

SAN MATEO COUNTY HEALTH SYSTEM
BEHAVIORAL HEALTH AND RECOVERY SERVICES

DATE: January 9, 2013

BHRS POLICY: 13-01

SUBJECT: Deep Brain Stimulation (DBS)

AUTHORITY: California W&I Code Sections 5326.15 through 5326.6

SUPERSEDES: New Policy

PURPOSE

- To provide a comprehensive policy for the provision of Deep Brain Stimulation (DBS) for certain individuals with refractory Obsessive Compulsive Disorder (OCD) and any other use(s) subsequently approved by the Food and Drug Administration (FDA), while protecting a patient's legislatively established medical/legal rights.
- To summarize the legal requirements for the use of DBS for voluntary and involuntary patients who may or may not be capable of giving informed consent.
- To identify mandatory documentation and reporting requirements concerning provision of DBS.

BACKGROUND

Status as a voluntary or involuntary client does not automatically determine competence to give informed consent. A person confined is considered incapable of written informed consent if he/she cannot understand, or knowingly and intelligently act upon, the information provided as specified in Section 5326.5. A person confined shall not be deemed incapable of refusal solely by virtue of being diagnosed as a person with a mentally illness.

PROTOCOL

I Basic Requirements of Informed Consent

- A The patient must give written informed consent to DBS, and must do so knowingly and without coercion. To constitute voluntary informed consent, the treating physician must

furnish the patient and, with the patient's consent, a responsible relative of the patient's choosing (defined, for purposes of this policy, as a spouse, parent, adult child, or adult brother or sister), and conservator or guardian if there is one, with the following information in a clear and explicit manner:

1. The reason for the treatment, specifically the nature and severity of the illness;
 2. The procedures to be used in the proposed treatment, including probable frequency and duration;
 3. The probable degree and duration (temporary or permanent) of improvement or remission expected with or without the treatment;
 4. The nature, degree, duration and probability of side effects and significant risks commonly associated with DBS; especially noting the degree and duration of memory loss, including its potential irreversibility; and how and to what extent they may be controlled;
 5. That there exists a division of opinion as to the efficacy of the proposed treatment;
 6. The reasonable alternative treatments, and why the physician is recommending this particular treatment, and
 7. That the patient has the right to accept or refuse the proposed treatment, and that if he or she consents, the right to revoke his or her consent for any reason, at any time prior to treatment.
- B The patient has a right to accept or refuse DBS, and if consent is given, has the right to revoke such consent at any time for any reason without prejudice to the client. Consent shall be for treatment within a specified maximum period of time, not to exceed 30 days. Withdrawal of consent may be either verbal or written, and shall take effect immediately. If the patient subsequently changes his/her decision, a new consent must be secured.
- C The patient must sign a written informed consent form before DBS can be provided. At least 24 hours must elapse between the oral advisement by the treating physician and the signing of the consent form by the patient.
- D The above should be explained so that there is no doubt the patient understands the procedure. This may require the presence of an interpreter for the hearing impaired or for clients whose primary language is not English.
- E Psychosurgery shall in no case be performed for at least 72 hours following the patient's written consent. Under no circumstances shall psychosurgery be performed on a minor.

II Documentation Requirements for All DBS Patients

The following information shall be placed in the treatment record by the treating physician:

- A Reasons for the procedure,
- B All reasonable alternative treatment modalities considered, and
- C A statement that DBS is clearly indicated and is a recognized treatment for otherwise intractable OCD (or other subsequent FDA approved conditions).

III Procedure for Verifying Capacity of Clients

- A Three physicians, one appointed by the treating agency and two appointed by the local mental health director, two of whom shall be either board-certified or eligible psychiatrists or board-certified or eligible neurosurgeons, shall personally examine the patient and unanimously agree with the attending physician's determinations, and agree that the patient has the capacity to give informed consent.
- B If the client does not have the capacity to give informed consent, then the procedure for involuntary patients is to be followed.
- C Physicians who serve on review committees must not be personally involved in the treatment of the patient whose case they are reviewing.
- D A responsible relative of the patient's choosing and the guardian or conservator, if there is one, shall be given the oral explanation by the attending physician as required by Section 5326.2. Should the person choose not to inform a relative or should such chosen relative be unavailable, this requirement is dispensed with.

IV Procedure for Involuntary Patients

The patient's attorney, public guardian or conservator must agree about the patients' capacity or incapacity to give written informed consent, and that the patient who has the capacity to give written informed consent has done so. If the attending physician, public guardian, conservator or attorney believes that the patient does not have the capacity to give informed consent, the following procedures are to be initiated:

- A A petition shall be filed in San Mateo County Superior Court to determine the client's capacity to give such consent. The court will hold an evidentiary hearing within three days after the petition is filed.
- B The patient is to be present and represented by legal counsel. If the court determines that the patient lacks the capacity to give written informed consent, then treatment may be performed upon gaining the written informed consent of a responsible relative or the person's guardian or conservator, as defined in Sections 5326.2 and 5326.5.

- C A patient declared incompetent has the right to regain competency at any time during the course of treatment. If this occurs, the patient competency must be reevaluated.

V Reporting Requirements

A Each physician or facility providing DBS shall report such treatments to the facility mental health director who shall forward a copy to the County Director of Mental Health. The County shall transmit a copy to the State Director of Health Care Services. The individual physician and facilities shall include in their reports the number of persons who received DBS wherever administered in each of the following categories:

1. Involuntary patients who gave informed consent;
2. Involuntary patients who were deemed incapable of giving consent and received DBS against their will;
3. Voluntary patients who gave informed consent; and
4. Voluntary patients deemed incapable of giving informed consent.

B These physician and facility reports shall be submitted quarterly to the BHRS Quality Management Office.

Approved: Signature on File
Stephen Kaplan, Director
Behavioral Health and Recovery Services

Approved: Signature on File
Robert Cabaj, MD, Medical Director
Behavioral Health and Recovery Services

Reviewed: _____

