONITORING PRACTICES ON SYMH/PHF'S INPATIENT UNIT.

This facility should overhaul its clinical and medical services, especially its medication prescribing and monitoring practices. However, this is not likely to occur in the absence of inspired leadership, critical self-evaluation, and effective oversight. As articulated by the physician PAI consulted:

Particularly disturbing is the facility's apparent failure to understand that they made serious mistakes in the care and treatment of this patient. There appears to be a lack of serious self-evaluation. They do not seem to understand that this somewhat unique case and the grave consequences which ensued [i.e., death likely due to an untreated adverse medication reaction] signal significant institutional failings that need to be addressed. The facility's focusing on the fact that the precise reason for this young man's death hasn't been determined with absolute certainty misses the point. This patient received grossly substandard care which likely culminated in his death.

In addition to the recent appointment of a new Mental Health Services Director, in November 1995, the facility hired a part-time Clinical Services Director who was responsible for directing and overseeing the clinical services provided, thus satisfying this important health and safety requirement for the first time in more than two years. On April 20, 1995, another physician assumed this responsibility and recruitment for a full-time permanent Medical Director has reportedly begun. Given the facility's history of serious and persistent care and treatment deficiencies, the opportunity to build upon the incremental improvements made to date, and the compelling need to implement institutional reforms so that adequate levels of care and treatment are assured on a consistent and lasting basis, it is critical that a qualified Clinical Services or Medical Director be fully involved in the day-to-day operations of the facility at the patient care level and that appropriate oversight and accountability occur. Consequently, the recently appointed Sutter-Yuba Mental Health Services Director should

immediately put together a quality assurance and improvement review crisis management team which focuses on determining:

- (1) What organizational, staffing, management, and supervision changes are indicated at SYMH/PHF and within the Mental Health Services Division itself to ensure that needed reforms are expeditiously implemented, including how effective and adequate levels of patients' rights advocacy services will be assured.
- (2) How appropriate Clinical Director and medical services will be assured on an ongoing and lasting basis, including an assessment of what specific resources, technical assistance or support is indicated until then (including, for example, whether psychiatric "rounds" are being made on a regular basis and whether a mechanism now exists to ensure that when, as with Levesque, a pattern of nonresponsiveness to treatment and/or deterioration occurs, an appropriate clinical consultation and/or in-depth interdisciplinary review is automatically conducted pursuant to routine SYMH/PHF protocol).
- (3) How full access to appropriate medical services on a 24-hour basis, either directly by SYMH/PHF or indirectly through an appropriate agreement with a local acute care medical facility, will be guaranteed.
- (4) Whether effective policies, procedures, and directives are being developed and implemented to ensure that clear and effective communication about patients' conditions and treatment needs occurs among all levels and all members of the interdisciplinary team, especially between physicians who may share responsibility for the delivery of medical and psychiatric care, as well as between licensed and unlicensed direct care nursing staff and medical staff.
- (5) Whether comprehensive policies, procedures, directives, in-service training, and education are now being put in place so that the adverse effects of medications are identified, monitored, and responded to by medical and nursing staff in an appropriate and timely fashion.

- (6) Whether effective protocols for identifying and responding to at-risk individuals such as Levesque are being implemented, including specific clinical directives for responding to potentially life-threatening conditions such as neuroleptic malignant syndrome (NMS).

- AS THE PRIMARY LOCAL GOVERNING AUTHORITY, THE SUTTER BOARD OF SUPERVISORS SHOULD PROVIDE MORE EFFECTIVE OVERSIGHT OF SYMH/PHF TO ENSURE THAT MENTAL HEALTH SERVICES ARE DELIVERED IN A SAFE, HUMANE, AND CONSTITUTIONALLY SUFFICIENT MANNER.

The Sutter-Yuba Bi-County Mental Health Services Department was created in 1969 pursuant to a joint powers agreement between the counties of Sutter and Yuba. Sutter County has, and continues to assume, "overall administrative responsibility" for the delivery of mental health services "throughout Sutter and Yuba Counties as specified by the Lanterman-Petris-Short Act and local policy." However, there is a long-standing pattern of inadequate care and treatment and denials of other basic civil and constitutional rights of persons who receive inpatient services at SYMH/PHF, including, but not limited to, the inappropriate and excessive use of seclusion, restraint and medications. This indicates that more effective and comprehensive local governmental oversight and intervention is needed if the facility is to become a viable, competent, and trusted provider of mental health services to the mentally disabled citizens of Sutter and Yuba Counties.

The Sutter Board of Supervisors should, without delay, pursue the following measures.

- (1) Develop a long-term corrective action plan in consultation with the Mental Health Advisory Board and consumers (especially present and former recipients of SYMH/PHF services) following an on-the-record hearing which affords the local mental health community, especially consumers, as well as family members, a full and fair opportunity to meaningfully influence the plan, particularly potential outcome performance measures.
- (2) Take all necessary steps to ensure that the newly appointed Mental Health Services Director is provided with the necessary resources

and support, as well as vested with the appropriate level of decision-making authority and discretion, to move forward with any and all needed changes to remedy the significant care, treatment, and patients' rights deficiencies at SYMH/PHF, as well as those evident within the Mental Health Services Division itself, as determined by qualified staff, outside consultants or agencies, and appropriate local, state, and federal governmental authorities.

