Multi-Systemic Therapy Provider Manual

Chapter Forty-Two of the Medical Services Manual

LOUISIANA MEDICAID PROGRAM

DEPARTMENT OF HEALTH AND HOSPITALS
BUREAU OF HEALTH SERVICES FINANCING

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MULTI-SYSTEMIC THERAPY

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OVERVIEW

Multi-Systemic Therapy (MST) is an intensive home/family and community-based treatment for youth who are at risk of out-of-home placement or who are returning home from placement because of problems related to an emotional/behavioral disorder.

The model is based on empirical data and evidence-based interventions that target specific behaviors with individualized behavioral interventions. Specialized therapeutic and rehabilitative interventions are available to address specific areas of need such as substance abuse, delinquency, violent behavior, etc.

Services include an initial assessment to identify the focus of the MST interventions to be used with the individual and family. Services are provided through a team approach to individuals and their families. MST strives to change how youth function in their natural setting (i.e. home, school, and neighborhood). Thus, services are primarily provided in the home, but workers also intervene at school and in other community settings.

The primary goals of MST are to reduce youth criminal activity, reduce antisocial behavior, and achieve these outcomes at a cost savings by decreasing rates of incarcerations and out of home placements.

COVERED SERVICES

Multi-Systemic Therapy (MST) services are provided through a team approach and provided exclusively to Medicaid eligible youth. The intent of the team approach is to:

- Promote the family's capacity to monitor and manage the youth's behavior;
- Involve families and other systems, such as the school, probation officers, extended families and community connections;
- Provide access to a variety of interventions 24 hours per day, seven days per week by staff that will maintain contact and intervene as one organizational unit; and
- Include structured face-to-face therapeutic interventions to provide support and guidance in all areas of functional domains (adaptive, communication, psychosocial, problem solving, behavior management, etc.).

NOTE: MST services are exempt from the CommunityCARE Program and do not require a PCP referral.

Services

MST services include:

- An initial assessment to identify the focus of the MST intervention;
- Therapeutic interventions with the individual and his or her family;
- Peer intervention which refers to the practice of intervening in peer relationships which may be unhealthy and thus hinder the recovery of the recipient.
- Specialized therapeutic and rehabilitative interventions which address all areas seen as contributing to an individual's delinquency including, but not limited to:
    - Substance abuse
    - Sexual abuse; or
    - Domestic violence
- Crisis stabilization.

Non-Covered Services

The following services/activities are not covered services and are *not* reimbursable:

- Tutoring activities;
- Teaching of job related skills (management of symptoms and appropriate work habits may be taught);
- Vocational rehabilitation;

- Transportation;
- Training of staff;
- Preparation for group activities;
- Attempts to reach the recipient by telephone to schedule, confirm, or cancel appointments;
- Supervision of staff;
- Completion of paper work (including but not limited to service logs, weekly reviews; individual treatment plans) when the recipient and/or their significant others are not present;
- Team meetings and collaboration exclusively with staff employed or contracted by the provider where the recipient and/or their significant others are not present;
- Recreational outings;
- Observation of the recipient;
- Staff research on behalf of the recipient; and
- Requiring recipients to be present for documentation purposes.

NOTE: This list is not all-inclusive.

Service Location

Services are provided primarily in the home but may also be provided at other community settings such as places where natural supports for the recipient may be found. In addition to the home and school, service locations may include a community center, church, library, Boys and Girls Club or local park. The service may not be provided in an inpatient setting such as a hospital or residential treatment facility.

Service Documentation

Service logs are the means for clearly documenting allowable services billed. The following information must be entered on the service log (Appendix A) to provide a clear audit trail:

- Service log number;
- Name of recipient;
- Name of employee providing the service and licensure (e.g. LCSW, etc.);
- Date of service contact;
- Begin and end time for service rendered;
- Indication if crisis occurred during the contact,
- Place of service contact;
- Type of contact; (i.e., phone or face-to-face)

- Service provided;
- Service participants;
- Purpose of service contact; and
- Content and outcome of service contact.

NOTE: The service log content must clearly note the overarching goal(s) addressed, current status, as well as the interventions and progress made.

Providers must document team coordination on each case at least once per week. Weekly standardized MST documentation is mandatory as required by MST Inc. The provider must allow the Bureau access to the standardized MST documentation.

Service Duration

The duration of a MST intervention is typically three to six months with 244 units of service, (e.g., each unit equals fifteen minutes of service) delivered during that time period. Weekly interventions may range from 3 to 20 hours per week and may be less as a case nears closure.

Prolonged treatment time in excess of the maximum hours per week will be subject to review by the Bureau.

Service Exclusions

MST services are comprehensive of all other behavioral health services, with the exception of psychiatric/psychological evaluation or assessment and medication management. These may be provided and billed separately for a recipient receiving MST services.

MST shall not be billed in conjunction with the following:

- Mental Health Rehabilitation (MHR), Community Mental Health Centers (CMHC), or Mental Health Clinics (MHC) other than medication management and assessment;
- Partial hospitalization;
- Day treatment;
- Residential services including Therapeutic Family Care;
- Respite care; or
- Any other outpatient therapies (individual, family and group).

NOTE: It is the provider's responsibility to determine at intake whether the recipient is currently engaged in treatment through other entities which may cause conflicts with this policy. The recipient must be allowed freedom of choice of providers, but is not entitled to duplicated services in violation of this policy.

MEDICAL NECESSITY

Recipient Qualifications

To be eligible for MST, a recipient must meet the following criteria:

- Be capable of participating in this therapy
- Be between the ages of 11-17 (Note: A recipient who turns 18 while in therapy may continue until discharge criteria are met.)
- Have serious emotional/behavioral disturbances
- Involved in, or at serious risk of involvement with the juvenile justice system
- At risk of out-of-home placement as a result of one or more of the following behaviors, or returning from out-of-home placement where one or more of these behaviors was the focus of treatment:
    - Anti-social behavior;
    - Aggressive/violent behavior;
    - Substance-abusing behavior.

Within 60 days of admission to the program, an individual must have on file a psychiatric, psychological or psychosocial assessment performed by a licensed psychiatrist, psychologist or licensed clinical social worker. This evaluation cannot be more than 12 months prior to receiving MST services.

Individuals receiving MST services must meet the following criteria to continue treatment:

- Treatment does not require a more intensive level of care;
- The treatment plan has been developed, implemented, and updated based on the youth's clinical condition and response to treatment, as well as the strengths of the family, with realistic goals and objectives clearly stated;
- Progress is clearly evident in objective terms, but goals of treatment have not yet been achieved, or adjustments in the treatment plan to address the lack of progress are evident; and
- The family is actively involved in treatment, or there are active, persistent efforts being made which are expected to lead to an engagement in treatment.

Criteria for Referral of Multiple Youth per Family

The MST team may open separate cases on youth within the same family as long as each youth meets the criteria for inclusion in MST. Services are provided and billed specific to the individual. However, with some services, such as family counseling, it is not reasonable to expect a family to attend double counseling sessions. In this case, only one claim for one recipient may be submitted.

Exclusionary Criteria

MST program staff and referral agency staff should have a clear protocol to follow regarding the identification and disposition of inappropriate referrals. Recipients who meet the following criteria may not clinically be appropriate for MST Services:

- Criteria for out of home placement are met due to suicidal, homicidal or psychotic behavior;
- Living independently or the primary care giver cannot be identified despite extensive efforts to locate all extended family, adult friends and other potential surrogate care givers;
- The referral problem is limited to a serious sexual misbehavior; or
- The primary diagnosis is a pervasive developmental disorder.

