

## Consensual Relationships: Questions and Answers Regarding Informed Consent, Psychotropic Drugs, and Nursing Home Residents



The misuse of psychotropic drugs for people with dementia has been receiving increased national (and international) attention in the last few years. The psychotropic drugging practices at nursing homes, which provide housing and services to hundreds of thousands of Americans with dementia, have been particularly scrutinized. Over half of all nursing home residents receive a psychotropic drug including powerful antipsychotics, which are known to nearly double the risk of death for elderly people with dementia. In many cases, the drugs are used as chemical restraints where the main goal is not to improve the resident's condition or quality of life but to sedate and subdue her. The use of chemical restraints is especially tragic considering that problematic "behavior" of people with dementia is usually a simple communication of pain, discomfort, or stress. When psychotropics are used to sedate residents and suppress their communication, they are less likely to participate in their care, maintain their remaining skills, or satisfy their needs.

Because psychotropics can cause significant health problems, are less effective than non-pharmacologic options, and often represent a short-cut to taking care of a resident's needs, their use is tightly proscribed by state and federal laws. As the overuse of drugs to "treat" dementia receives closer examination, more and more nursing homes can expect to be sued unless they have good dementia care processes and comply with the rules about psychotropic drugs. The most basic rule about psychotropics is that the resident, or a decision-maker authorized to make decisions on his behalf, must consent to their use, after being informed of the possible risks, benefits, and alternatives. This guide is meant to assist nursing homes in understanding the rules about informed consent, with an eye toward reducing legal liability while improving dementia care for their residents.

### **What is Informed Consent?**

Informed consent is a simple concept incorporating two logical elements: information and consent.

The information that must be provided is anything that would be "material" to the patient, meaning anything that a reasonable person would want to know before deciding about the proposed treatment. Failing to provide the relevant information to a patient before administering treatment is actionable negligence.<sup>1</sup> At a minimum the information conveyed to the patient must include:

- 1) diagnosis;
- 2) nature and purpose of proposed treatment & desired outcome;
- 3) risks and benefits; and
- 4) alternative treatments (including doing nothing).

In nursing homes, proposed treatment with psychotropic drugs has special requirements regarding informed consent. Among the requirements is that the resident be informed of all the following:

- (1) The reason for the treatment and the nature and seriousness of the patient's illness.
- (2) The nature of the procedures to be used in the proposed treatment including their probable frequency and duration.

- (3) The probable degree and duration (temporary or permanent) of improvement or remission, expected with or without such treatment.
- (4) The nature, degree, duration and probability of the side effects and significant risks, commonly known by the health professions.
- (5) The reasonable alternative treatments and risks, and why the health professional is recommending this particular treatment.
- (6) That the patient has the right to accept or refuse the proposed treatment, and if he or she consents, has the right to revoke his or her consent for any reason at any time.

The second element of informed consent is the consent itself. All adult patients have the right to determine what shall be done with their own bodies and thus must consent to any proposed health care treatment. This precept is at the heart of American notions of personal autonomy and has been reinforced by a century of court cases and statutory law. If consent is not obtained before treatment is administered, the health care provider is guilty of battery.<sup>2</sup>

### **Who Can Give Informed Consent?**

The patient is the only person who can provide consent to health care treatment. For patients who lack capacity to make decisions about their care due to cognitive disability, informed consent must nonetheless be obtained from a surrogate or substitute decision-maker. The most common surrogate is the patient's spouse or a close family member. In other cases, the surrogate has a more formalized status for decision-making such as a power of attorney for health care (part of California's Advance Health Care Directive) or a court-appointed conservatorship. Regardless of a patient's alleged incapacity, he or she nonetheless retains the right to refuse offered treatment and has the power to override the decisions of any surrogate, except for a court-appointed conservator with special informed consent powers.<sup>3</sup>

Physicians or other health care providers, may not act as surrogates for their patients. Various state laws, court cases, and policies prohibit health care providers from making decisions on behalf of their patients or outright prohibit their acting as surrogates.<sup>4</sup> The reason informed consent requirements exist in the first place is to prevent health care providers from providing care based solely on their opinion.

### **What If The Patient Has No Capacity and No Surrogate?**

Nursing home residents who have no capacity to make treatment decisions and no surrogate available are often called "unrepresented residents." In most health care instances, patients without capacity and a surrogate must have court intervention to receive non-emergency health care treatment. Nursing home residents, however, have Health and Safety Code Section 1418.8, also known as the "Epple Act." Section 1418.8 authorizes the resident's treatment team, a group composed of nursing home staff members, a physician, and a "resident representative" to make routine decisions on behalf of an unrepresented resident. The treatment team must follow specified procedures intended to acknowledge the resident's autonomy and ensure the decision made is the product of rational deliberation and not personal or professional biases.