- (3) Hire an independent, outside clinical consultant to assist SYMH/PHF in implementing a long-term systemic plan which focuses on correcting deficiencies identified by the DMH Licensing Evaluator and other appropriate agencies by improving the facility's quality assurance and review capabilities, especially as those capabilities pertain to:
 - improving the facility's medication monitoring and prescribing practices; and
 - preventing the inappropriate and excessive use of seclusion and restraint.
- (4) Place an independent "monitor" in the facility to oversee the implementation of a comprehensive corrective action plan which addresses all of the deficiencies identified by the DMH Licensing Evaluator and other appropriate agencies, including how effective patients' rights advocacy services will be assured.
- (5) Require SYMH/PHF to, within a reasonable period of time, seek and obtain accreditation by the Joint Commission on Accreditation of Health Care Organizations (JCAHO).

- THE FACILITY SHOULD IMMEDIATELY IMPLEMENT AN EFFECTIVE PLAN TO ENSURE ADEQUATE PATIENT CARE DOCUMENTATION PRACTICES.

As pointed out by the physician PAI consulted, the clinical record is not only the facility's official business record of the care delivered to an individual patient, but is also an important tool of communication for the various members of the interdisciplinary team, who, throughout the individual's inpatient stay, share responsibility for making and carrying out decisions which determine the quality of care delivered. Sound decision-making

may, as in Levesque's situation, be impeded when the rationale for important clinical decisions is not charted and critical information, such as the routine recording of vital signs in the medical record is not documented. Additionally, adequate documentation is critical to the facility's (as well as outside agencies such as the Coroner's) ability to conduct effective quality assurance as well as morbidity and mortality reviews and investigations. Consequently, the Mental Health Services Director should immediately take all necessary steps to ensure that:

- (1) All special incident and other reporting guidelines, policies, procedures, and directives which involve significant health, safety, care, treatment, patients' rights, and potential abuse or neglect issues contain sufficient documentation requirements so that appropriate investigations and reviews by outside agencies are not unnecessarily impeded.
- (2) All health record content, policies, procedures, protocols, and directives meet all regulatory and interpretive guidelines.
- (3) An intensive in-service education and skills-building training for all direct care staff occur without delay and on a routine basis thereafter which focuses on:
 - increasing all direct care staff's appreciation of the individual patient's chart as a "living" document of communication that directly affects the quality of care delivered;
 - enhancing nursing staff's capacity to describe patients' symptoms and conditions more effectively and to "flag" significant care and treatment issues (such as potential adverse reactions to medications) which warrant more intensive evaluation and follow-up;
 - improving physician's skills and willingness to articulate more thoroughly, in the medical record, the clinical thinking underlying treatment decisions; and
 - ensuring that the clinical chart is viewed as an appropriate part of the overall communication network for responding to the care-related observations and concerns of unlicensed, as well as licensed, staff.

- THE DEPARTMENT OF MENTAL HEALTH (DMH) SHOULD TAKE ACTION TO PROMULGATE APPROPRIATE REGULATORY ENFORCEMENT PENALTIES.

Despite considerable efforts by the DMH Licensing Evaluator, serious and recurring patient care deficiencies went uncorrected for more than five years. When DMH assumed responsibility for licensing and inspecting psychiatric health facilities (PHFs), this statutory policy was, in substantial part, based on the rationale that DMH, because of its expertise, could better evaluate the quality of mental health services and programming being provided in such facilities than could the Department of Health Services. At the same time, the Legislature directed DMH to develop and adopt regulations to implement this new regulatory responsibility. While it is true that the Legislature also permitted reliance on preexisting standards until, or if, new implementing regulations were promulgated by DMH, it is now five years later and reliance on preexisting enforcement standards has proven inadequate. As demonstrated by DMH's inability to effectively regulate this PHF, there is a compelling need for DMH to develop and implement interim enforcement sanctions, such as giving notice of violations, imposing fines, and/or putting facilities on probationary status pending timely compliance with ordered plans of correction.

Otherwise, the only punitive sanctions available to render DMH a credible regulatory enforcement agency are the suspension and/or revocation of a PHF's license (which, of course, results in the cessation of mental health services not likely otherwise readily available). To date, these drastic options have never been exercised by DMH, even in light of the pervasive and known pattern of potentially dangerous noncompliance in the years preceding Levesque's death. In fact, according to the DMH Licensing Evaluator, it is only since Levesque's death that some "incremental but positive improvements" (such as appointing an In-service Coordinator and hiring of a Clinical Services Director) have occurred. However, also according to the DMH Licensing Evaluator, as recently as March 20, 1995, the facility remained "below standards," and some administrative staff still seemed "confused" about such basic, but "significant," requirements as those governing the use of seclusion and restraint.

DMH plans to review the facility in the fall of this year. In the meantime, DMH should exercise its authority to identify specific deficiencies relating to the care and treatment of Roy Dean Levesque and take whatever action is

necessary to assure that "incremental" improvements are ongoing and "significant" improvements are forthcoming in a timely enough manner so that safe and adequate levels of care are guaranteed to persons with mental disabilities who must continue to receive services from SYMH/PHF. If during the facility's review in the fall or during the potential relicensure audit DMH identifies:

- significant noncompliance with basic care and monitoring requirements, such as those governing the provision of adequate medical care and other clinical services, including substandard medication prescribing and/or monitoring practices; or
- a continued practice of using seclusion or restraint when less restrictive measures are indicated; and
- DMH has remained unable or unwilling to promulgate interim enforcement sanctions that, once invoked, would have a substantial probability of resulting in the timely correction of identified deficiencies; the facility's license should be revoked.