Recipients who are inmates of a public institution which is under the jurisdiction or responsibility of a governmental unit are not eligible for MST. This includes juveniles confined involuntarily for any length of time in State or Federal prisons, jails, detention facilities or other penal facilities while awaiting criminal proceedings, penal dispositions, or other involuntary detainment determinations (i.e. juveniles being held involuntarily in a detention center awaiting trial; involuntarily residing at a wilderness camp under governmental control or involuntarily residing in a half-way house under governmental control).

Discharge Criteria

Listed below describes when a recipient no longer meets the medical necessity criteria and resulting in the recipient's discharge.

- The treatment plan goals and objectives have been substantially met;
- The criteria for higher or lower level of care are met;
- The recipient, family, guardian and/or custodian are not engaging in treatment or are not following program rules and regulations despite attempts to address this behavior;

- The consent for treatment has been withdrawn; or
- The recipient and/or family have not benefited from MST despite documented efforts to engage and there is no reasonable expectation of progress at this level of care with continued treatment.

The determination to discharge a youth from MST should always be based upon measurable behavior change rather than arbitrary and predetermined criteria, such as length of treatment. However, discharge from MST must occur when few of the overarching goals have been met, and despite consistent and repeated efforts by the therapist and supervisor to overcome the barriers to further success: the treatment has reached a point of diminishing returns for the additional time invested.

Runaway Policy

If the recipient runs away, the family may be engaged in treatment for up to 14 days. For additional days, the provider must seek approval from the Bureau. To request continuation of services after 14 days, the Bureau must be notified by telephone, email, or mail. The request must accompany service logs documenting progress towards re-engaging with the recipient. If the request is granted and the youth has not returned home by the 30th day, the recipient must be discharged.

NOTE: To re-enter MST after discharge criteria have been previously met, the youth must meet the admission criteria and be treated as a new admission. If admission criteria are not met, the youth should be referred to an appropriate higher or lower level of services.

PROVIDER REQUIREMENTS

Licensing

MST providers must be licensed by MST Services, Inc. of Mount Pleasant, South Carolina, or any of its approved subsidiaries and be enrolled as an MST provider with the Louisiana Medicaid Program.

An MST agency must be a behavioral health/substance abuse provider and a legally recognized entity in the United States, qualified to do business in Louisiana and must meet the standards established by the Bureau or its designee.

Provider Responsibilities

Providers who provide services to Medicaid recipients must:

- Comply with all specified Medicaid participation requirements;
- Verify that individuals are eligible for Medicaid at the time services are delivered and determine if Medicaid recipients have other health insurance; and
- Maintain records that are sufficient to fully disclose the extent and medically necessary nature of the services provided to recipients.

PROGRAM OPERATIONS

General Provisions

The policies and procedures described in this section specify the requirements necessary to provide effective services. The provider shall:

- Assume full responsibility for the delivery of all services, including those delivered through contracts, subcontracts, or consultant agreements.
- Ensure that the office locations meet all applicable federal, state, and local requirements. The transferring of certifications to a new location is strictly prohibited.
- Ensure each office is separately enrolled.
- Ensure that services provided by contractors, subcontractors and consultants conform to all federal and state regulations regarding delivery and documentation of services and staff qualifications.
- Report any suspected or known violations of any civil or criminal law immediately to the appropriate authority and to the Bureau.
- Maintain written procedures and implement all required policies and procedures immediately upon acceptance of recipients for services.

Organizational Structure

The provider must maintain a current, functional organizational chart that defines the lines of authority. The owner must designate an administrator who will have overall responsibility for management of daily operations. The administrator or designee shall be accessible to the Bureau's staff during all normal business hours.

Provider Business Operations

The provider must establish regular business office hours for all certified and enrolled office locations. These locations must be operational at least eight hours a day, five days a week between 7 a.m. and 7 p.m. This requirement does not apply to off-site service delivery locations.

The provider must have a 24 hour/day, 7 day/week on-call system to provide coverage when the designated MST therapist is unavailable. This system must be staffed by MST therapists who are familiar with the details of each MST case.

The backup staff must meet all staff qualifications, training, and supervision requirements outlined in the manual. Critical information, including the comprehensive crisis plan, the current assessment, and the current service plan, must be available to the back-up staff. Backup staff must complete the same training as regular staff members. As outlined by MST, Inc., below are six minimum standards of practice that all MST programs should use to develop their policies for on call procedures:

- The person who is providing coverage is required to attend supervision and consultation the week that coverage is provided and the week prior.
- The person who is providing coverage is fully informed of any current/recent high risk or crisis situations and crisis plans among all of the families.
- The person who is providing coverage has direct access to case paperwork on every family while providing coverage.
- New MST therapists receive training and/or shadowing about on call coverage prior to first taking call.
- The MST supervisor or a back-up is available to therapists who are on-call at all times.
- The MST supervisor has back-up support and the policy for this strategy must be consistent with MST, Inc.'s guidelines for coverage.

Policy Manual

The provider shall develop, maintain, and implement a written internal policy manual. The provider must document that staff has been trained on the policy manual and make it available to all staff. The manual must be made available to the Bureau and recipients upon request. The manual must include the following:

- Policy governing creation and retention of administrative and personnel records;
- A policy for adhering to Americans with Disabilities Act (ADA) guidelines;
- Written procedures for maintaining the security and the confidentiality of recipient records;
- A comprehensive training policy for all employees, volunteers and students which meets specified requirements;
- A brief description of services provided;

- An operations policy that includes a mission statement, program philosophy, and goals of the provider;
- Complaint resolution procedures, including DHH as the final point of resolution;
- Policies and procedures for reporting and investigating suspected cases of abuse, neglect, extortion or exploitation.

Abuse, Neglect, Extortion or Exploitation Policy

Providers must have a policy that clearly defines abuse, neglect, extortion and exploitation of children and adults. All such policies and definitions must be in accordance with applicable state and federal laws, including, but not limited to the following:

- LSA-R.S. 14:403.2 et seq. (or subsequent updates);
- LSA-Ch.C Art. 601 et seq (or subsequent updates);
- LSA-R.S. 40:2009.13 et seq. through 2009.20, excluding 2009.18 (or subsequent updates).

Providers must have a documented policy and procedure for reporting suspected cases of abuse, neglect, extortion or exploitation, including mandatory reporting by staff as required by state laws (LSA-R.S. 14:403.2, LSA-CH.C Art. 601 et seq, LSA-R.S. 40:2009.20) and the Department of Health and Hospitals' (DHH) regulations. A staff member, subcontractor, volunteer or intern who witnesses, has knowledge of, or otherwise has reason to suspect that such an incident may have occurred must report the incident to the appropriate law enforcement and state agencies such as Office of Community Services (Child Protection), Adult Protective Services, and the Bureau.

Providers must also have an internal procedure to investigate and report such incidents allegedly committed by an employee. The procedure shall include, at a minimum, the following:

- The incident must be reported to the appropriate law enforcement and state agencies such as the Office of Community Services, Adult Protective Services, and the Bureau;
- Any allegation of abuse, neglect, extortion or exploitation lodged against an employee must be reported to the administrator, and the administrator must cooperate in any investigation of the incident;
- Individuals under investigation are not to be part of the investigation team;
- Individuals under investigation are prohibited from working or having any contact with the recipient who made the allegation.

- The findings of the investigating team are to be reviewed at the appropriate administrative level and forwarded to the governing body.
- In substantiated cases of neglect, appropriate action is to be taken to prevent a reoccurrence.
- In substantiated cases of abuse, extortion or exploitation, the employee must be terminated.
- The incident must be reported to the appropriate licensing board.