Section 1418.8 treatment teams are limited in the decisions they can legally make. In passing the law, the legislature stated its intent that Section 1418.8 be used only for "on-going" and "day to day" decisions when judicial proceedings are too costly and cumbersome.<sup>5</sup> In an appellate case challenging the validity of Section 1418.8, the court specifically cited the statute's limitation to "nonintrusive and routine, ongoing" treatment in support of its constitutionality.<sup>6</sup> Therefore, serious or invasive treatments such as end-of-life care decisions, feeding tubes, and psychotropic drug administration are beyond the purview of a Section 1418.8 team and must be pursued in a judicial proceeding.

### **Who Must Obtain Informed Consent?**

Traditionally, the duty of obtaining informed consent has been with the physician. The physician is most likely the best source of information regarding the proposed treatment and has the best sense of why it is recommended. To minimize provider liability for failing to obtain informed consent, the physician who orders or recommends the proposed treatment should obtain it.

In nursing homes, California regulations make physicians responsible for obtaining informed consent for any psychotropic drug.<sup>7</sup> The facilities are required to ensure that informed consent verification is in the resident's medical record.<sup>8</sup> The facility is also required to ensure that the resident's right to receive all material information about a proposed treatment is not violated.<sup>9</sup> Therefore, if a resident receives psychotropic drugs without receiving material information and giving consent, the facility may be liable. To ensure compliance with the law, a facility should have policies and procedures that ensure physicians are engaging the residents in thorough informed consent conversations and that those conversations (and consent) are well-documented.

### **What Are the Exceptions to Informed Consent?**

Despite the primacy of patient autonomy regarding health care decisions, courts have developed a handful of narrow exceptions to the informed consent doctrine.

- (1) Emergencies: consultation with the patient is impractical due to the urgent need for treatment;
- (2) Therapeutic Privilege: providing information would confuse or psychologically harm the patient;<sup>10</sup>
- (3) Patient Waiver: Patients may agree to waive their right to informed consent in advance of treatment, telling their physician to simply do whatever is necessary.

### **How Can Informed Consent Be Obtained?**

There is no specifically required method for obtaining informed consent. As long as the patient or surrogate receives all of the pertinent information and affirmatively indicates consent to the proposed treatment, the health care provider may initiate it. In nursing homes, the facility staff are required to verify that informed consent has been obtained for any psychotropic drug and enter the verification into the resident's records.

In order to limit liability regarding informed consent misunderstandings, providers are encouraged to seek written verification of informed consent, signed by the patient or his or her legal representative.

### **What Information Should be Included in Informed Consent?**

The informed consent process (and ideally, the consent form) should recount all of the risks, benefits, and alternatives to the proposed treatment and explain that the patient has the right to withhold consent. The best form reflects the conversation that took place between the patient and physician and then confirms the patient's understanding and acceptance. A good informed consent form for psychotropic drugs should include:

- the class of drug prescribed (antipsychotic, antidepressant, etc.)
- frequency, dose, duration
- dosing guidelines / ranges
- method of administration
- the nature and seriousness of the targeted illness
- alternatives to consider and those that have been attempted or ruled out

- nature, degree, duration, and probability of side effects
- black box warning; statement that use is off-label, if applicable
- expected benefits
- physician signature (confirming conversation with the patient)
- patient (or representative) signature
- witness signature
- facility staff person signature confirming physician discussed risks, benefits, and alternatives with patient
- statement that adjusting dosage will not require a new form but will require patient be informed and patient can refuse
- statement that interpreter is required if applicable
- statement that consent may be withdrawn at any time
- statement that the resident / representative must be given a copy of the form
- a list of clinically inappropriate indications (e.g. antipsychotics are inappropriate when the only reason for use is one or more of the following: 1) wandering; 2) poor self-care; 3) restlessness; 4) impaired memory; 5) mild anxiety; 6) insomnia; 7) unsociability; 8) inattention or indifference to surroundings; 9) fidgeting; 10) nervousness; 11) uncooperativeness; 12) verbal expressions or behavior that are not due to mental illness or delirium and do not represent a danger to the resident or others).

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1 Salgo v. Leland Stanford Jr. University Bd. of Trustees, 154 Cal. App. 2d 560 (1st Dist., 1957).

2 Cobbs v. Grant, 8 Cal. 3d at 234, 502 P. 2d at 4.

3 See inter alia, Probate Code Section 4689.

4 California Probate Code Section 4659.

5 California Stats. 1992, Chapter 1303, Sec. 1(b)

6 Rains v. Belshe, 32 Cal. App. 4th 157, 186, 38 Cal. Rptr. 2d 185, 202 (1st Dist., 1995).

7 22 California Code of Regulations Section 72528(a).

8 22 California Code of Regulations Section 72528(c).

9 22 California Code of Regulations Section 72527.

10 See Ackerman v. Mecta Corp., Inc., 152 Cal. App. 4th 1094 (2d Dist. 2007); see also Salgo v. Leland Stanford Jr. University Bd. of Trustees, supra note 1.