

SNF Informed Consent

Presented By:

Edwin Hoffmark, RN, Chief of RN Unit

Brief History of Informed Consent

1992 to 2011

- 1992 – Title 22 Section 72528 Promulgated
- 1993 – Release of Pharmacy Training Bulletin PTB-93-4
- 2010 2nd Qtr- Promulgation of 72528 revision
- 2010 3rd Qtr – Review of past training
- 2011 – AFL 11-08

Definitions and Meanings

For the purposes of this presentation:

The only facility that is covered by Title 22 Section 72528 is the Skilled Nursing Facility.

Patient = Resident

Whenever Patient is mentioned, it will include Responsible Party if applicable.

What is Informed Consent

- Informed consent is first and foremost a Patient Right.
- Informed consent is granted by a Patient or a person who may act as a Patient's Representative (Responsible Party.)
- Informed consent may be withdrawn at any time by the Patient or the RP (if applicable).
- Informed consent is a process that does not end with a signature or the start of therapy.

Informed Consent is **NOT**

- Informed consent is not automatic.
- Informed consent is not a form.
- Informed consent is not finished when consent is obtained.

PERTINENT STATE REGULATIONS

- CCR Title 22, Division 5
- 72018.1: Definition of Consent
- 72052: Definition of Informed Consent
- 72082: Definition of Physical Restraint
- 72092: Definition of Psychotherapeutic Drug
- 72527: Patient Rights (includes consent)
- 72528: Informed Consent Requirements

OTHER PERTINENT STATE LAWS and DOCUMENTS

- Health and Safety Code
- HSC 1418.8 (Eppel Act)
- HSC 1418.9
- Other related references:
- *Schloendorff v. Society of New York Hospital* (NY Supreme Court, 1914)
- *Cobbs v. Grant*, (Calif. Supreme Court, 1972)
- AFL 09-12 (Reiterates provisions of H&S 1418.8)
- AFL 11-08 (Informed Consent)
- AFL 11-31 (Q & A Regarding Informed Consent)

Q&A's

1. Agents
2. Psychotherapeutic Medications
3. Antipsychotics
4. Exceptions
5. Devices
6. Material Circumstances...
7. Verification
8. Miscellaneous

Agents

Not Allowed

Title 22 Section 72528(b) and HSC 1418.9

Agents (cont.)

Title 22 Section 72528(b)

(b) The information material to a decision concerning the administration of a psychotherapeutic drug or physical restraint, or the prolonged use of a device that may lead to the inability of the patient to regain use of a normal bodily function shall include at least 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.

Agents (cont.)

HSC 1418.9

If the attending physician and surgeon of a resident in a skilled nursing facility prescribes, orders, or increases an order for an antipsychotic medication for the resident, the physician and surgeon shall do both of the following:

- (1) Obtain the informed consent of the resident for purposes of prescribing, ordering, or increasing an order for the medication.

Psychotherapeutic Medications

What is a psychotherapeutic medication?

Any medication used to control behavior or to treat thought disorder processes.

It is the use of the medication and not the classification*

(*except antipsychotics)

Psychotherapeutic Medications

Includes:

- Medications not normally thought of as psychotherapeutic medications.
- Beta blockers used to control aggressive behavior.
- Sleeping medications used to control behavior e.g.; climbing out of bed, wandering...
- Any antipsychotic medication

Psychotherapeutic Medications

Does NOT Include:

Sleeping medications used for sleep.

Diazepam used for muscle spasms

Antipsychotics

Defined in HSC 1418.9(c)(3)

"Antipsychotic medication" means a medication approved by the United States Food and Drug Administration for the treatment of psychosis.

Exceptions to Informed Consent

Title 22 Section 72528(e)&(f)

- Emergencies
- Documentation that the patient doesn't want to be informed of the risk v. benefits.
- Informing patient would cause harm.

Devices

1. Physical Restraints – Title 22 § 72082

2. The prolonged use of a device that may lead to the inability to regain use of a normal bodily function.

The Department has not specified any specific device or device category that would meet the informed consent requirements.

Material Circumstances...

The phrase is found in 72528(d) ... unless material circumstances or risks change.

A "change in material circumstances" usually means a change in the patient's medical or psychosocial condition which indicates that a different treatment plan should be considered. "Material circumstances" in this context are determined by licensed healthcare practitioners who are responsible for initiating a new informed consent discussion about any proposed changes to treatment. Healthcare practitioners are required to provide sufficient material information for the patient to make an informed decision to agree to the new treatment plan, to choose an alternative treatment or to refuse treatment altogether.

Verification

Verification required by Title 22 Section 72528(c)

...facility staff shall verify that the patient's health record contains documentation that the patient has given informed consent ...

1. Licensed Healthcare Practitioners
2. Patient or Family

Miscellaneous

1. Admission issues
2. Documentation
3. Acute Care Hospitals
4. Policies and Procedures

Informed Consent

“...In the communications process, you, as the physician providing or performing the treatment and/or procedure (not a delegated representative), should disclose and discuss with your patient:...This communications process, or a variation thereof, is both an ethical obligation and a legal requirement spelled out in statutes and case law in all 50 states...”

Questions???

Please ask questions as directed by the facilitator of this session so that we can ensure an accurate and thorough response.



Contact Information

- If you have further questions about Informed Consent please contact **Edwin Hoffmark**, Chief of RN Unit at:
 - California Department of Public Health
- Licensing & Certification Program
- Fax: (916) 324-4820
- Email: RNUnit@cdph.ca.gov
- Phone: **1-800-236-9747**