Employment and Personnel Policies

Each provider must have written employment and personnel policies, which include job descriptions for all positions that specify duties, qualifications, and competencies and describe the hiring policies and practices including the following:

- A policy for the prevention of discrimination based on race, color, religion, sex, age, national origin, disability, disabled veteran, or any other non merit factor;
- A procedure for maintenance of time and attendance logs for all employees and contractual staff;
- A procedure for the creation and retention of personnel records;
- A procedure for conducting Tuberculosis (TB) Tests. Each provider must coordinate processes to reduce the risk of such infections in recipients and staff; Skin testing procedures should be made part of the provider's infection control program. All persons, prior to or at the time of employment shall be free of TB in a communicable state;
- Policies and procedures regarding personal safety of staff while providing services;
- A policy on criminal background checks.

Personnel Records Policy

The provider shall develop, implement and maintain a personnel records creation and retention policy. All relevant information necessary to assess qualifications for all staff, volunteers and consultants shall be verified and documented. All required licenses as well as professional, educational, work experience and dates of employment must be verified. All verifications must be documented in the employee's personnel record prior to the individual providing billable Medicaid services. See Record Keeping (Section 42.6) for more information regarding personnel records.

Employee Tuberculosis Tests

Any employee who has a negative Mantoux skin test for TB shall be retested annually in order to remain employed. Any employee who has a positive Mantoux skin test must provide evidence of a normal chest X-ray, a statement from a physician certifying that the individual is non-infectious if the chest X-ray is other than normal or completion of an adequate course of therapy as prescribed by a licensed physician, if active TB is diagnosed. Any employee who has a positive Mantoux skin test must provide an annual physician's statement that they are free of TB in a communicable state.

Criminal Background Checks

As a provider offering services to children and/or adolescents, the background checks must be performed as required by R.S. 15:587.1 and R.S. 15:587.3 et seq.

Providers must conduct criminal background checks through the Louisiana Department of Public Safety (State Police) on all employees prior to employment. Forms to request background checks may be found at http://www.lsp.org/pdf/crAuthorizationForm.pdf. If the healthcare provider works with children, "working with children" must be selected on the form in order to comply with LSA 15.587.3.

If the results of any criminal background check reveal that the employee was convicted of any offenses against a child or an elderly or disabled person, the employer shall not hire and/or shall terminate the employment of such person. In the case of an individual with a criminal background record involving other offenses, the provider should exercise caution and good judgment in conjunction with their liability insurance carrier regarding hiring that individual. The provider shall not hire an individual with a record as a sex offender or permit these individuals to work for the provider as a subcontractor.

Drug Testing Policy

The provider shall have a policy to ensure an alcohol and drug-free workplace and a workforce free of substance abuse. The policy must include:

- A pre-employment drug screen before an offer of employment is made. A prospective employee who tests positive for the presence of illegal drugs in the initial screening shall be eliminated from consideration for employment;

- A provision prohibiting employees from reporting for work or performing work with alcohol, illegal drugs, controlled substances, or designer (synthetic) drugs present in their bodies;
- A prohibition from illegal use, possession, dispensation, distribution, manufacture, or sale of controlled substances, designer (synthetic) drugs, and illegal drugs at the work site and while on official business, on duty or on call for duty;
- A provision for random drug testing of employees and a written plan to handle employees who test positive for illegal drug use whether the usage occurs at work or during off duty hours;
- Documentation shall be readily retrievable upon request by the Bureau.

Financial Management Policy

The provider shall establish a system of business management and staffing to assure maintenance of complete and accurate accounts, books and records in keeping with generally accepted accounting principles. The provider must:

- Be capable of reporting fiscal data from July 1 through June 30.
- Maintain adequate funding for required staff and services.
- Maintain a separate business bank account.

Recipient Orientation Policy

Orientation must be conducted for all new recipients. Information must be provided to the recipient verbally and in writing. The recipient must sign an acknowledgement form that he/she received the information. A copy of the signed acknowledgement form must be given to the recipient. The orientation information must include the following:

- A mission statement;
- Type of intervention service offered;
- Staff qualifications;
- A statement of afterhours access to services;
- Recipients crisis management procedures, including de-escalation;
- Complaint resolution procedures, including DHH as the final point of resolution;
- Discharge planning procedure;
- Emergency preparedness plan;

- Recipient's rights including but not limited to:
  - Freedom to choose his/her provider;
  - The right to ask for a different provider;
  - The right to request changes to their initial treatment plan, crisis plan and discharge plan;
  - The right to confidentiality;
  - The right to review their record; and
  - The right to complain about their services without fear of reprisal, such as discontinuance of services.

NOTE: Recipients have these rights regardless of their age, race, sex, religion, culture, lifestyle, ability to communicate, or disability.

Quality Management Policy

The provider must utilize MST, Inc. Quality Assurance Program system for the ongoing monitoring of the quality, appropriateness and utilization of services delivered. Data collected must be reliable, valid, complete and accurate and must be made available to the Bureau upon request. Provider staff performing the quality management (QM) function should be knowledgeable regarding QM procedures.

Findings should be used to make programmatic changes, to identify training needs, to improve the quality of services and in financial and resource planning.

Emergency Preparedness Plan

Each provider must develop and implement an emergency preparedness plan that includes:

- The measures that will be taken to ensure the safety and security of employees and recipients;
- Provisions to protect business records, including employee and recipient records; and
- A means of communication with the Bureau to report status of the provider post-disaster.

NOTE: If the provider must close its offices due to a disaster, the provider may not resume or continue to provide g reimbursable services until authorized to do so by the Bureau.

STAFFING AND TRAINING

The Bureau has established staffing requirements to maintain an adequate level of effective, efficient, and professional services. The provider must ensure that the staff members possess the minimum requisite skills, qualifications, training and provide supervision and coverage in accordance with the requirements described in this manual chapter.

Appropriate staffing must be available to adequately implement the recipient's service plan.

Licensed behavioral practitioners must provide clinical services and supervision in accordance with their scope of practice. All practitioners must hold an unrestricted Louisiana license.

Staffing Requirements

Staffing for MST services shall be comprised of no more than one-third bachelor's level staff and at a minimum, two-thirds licensed master's level staff. MST team members must include, at a minimum:

- Masters level clinical supervisor who is an independently licensed behavioral health professional; and

- Licensed masters, non-licensed masters or bachelors level behavioral health staff able to provide 24 hour coverage, seven days per week.

NOTE: All degrees must be from a nationally accredited institution of higher education as defined in Section 102(b) of the Higher Education Act of 1965, as amended.

Staff Licensing and Responsibilities

Mental/Behavioral Health Practitioners
Licensed master's level may perform all therapeutic interventions and supervision of non-licensed staff.

Non-Licensed master's level and bachelor's level may *not* provide clinical supervision and must be supervised by a licensed master's level practitioner for all clinical activities.

MST Supervisors

PH.D level or Licensed Master's level mental/behavioral health practitioners may perform as MST supervisors.

MST Supervisors must:

- Conduct weekly group supervision for MST team to assure adherence to MST principles and the MST analytic process;
- Conduct individual supervision as needed to target clinician competency needs and to remove individual barriers to effective implementation of MST treatment;
- Assure appropriate documentation of clinical effort to allow for peer and supervisory input, and to meet all reporting and communication needs of funding and referral sources;
- Provide supportive and corrective feedback to clinicians to promote client outcomes.
- Provide administrative support targeting in systemic barriers to treatment success;
- Assure availability of clinical and administrative support to clinicians 24 hours/day, 7 days/week;
- Assure therapist accessibility to clients when needed at times most likely to promote engagement;
- Assure that clinicians achieve engagement with all key participants;
- Provide direct clinical training to assure clinician competency in all clinical areas relating to the implementation of MST interventions.

Assure all assessments are comprehensive, multi-systemic, and provide adequate information to determine the causes and correlates to referral behaviors to direct effective treatment within the ecological context.

NOTE: Supervision, following MST supervisory protocol, shall be provided to team members on topics directly related to the needs of MST recipients and their families ongoing. Additionally, a minimum of one-hour local group supervision per week and one hour of telephone consultation per week with an MST systems supervisor is required.

MST Therapists

MST Therapist must have a master's degree in psychology, social work, counseling or a related subject area. Although a master's degree is preferred, a **bachelor's degree** in social work, counseling, psychology or a related human services field ***and at least 3 years of experience working with the target population (youth and their families)*** is allowed. However, a master's degree is preferred.

MST Therapist must:

- Conduct MST assessment including review of referral information, identifying and engaging key participants, identifying systemic strengths and weaknesses, and developing an analysis of the fit of problem behaviors within the ecological context.
- Engage primary caregiver and other key participants in active change-oriented treatment by identifying and overcoming barriers to engagement.
- Implement a problem conceptualization, treatment planning, intervention implementation, and outcome review and strategy revision procedure using the MST Analytic Process.
- Maintain clear and concise documentation of treatment efforts that promote peer and supervisory review and feedback, and that demonstrate compliance with the 9 MST Principles and the MST Analytic Process.
- Collaborate with all relevant systems and key participants within each system to ensure their buy-in and cooperation throughout MST treatment.
- Provide direct clinical treatment using methods compatible with MST principles and practices.
- Participate in all MST training, supervision and consultation activities.

Program Staffing Requirements and Clinical Supervision

MST providers must meet the following program staffing requirements:

- MST therapists are full-time staff with low caseloads of 4 to 6 families.
- One supervisor per each team consisting of two to four full-time therapists.
- One 50% supervisor to one MST team or one 100% supervisor to two teams.
- MST supervisors carrying a partial MST caseload (one team) must be assigned to one to three cases – depending on the experience of therapist.

Staffing Ratios

MST direct service staff to family ratio shall not exceed one to six (1:6).

Staff Training

All clinical staff are required to participate in and complete a five day MST introductory training and subsequent quarterly training as required by MST Inc. This training must be documented in the employee's personnel record.

Orientation

Staff orientation must consist of 16 hours of on-site instruction which includes all of the following content areas:

- Confidentiality, including HIPAA;
- Protection of rights and reporting of violations;
- Abuse and neglect policies and procedures;
- Emergency and safety procedures;
- Infection control procedures;
- Agency policies and procedures;
- Ethics, including advertising and solicitation;
- Basic information about mental illness;
- Developing and implementing behavioral interventions;
- Skills training (specific teaching methods and methods to track consumer progress);
- Linking and coordinating natural and community supports;
- Crisis intervention;
- Suicide and homicide precaution procedures;
- Person and family centered services;
- Prevention of workplace violence;
- Expectations regarding professional conduct; and
- Recipient rights.

Bureau Training

The provider staff must attend and participate in all trainings and meetings mandated by the Bureau.

RECORD KEEPING

Provider records must be maintained in an organized and standardized format at the enrolled office site. Original records shall not be kept in off-site service delivery locations. The provider must have adequate space, facilities, and supplies to ensure effective record keeping.

Retention of Records

MST providers must retain administrative, personnel and recipient records for five years from the date of the last payment. However, if the provider is being audited, records must be retained until the audit is complete, even if the five years is exceeded.

In the event records are destroyed or partially destroyed in a disaster such as a fire, flood or hurricane and rendered unreadable and unusable, such records must be properly disposed of in a manner, which protects recipients' confidentiality. A letter of attestation must be submitted to the fiscal intermediary.

NOTE: Upon agency closure, all provider records must be maintained according to applicable laws, regulations and the above record retention requirements. The Bureau must be notified of the location of the records.

Destruction of Records

After the required record retention period has expired, records may be destroyed. Confidential records must be incinerated or shredded to protect sensitive information. Non-paper files, such as computer files, require special means of destruction. Disks or drives can be erased and reused, but care must be taken to ensure all data is removed prior to reuse. Commercially available software programs can be used to ensure all confidential data is removed.

Confidentiality and Protection of Records

Administrative and recipient records are the property of the provider. Records must be secured against loss, tampering, destruction or unauthorized use in accordance with Health Insurance Portability and Accountability Act (HIPPA) regulations.

The provider must safeguard the confidentiality of any information, which may identify the recipients or their families. The information may be released only under the following conditions:

- By a court order,
- By the recipient's written, informed consent for release of information,
- If the recipient has been declared legally incompetent, his/her legal representative must provide written consent, or
- If the recipient is a minor, the parent or legal guardian must provide written consent.

Recipient records information must be made available upon request to the recipient, legal guardian, or other service providers including another MST provider in case of a recipient transfer. If in the professional judgment of the provider, information contained in the record would be harmful to the recipient; this information may be withheld from him/her except when a court order is presented.

A provider may use material from recipient records for educational purposes if names are deleted and other identifying information is removed. For research purposes, providers must comply with Bureau's research policy (refer to Appendix B).

NOTE: Under no circumstances should providers allow staff to remove recipient records from the provider's site.

Review by State and Federal Agencies

Providers must make all administrative, personnel and recipient records available to the Bureau and appropriate state and federal personnel upon request. Failure to allow access to records in a timely manner may result in a sanction.

Administrative Records

The provider's administrative files must have critical program information including but not limited to documentation of Medicaid enrollment, insurance policies, minutes of formal meetings, bylaws of the governing body, if applicable, training and supervision documentation, and required policies and procedures as detailed in Section 42.5 Staffing and Training. An employee must have reasonable access to his/her personnel file and must be allowed to include any written statement he/she wishes in the file.

Personnel Records

Personnel records shall be maintained for all staff, subcontractors, volunteers and interns. The record must contain all information as detailed in Section 42.5 Staffing and Training. All verifications must be documented in the employee's or agent's personnel record prior to the individual providing billable Medicaid services. An employee must have reasonable access to his/her personnel file and must be allowed to include any written statement he/she wishes in the file. A provider must not release a personnel file without the employee's written permission except according to state law. Below is a description of items which must be included in personnel records.

Employment Verification

Employment verification must include the employee's resume or employment application with documentation of previous employment.

Employment verification must also include written documentation from a previous employer or a signed statement verifying that verbal contact was made with the previous employer. The statement must document the applicant's experience, and include the name, address and current telephone numbers of the former employer or supervisor. The month and year of past employment must be documented.

If the past employer is no longer in business, and employment cannot be verified, that job experience may not be included toward required experience.

Experience must be in a paid, 40 hours per week position. If experience is in a part-time position, the provider must be able to verify the amount of time worked equals the required period for full time employment. College work/study or internship related to completion of a degree cannot be counted as work experience. Experience obtained while working in a position for which the individual is not qualified cannot be counted as experience.

Education Verification

Educational documents including current professional license, degrees and certified transcripts shall be maintained in the records. All college degrees must be from a nationally accredited institution of higher education as defined in Section 102(b) of the Higher Education Act of 1965, as amended.

References

Three references must be obtained prior to employment for any employee who will be directly providing services. At least two of the references must be professional and/or work related. Professional/work related references must be explicit with regard to previous work experience and performance. The reference documentation must include the date, address and telephone number of the individual who is providing the reference.

Driver's License

A current and valid Louisiana driver's license and current automobile insurance is required and must be included in the employee's personnel record.

Employee Training

Employee training and orientation documentation as required by the Bureau.

Confidential Personnel Information

The following are to be maintained in a separate confidential file available for review when requested by the Bureau or other legitimate governmental entities:

- Drug testing results,
- Criminal background check, and
- TB test results.

Recipient Records

Records must be maintained in chronological order. Documentation shall be sufficient to verify that services conform to the Bureau policy as stated below and that the reimbursement amount is correct.

The organization of individual records and location of documents must be uniform. Records must be appropriately purged so that material can be easily located. Records must contain all current pertinent information relating to services provided. Records older than six months must be kept on-site and be available for review upon the request of the Bureau.

All entries and forms completed by staff in recipient records must be:

- In ink, in a color other than black,
- Legible,
- Fully dated,
- Legibly signed, and
- Include the functional title of the individual making the entry.

Any error in a recipient's record must be corrected using the legal method, which is to draw a line through the incorrect information, write "error" by it and initial the correction. Correction fluid must never be used in a recipient's records. If information is typed, signatures must be in ink, in a color other than black.

Components of Recipient Records

The recipient's record must consist of the current and active information as well as any other stored files or folders. The active information is detailed below. However, the recipient may refuse to provide information related to race, ethnic origin, sex, or marital status, in which case the refusal of the recipient must be documented.

Active information recorded in a standardized format must include the following:

- Name
- Home address
- Home telephone number
- Date of birth
- Sex
- Race or ethnic origin
- Verification of recipient's Medicaid eligibility and if applicable, other health insurance coverage
- Living arrangements
- Closest living relative/guardian
- Education
- Name, address, and telephone number of school and employer if applicable
- Date of initial contact
- Court and/or legal status, including relevant legal documents
- Names, addresses, and telephone numbers of others involved with the recipient's treatment plan
- Date this information was gathered
- Required signatures on all forms, and
- Signed release of information form.

- Documentation verifying the recipient meets medical necessity criteria including copies of required professional evaluations, past treatment records, the MST screening form, the MST initial and reassessment reports, and other reports and information concerning the recipient's medical, social, familial, cultural, developmental, legal, educational, vocations, psychiatric and economic status;
- A completed and signed treatment plan including the crisis and discharge plan;
- A discharge summary including the reason for case closure and any agreements with the recipient at closure must always be completed and maintained;
- Service Logs;
- Copies of all pertinent correspondence; and
- A description of any current treatment or medication necessary for the treatment of any serious or life threatening medical condition or known allergies. This may include documentation from the treating physician.

Service Logs

Service logs document the allowable service and must reflect the services delivered. To obtain a copy of the service log, refer to Appendix A. Service logs will be reviewed during monitoring, and when deemed necessary by the Bureau. Record entries must correspond with the services provided including billable services entered into the statewide data system as well as non-billable services. See section 42.1 for further details on service log documentation.

CLAIMS RELATED INFORMATION

Claims Filing (Billing)

MST services must be billed using the electronic 837P transaction or the most current hard copy CMS-1500 claim form. Filing electronically is preferred.

Separate line items are available to accommodate reporting of different places of service on the same date.

Telephone conversations with MST families and collateral contacts are billable as long as they are related to a service intervention provided to an eligible recipient, rather than administration-related. Thus, a collateral contact with a school teacher would be billable, while a call to schedule an appointment or supervisory discussion between staff members would not.

NOTE: ***Billing Medicaid Recipients Reminder*** **-** Recipients shall not be held responsible for claims denied due to provider error. Medicaid providers are also reminded that if they accept Medicaid reimbursement for services rendered, any reimbursement is considered payment in full for those services and the Medicaid recipient cannot be billed for the difference.

Reimbursement Methodology

Reimbursement is a prospective flat rate fee for service for each approved unit. One-quarter hour (15 minutes) is the standard unit of service and covers both service provision and administrative costs.

Partial units are billed by adding up the total minutes for the specified date of service; dividing by 15 and round down to the nearest whole number.

Services are billed with procedure code H2033, by date of service and in 15 minute increment/units of service. This procedure code is used to bill for any services provided by the MST team, including assessment and ongoing treatment.

The procedure code is billed with the modifier HN to signify that the services were rendered by a bachelor's level therapist. The fee is 80% of the fee on file for H2033. Providers must bill using usual and customary rate. Providers cannot bill more for Medicaid recipients than for other patients receiving the same service.

PROGRAM MONITORING

The Bureau shall use various methods of program monitoring to ensure that all services comply with the program standards. It is the provider's responsibility to be knowledgeable regarding the policies and procedures governing the program. Non-compliance may result in the recoupment of Medicaid payments, administrative sanctions and/or a referral to the appropriate state and/or federal authorities for further investigation, which may result in additional punitive action.

Monitoring

The Bureau may conduct a monitoring review for reasons including, but not limited to, ensuring compliance with program requirements, reviewing billing practices and investigating complaints and grievances.

A monitoring review may include a review of recipient, personnel and administrative records as well as provider profile data, including, but not limited to, access and review of MST Inc. quality monitoring data (e.g. Therapist Adherence Measures (TAM) data, Supervisor Adherence Measures (SAM) data, MST utilization and client survey data, etc.), staff and recipient interviews and any other requested data or file.

Monitoring interviews may include speaking with a representative sample of recipients, the family, teacher(s) and other school personnel, with the approval of the parent or guardian. Interviews with current and/or former staff, MST Inc., network partners and clinical supervisors may also be included.

Upon completion of a monitoring review, the Bureau staff may conduct an exit interview to discuss the findings. A written summary of the findings will be sent to the provider, stating whether a plan of correction is required.

Plan of Correction

A plan of correction, if required, must be submitted to the Bureau within 10 working days of the date of the summary of the monitoring review findings. The plan must address the correction of each deficiency cited in the summary.

If the plan is not submitted within 10 working days from request, sanctions as described in Chapter 1 (General Information and Administration) of the Medicaid Provider Manual may be applied. If the plan of correction submitted does not meet Bureau standards, it will be returned to the provider for revision.

All deficiencies must be corrected within **60 days** of receipt of the notice. Failure to do so may result in sanctions. A follow-up review may be conducted by the Bureau to ensure that all deficiencies have been corrected.

ADMINISTRATIVE SANCTIONS

Administrative sanctions may be imposed against a provider that does not meet the requirements as established in laws, rules, regulations or policies. This section explains the administrative actions and sanctions as they apply to an MST provider. In addition, sanctions cited in Chapter 1 (General Information and Administration) and the Surveillance and Utilization Systems (SURS) rule, LAC 50:1 Chapter 41 (Louisiana Register, Volume 29, Number 4) may be imposed.

The following sanctions may be applied to any provider independently, consecutively and/or collectively.

- The provider's staff may be required to complete education and training, including training in MST policy and billing procedures provided by DHH. The provider may also be required to obtain other education or training relevant to providing quality MST services which the Bureau will not provide.
- Payments for services rendered may be suspended or withheld until program compliance is verified.
- The provider may be terminated. Terminated providers, including all of the owners, officers, or directors may not apply for certification as an MST provider for a period of up to five years. The provider must assist the recipient in locating other services.
- New requests for payments may be denied until program compliance is verified.
- The provider's current recipients shall be transferred to another provider if the Bureau determines that recipient health and safety are compromised. In the absence of an available provider, the recipient may be referred to an alternate treatment source.
- Individuals employed by the provider may be suspended or excluded from providing MST services.

NOTE: Health and safety issues will be resolved on a case-by-case basis by Bureau personnel making a determination after examining the circumstances surrounding each particular event or finding. The Bureau is allowed the flexibility to explore fully any circumstances surrounding each unique situation to ensure that the well-being of the recipient and the integrity of the Medicaid Program are protected.

Grounds for Sanctioning Providers

The following are grounds for sanctioning of an MST provider:

- Failure to comply with any and all licensing agreements, certification, administrative, accreditation, training or operational requirements at any time;
- Failure to provide services specified in the recipient's service agreement;
- Failure to uphold recipients' rights when violations may or could result in harm or injury;
- Failure to notify proper authorities of all suspected cases of neglect, criminal activity, or mental or physical abuse which could potentially cause, or actually causes harm to the recipient.
- Failure to maintain adequate qualified staff to provide necessary services;
- Failure to adequately document that services billed were actually performed;
- Failure of an MST provider's subcontractors to meet all required standards;
- Failure to fully cooperate with a Bureau survey or investigation including, but not limited to failure to allow Bureau staff entry to the provider's or subcontractor's offices or denial of access to any requested records during any survey or investigation;
- Failure to comply with all reporting requirements in a timely manner;
- Failure to provide documentation that verifies compliance with any requirement as set forth in this policy;
- Failure to comply with any or all federal and state regulations, the provider manual and any other notices or directives issued by the Bureau;
- Failure to protect recipients from harmful actions of an MST provider's employees or subcontractors including but not limited to health and safety, coercion, threat, intimidation, solicitation or harassment;
- Failure to remain fully operational at all times for any reason other than a natural disaster;
- A substantial pattern of consistent complaints filed against a MST provider, within a one year period;
- A false statement of a material fact knowingly (or with reason to know) made by an owner or staff person of the MST provider in the following areas;
    - An application for enrollment;
    - Data forms;
    - A recipient's record;
    - Any matter under investigation by the Bureau; or
    - Licensing renewal.
- Use of false, fraudulent or misleading advertising;
- Failure to disclose a conviction for a criminal offense by a person who has ownership or controlling interest in the provider agency, or by a person who is an agent or managing employee of the MST provider, or
- If the facts determined by the department indicate a failure to provide optimum care in accordance with current standards of practice.

Informal Review

Any provider receiving a notice of sanction may be provided an opportunity to request an informal review. The request for an informal review must be made in accordance with the instructions in the notice of sanction.

The informal review process is designed to allow the provider to:

- Review the reasons and rationale for the proposed sanction(s);
- Discuss the reasons and findings related to the proposed sanction(s);
- Ask questions and seek clarification; and/or
- Submit additional relevant information.

To arrange an informal review, the request must be made by the provider in writing and within 15 calendar days (including Saturdays and Sundays) of receipt of original notice of sanction. All such written requests must be sent to the DHH Program Integrity Section.

The provider may be represented by an attorney or an authorized representative at the review. The attorney or authorized representative must file a written notice of representation identifying himself/herself by name, address, and telephone number at the address given above.

After the informal review is completed, the Bureau shall inform the provider in writing of the results and conclusions. The provider has the right to seek an administrative appeal of the sanction within thirty (30) days of the receipt of the results of the informal review.

Fraud and Abuse

Sanctions in the form of a termination based on fraud and abuse or health and safety shall take effect immediately upon notice by the Bureau.

In cases not involving health and safety or program integrity issues where fraud or abuse is at issue, a sanctioned provider who has timely filed an appeal shall be allowed to accept new recipients during the appeals process unless the appeal is delayed beyond 90 days due to action on the part of the provider. If the appeal is delayed beyond 90 days due to action on the part of the provider, the provider may be prohibited from taking on new recipients until a ruling on the appeal has been issued.

Notice and Appeal Procedure

A provider that contests any adverse action taken by the Bureau may appeal such action by submitting a written request for an appeal to the Department's Bureau of Appeals. The request must be received by the Bureau of Appeals within 30 days of the provider's receipt of the notification of the Bureau's action.

ACRONYMS/DEFINITIONS/TERMS

APS – Adult Protective Services

BHSF/Bureau – Bureau of Health Services Financing (or its designee)

DHH – Department of Health and Hospitals

FI – Fiscal Intermediary

HIPAA – Health Insurance Portability and Accountability Act

MHR – Mental Health Rehabilitation

MST – Multi-Systemic Therapy

MST Services, Inc. – MST providers must be licensed by MST Services, Inc. of Mount Pleasant, South Carolina or any of its approved subsidiaries.

OCS – Office of Community Services / Child Protection Agency

POC – Plan of Care

QM – Quality Management

SAM – Supervisor Adherence Measure

TAM – Therapist Adherence Measure

TB – Tuberculosis

TPL – Third Party Liability

APPENDIX A

MST Service Log

Department of Health and Hospitals Behavioral Health
Multi-Systemic Therapy Log

Service Log #: __ __ __ __ __ __

Case Number: __ __ __ __ Recipient Name: _____

Provider #: __ __ __ __ __ __ __

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1. Date: __/__/__

2. Begin Time: __ : __ (hh:mm)

End Time: __ : __ (hh:mm)

3. Place of Service: __

4. Type of Contact: __

5. Procedure Code: _ _ _ _ _ **Modifier:** __

6. Service Participants: __

__

__

__

NOTE:
*Please include persons present and relation to child, purpose of service contact (overarching goals addressed), interventions and progress.

Therapist's Signature, Licensure *(required)* Date

MST SERVICE LOG CODES

3. PLACE OF SERVICE

03 School
11 Office
12 Home
14 Group Home
99 Other Place of Service

4. TYPE OF CONTACT

01 In Person
02 Telephone
03 Written

6. SERVICE PARTICIPANTS

01 Recipient
02 Family Member/Legal Guardian
03 Essential Other
04 Mental Health Provider
05 Education
06 OCS
07 Substance Abuse
08 Probation/OYD
09 Health
14 Clinical Management Team Member
99 Other

APPENDIX B

POLICY NUMBER:	0021-98
SUBJECT:	Departmental Research
CONTENT:	Policy and procedures for the protection of human subjects of research projects conducted in facilities and programs operated or funded by the Department of Health and Hospitals
EFFECTIVE DATE:	Issued: March 1, 1991 (Office of Human Services Research Policy) Revised: March 20, 1998
INQUIRIES TO:	Office of Management and Finance Division of Research and Development P.O. Box 2870 Baton Rouge, LA 70821-2870 Telephone: (225) 342-3807 FAX (225) 342-0080

I. PURPOSE

These policies are designed to assure the protection of the rights of human subjects of research conducted in programs or facilities operated or funded by the Department of Health and Hospitals (DHH).

II. APPLICABILITY

These policies apply to all research conducted in programs/facilities operated or funded by the DHH.

III. DEFINITIONS

Cognitively Impaired - having either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders), an organic impairment (e.g., dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgement and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps may also be compromised in their ability to make decisions in their best interests.

Competence - technically, a legal term, used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. (See also: *Incompetence*, *Incapacity*.) Competence may fluctuate as a function of the natural course of a mental illness, response to treatment, effects of medication, general physical health, and other factors. Therefore, mental status should be re-evaluated periodically. As a designation of legal status, competence or incompetence pertains to an adjudication in court proceedings that a person's abilities are so diminished that his or her decisions or actions should have no legal effect. Such adjudications are often determined by inability to manage business or monetary affairs and do not necessarily reflect a person's ability to function in other situations.

DHH - Department of Health and Hospitals (Louisiana).

DHHS - U.S. Department of Health & Human Services. This Federal agency promulgated 45 CFR, Part 46, *Protection of Human Subjects*, revised June 18, 1991, effective August 19, 1991. DHH's research policies are based upon 45 CFR, Part 46.

Human Subject - a living individual about whom an investigator (whether professional or student) conducting research obtains:

1. data through intervention or interaction with the individual; or

2. identifiable private information.

Identifiable Private Information - private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identification of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Incapacity - refers to a person's mental status and means inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. Often used as a synonym for incompetence.

Incompetence - technically, a legal term meaning inability to manage one's affairs. Often used as a synonym for incapacity.

IRB Approval - the determination of the IRB that the research has been reviewed and may be conducted within the constraints set forth by the IRB and by other State and Federal requirements.

Institutional Review Board (IRB) - the DHH committee with responsibility for reviewing and recommending approval/disapproval of all research proposals.

Interaction - includes communication or interpersonal contact between investigator and subject.

Intervention - includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or his/her environment that are performed for research purposes.

Investigator - the person conducting research.

Minimal Risk - the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Programmatic Offices - the major programmatic offices in DHH are: Bureau of Health Services Financing (BHSF), Office of Alcohol and Drug Abuse (OADA), Office for Citizens with Developmental Disabilities (OCDD), Office of Mental Health (OMH), and Office of Public Health (OPH).

Research - systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

IV. STATEMENT OF PRINCIPLES

A. The DHH believes that research involving human subjects must be based upon the principles of *respect for persons, beneficence, and justice*.

1. *Respect for persons* involves a recognition of personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy.

2. *Beneficence* entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm.

3. *Justice* requires that benefits and burdens of research be distributed fairly.

B. DHH also recognizes that many consumers of its services may be cognitively impaired and therefore deserve special consideration as potential research subjects. The predominant ethical concern in research involving persons with psychiatric, cognitive, developmental, or chemical dependency disorders is that their conditions may compromise their capacity to understand the information presented and their ability to make a reasoned decision about participation. Consequently, approval of proposals to use these individuals as research subjects will be conditioned upon the researcher demonstrating that:

1. such individuals comprise the only appropriate subject population;

2. the research question focuses on an issue unique to these subjects;

3. the research involves no more than minimal risk, except when the purpose of the research is therapeutic for these individual subjects and the risk is commensurate with the degree of expected benefit.

V. POLICIES AND PROCEDURES

A. Policy Basis

Research conducted and authorized by the DHH will meet all applicable federal and state laws and regulations, accreditation standards, and professional codes of ethics. These policies derive primarily from 45 CFR, Part 46, *Protection of Human Subjects* and are also consonant with 21 CFR, Parts 50 and 56, adopted by the Food and Drug Administration. (Both sets of regulations were effective on August 19, 1991.) 45 CFR, Part 46 is applicable to other DHHS components, including the Health Care Financing Authority (Medical Assistance Programs).

B. Establishment of Institutional Review Board (IRB)

There is hereby established a DHH IRB to review and evaluate all proposed research projects.

1. Twenty-four hour facilities may either utilize these policies as written or amend them to provide for an in-house IRB for initial assessment of research projects prior to submission to the DHH IRB for final review.

2. All research involving DHH consumers, employees, or services in the community and in institutions will be reviewed by the DHH IRB before it is submitted to the Secretary or designee for final approval.

3. The IRB is a permanent standing committee which meets quarterly or as needed.

4. The membership shall consist of at least seven members, appointed by the Secretary, partly from recommendations by the assistant secretaries and the director of the BHSF:

    a. The director of Research and Development or his/her designee shall serve as permanent chairperson of the IRB. In the event of an extended absence from duty of the permanent chair, the Secretary shall appoint a temporary replacement to serve during that period;

    b. each office and the BHSF shall have at least one member;

    c. relevant professional disciplines shall be represented in the membership;

    d. at least one member shall be a direct service provider;

e. one member shall not be employed by the DHH. If possible, this member should be an ethicist (specialist in ethics) or an attorney;

f. at least one member shall be either a primary consumer, or a family member, or an advocate;

g. at least one member's primary concerns shall be in science areas and at least one member's primary concerns shall be in non scientific areas. If not selected under Section V.B.4.e., an attorney or ethicist should fill the latter slot.

5. The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available to the IRB. Such individuals shall not vote with the IRB.

6. IRB members should have appropriate research training, experience or interest. Membership should also represent sufficiently the cultural, ethnic, and gender diversity of the State and be sensitive to diverse community attitudes.

7. Except for the chair, members shall be appointed for one-year terms and may be reappointed.

8. No IRB member may participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

9. Once constituted, the IRB shall adopt written by-laws and guidelines/application materials for conducting research in DHH operated/funded programs or facilities.

10. Research approved by the Office of Public Health's (OPH) IRB prior to the adoption of these policies does not require DHH IRB approval. However, copies of proposals approved by the OPH IRB shall be provided to the chair of the DHH IRB.

C. IRB Review Process

Prior to authorization and initiation of research, an IRB meeting shall be convened to conduct a detailed review of the project in order to determine that all of the following requirements are met.

1. Proposal incorporates procedures designed to minimize the risk to participants. Risks to subjects are minimized by using procedures which are consistent with sound research design and do not unnecessarily expose subjects to risk and,

whenever appropriate, by using procedures already being performed on subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits and the importance of any knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research, as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research. The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., possible effects of research on public policy) as among those research risks that fall within its purview.

3. Selection of subjects is equitable. In making this assessment, the IRB should take into account the purposes and setting of the research. It should be particularly cognizant of special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

4. Research design minimizes possible disruptive effects of project on organizational operation.

5. Research design is in compliance with accepted ethical standards.

6. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required in Section V.E. of this document.

7. Informed consent will be appropriately documented, in accordance with and to the extent required by Section V.E.1 - E.5 of this policy.

8. When appropriate, the research plan provides monitoring of the data collected to ensure subjects' safety.

9. Research proposal contains requisite safeguards to protect the privacy of subjects and to maintain the confidentiality of data.

10. Research proposal has been approved at the appropriate program administrative level, beginning with the program/facility.

D. IRB Recommendations and Notification

1. Researchers should be either present at the IRB meeting which considers their proposals or available for questioning at an indicated phone number during that time.

2. Following detailed review, the IRB by majority vote approves (fully or provisionally) or disapproves the research proposal.

   a. Provisional approval means that minor modifications, specified in writing by the IRB, must be received by the chair within 30 days in order to recommend full approval.

   b. Proposals receiving full approval are sent to the Secretary or designee for authorization to begin research.

3. The Secretary or the director of Research and Development will notify the researcher in writing of the IRB's decision to approve or disapprove the proposed research within 10 working days.

   a. If the proposal is not approved, the letter will indicate reasons for disapproval and give the researcher an opportunity to respond in writing to the IRB.

   b. There are no appeals for research proposals disapproved on the basis of ethical shortcomings or potential harm to subjects.

   c. No research, subject to IRB review, can begin until written authorization from the Secretary or designee is received.

   d. Research approved by the IRB may be subject to further administrative review and approval or disapproval. However, no administrator can approve research which has not been approved by the IRB.

   e. After approval, the IRB shall review the research in progress at appropriate intervals, but not less than once per year.

   f. The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected harm to subjects. Any suspension or termination of approval shall be in writing, include the reasons for this action, and be reported promptly to the investigator, appropriate agency officials, and the Secretary.

g. Cooperative research refers to those projects covered by this policy which involve more than one institution or agency. In the conduct of cooperative research projects, each institution or agency is responsible for safeguarding the rights and welfare of human subjects and for complying with 45 CFR, Part 46. With the approval of the DHH or agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

4. Expedited Review Procedure

a. Research that involves no more than minimal risk and in which the only involvement of human subjects will be in one or more of the following categories (carried out through standard methods) may be reviewed by the IRB through an expedited review procedure. Under this procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chair from among IRB members. In reviewing the research, the reviewers may exercise all of the authority of the IRB except that they may not disapprove the research. Research may be disapproved only after review in accordance with the non-expedited procedures set forth in Section V.C. A report of all research approved by expedited review will be presented by the chair to the full IRB at its next regularly scheduled meeting. Categories of research which may qualify for expedited review include:

i. research conducted in established or commonly accepted educational settings, involving normal educational practices (e.g., research on special education instructional strategies);

ii. research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior if such research does not record information or identifiers which can be linked to individual human subjects;

iii. research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens;

iv. research and demonstration projects which are conducted by or subject to the approval of the Secretary or heads of programmatic

offices and are designed to study, evaluate, or otherwise examine public benefit of services or programs.

v. research conducted by faculty or students at colleges/universities if all of the following conditions are met:

(a). a copy of the university's IRB policies is on file with the DHH IRB;

(b). university IRB's approval of the research is documented;

(c). a copy of the full research proposal is included;

(d). for student research, written approval of the project by both a faculty advisor and a DHH staff sponsor must be provided;

vi. research approved by an IRB in 24-hour facilities if requested via the chief executive officer of the facility to the DHH IRB chair;

vii. requests from investigators for minor changes in research approved less than one year prior to such request;

viii. cooperative research which has been approved by the IRB and head of an agency outside of DHH.

b. The Secretary or agency heads may restrict, suspend, terminate, or choose not to authorize use of the expedited review procedure.

E. Informed Consent of Research Subjects

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research unless the investigator obtains the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or representative shall be in language easily understandable to the subject or representative. No informed consent document may include any exculpatory language through which the subject or representative is made to waive or appear to waive any of the

subject's legal rights or the investigator, the sponsor, or the agency and its agents are/appear to be released from liability for negligence.

1. Basic Elements of Informed Consent

Except as provided below, the investigator shall provide each subject the following information:

a. a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

b. a description of any reasonably foreseeable risks or discomforts to the subject;

c. a description of any benefits to the subject or to others which may reasonably be expected from the research;

d. a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

e. a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

f. for research involving more than minimal risk, explanations as to whether any compensation and medical treatment are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

g. an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research related injury to the subject;

h. a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

2. Additional Elements of Informed Consent

When appropriate, one or more of the following elements of information shall also be provided to each subject:

a. a statement that the particular treatment or procedure may involve risk that is currently unforeseeable;

b. anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

c. any additional costs to the subject that may result from research participation;

d. the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

e. a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject;

f. the approximate number of subjects involved in the study.

3. Waiver of Informed Consent

The IRB may waive the requirement to obtain informed consent provided that the IRB finds and documents that:

a. the research or demonstration project is to be conducted by or subject to the approval of state government officials and is designed to study or evaluate public benefit of services provided or funded by DHH;

b. such project deals with improving procedures for obtaining benefits/services under those programs and/or suggesting possible changes in or alternatives to those programs/procedures or in the methods/levels of payment for benefits or services under those programs; and

c. such research or projects shall not involve identifying individual recipients of services/benefits.

4. Documentation of Informed Consent

a. Informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

b. The written consent document must embody the elements of informed consent required in Section V.E.1. This form may be read to the subject or the subject's legally authorized representative but, in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed. An IRB recommended informed consent document will be included in the guidelines/application materials for conducting research in DHH operated/funded programs or facilities.

c. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

i. that the only record linking the subject and the research would be the consent document and the principal risk would be the potential harm resulting from a breach of confidentiality. Each subject will be asked if he/she wants documentation linking him/her with the research, and the subject's wish shall govern; or

ii. that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

d. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

5. The IRB shall demand additional protection and informed consent rights if the research involves fetuses, pregnant women and human in-vitro fertilization (45 CFR 46:201-211), prisoners (45 CFR 46:301-306), or children (45 CFR 46:401-409).

F. Responsibilities of Research Investigators

In addition to all of the requirements detailed above, researchers shall be responsible for the following.

1. Research investigators shall prepare and submit a protocol giving a complete description of the proposed research.

a. The protocol shall include provisions for adequate protection of the rights and welfare of prospective research subjects and ensure that pertinent laws and regulations are observed.

b. Samples of proposed informed consent forms shall be included with the protocol.

c. A completed DHH Application To Conduct Research must be submitted with the protocol.

2. Research investigators shall obtain and document appropriate administrative approval (beginning at the program/facility level) to conduct research before the proposal is submitted to the DHH IRB.

3. Prior to the beginning of the research, the investigator shall communicate to impacted staff the purpose and nature of the research.

4. Upon completion of the research, the principal investigator shall attempt to remove any confusion, misinformation, stress, physical discomfort, or other harmful consequences, however unlikely, that may have arisen with respect to subjects as a result of the research.

5. Within 30 working days of the completion of the research, the principal investigator shall communicate the outcome(s) and practical or theoretical implications of the research project to the program administrator and, when appropriate, program staff in a manner that they can understand.

6. The researcher shall submit progress reports as requested by the IRB (at least annually). As soon as practicable after completion of the research, but in no case longer than 90 working days later, the research investigator shall submit to the IRB a written report, which, at a minimum, shall include:

   a. a firm date on which a full, final report of research findings will be submitted;

   b. a succinct exposition of the hypotheses of the research, the research design and methodologies, and main findings of the research;

   c. an estimate of the validity of conclusions reached and some indication of areas requiring additional research; and

   d. specific plans for publishing results of the research.

7. A final report of the research as well as copies of any publications based upon the research will be submitted to the IRB as soon as possible. The State owns the final report, but prior permission of the IRB for the investigator to publish results

of the research is not required. The publication is the property of the researcher and/or the medium in which it is published. However, failure to provide the IRB with required periodic and final reports or publications based on the research shall impact negatively that researcher's future requests to conduct research in DHH operated/funded programs or facilities.

G. Initiation of the Research Review Process

1. The first contact in the process should be by the research investigator with the manager of the program or facility from which subjects will be drawn.

2. If the manager agrees that the research is feasible and desirable, the researcher will obtain his/her written authorization and send the protocol to appropriate staff at headquarters for consideration and approval by the assistant secretaries or the director of BHSF.

3. The assistant secretaries or the director of BHSF, in approving the research proposal, will certify that:

   a. the research design is adequate and meets acceptable scientific standards;

   b. appropriate ethical considerations have been identified and discussed;

   c. the proposal contains provisions to minimize possible disruptive effects of the project on organization's operation;

   d. the research will potentially benefit the participants directly or improve the service system; and

   e. the research topic is compatible with the agency's research agenda.

4. The assistant secretaries or the director of BHSF, after approval of the research, will submit the proposal to the IRB for further consideration.

H. IRB Records

1. The IRB shall prepare and maintain adequate documentation of IRB activities, including the following:

   a. copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents,

progress reports submitted by investigators, and reports of injuries to subjects;

b. minutes of IRB meetings in sufficient detail to show attendance at the meeting; actions taken by the IRB; the vote on these actions, including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution;

c. records of continuing review activities;

d. copies of all correspondence between the IRB and investigators;

e. a list of IRB members identified by name; earned degrees; representative capacity; indications of experience sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and DHH;

f. written procedures for the IRB and statements of significant new findings provided to subjects.

2. The records required by Section V.H. shall be retained for at least three years, and records relating to research which is conducted shall be retained for at least three years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of DHHS or the agency at reasonable times and in a reasonable manner.