INFORMED CONSENT

The Enforcement Landscape and a Review of the Basics

DPH All Facilities Letter
June 4, 2009

Informed Consent
for Antipsychotic Medication

DPH AFL June 4, 2009 – Informed Consent

- The AFL discusses the provisions of current law regarding informed consent for prescribing antipsychotic medication pursuant to Health & Safety Code 1418.9.
- The H&S Code section referenced above pertains to residents who have the capacity to offer consent.
- If a resident does not have the capacity, then a designated family member may offer consent. A physician makes the determination on whether capacity exists.

DPH AFL June 4, 2009 – Informed Consent

- **If the attending physician of a resident in a SNF prescribes, orders, or increases an order for an antipsychotic medication for the resident, the physician shall do the following:**
  - Obtain informed consent of the resident for purposes of prescribing, ordering, or increasing an order for the medication; and
  - Seek the consent of the resident to notify the resident's interested family member, as designated in the medical record.

DPH All Facilities Letter January 7, 2011

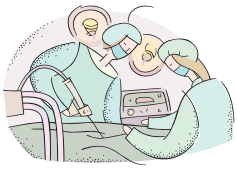
Changes to DPH Interpretation of Section 72528(c)

DPH AFL January 7, 2011 – Informed Consent

- Previously found that unchanged, pre-existing orders for psychotherapeutic drugs/physical restraints or prolonged use of certain devices did not require verification of informed consent in medical records
- DPH now requires verification present in medical records in AFL 11-08

DPH AFL January 7, 2011 – Informed Consent

- **DPH issues comprehensive Q&A in AFL 11-31 (April 12, 2011)**
- **Significant Issues**
  - AFL 11-08 requirement of documenting verification of informed consent
  - No "delegation" of informed consent from M.D. to facility staff permitted
  - Phone informed consent acceptable
  - Facility policies and procedures need to reflect how verification to be obtained



Informed Consent Basics

- Informed consent is not required for the performance of "simple and common" procedures, where the related risks are commonly understood.
- The determination of which procedures are "complex" and, therefore, require informed consent is medical in nature.
- The medical staff at the facility is responsible for identifying those procedures which require informed consent.

Informed Consent Basics

- It is the treating physician's responsibility to obtain informed consent
- How the physician obtains informed consent is within the discretion of the physician, and may include:
  - Verbal discussion
  - Written information (i.e., patient information sheets, informed consent forms)
  - Audiocassette and videocassette

Informed Consent Basics

- Regardless of how the informed consent is obtained, it is recommended that the physician carefully document in the medical record that a discussion was held with the patient (or legal representative) and that informed consent was obtained.
- It is also recommended that the physician place in the medical record a copy of any written information provided to the patient.

Informed Consent Basics

- Note: Physicians may use other health professionals to provide information within their area of expertise (e.g., pharmacists, occupational therapists, etc.). However, the physician is ultimately responsible.

- The facility's role in the informed consent process is limited to verifying that the physician obtained and documented the patient's informed consent prior to initiation of the medical treatment.

Informed Consent Basics

- It is the facility's responsibility to develop policies and procedures and ensure patient's are provided their rights to consent and informed consent.
- Facility policies and procedures must describe how the facility will verify that informed consent was obtained or a treatment or procedure was refused pertaining to key treatments.
- Note: The regulations require that the facility verify that informed consent was obtained prior to initiating the treatment the first time, not each time a treatment is continued or re-applied.

Informed Consent Basics

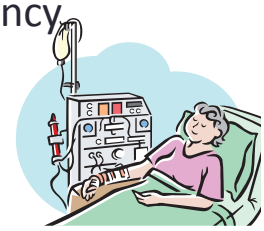
- However, if material circumstances or risks change (as determined by the physician) concerning the treatment, it is necessary to obtain informed consent again.
- If informed consent is not obtained, there must be documentation of an emergency. Documentation of an emergency can be made after treatment is initiated.

Compliance Considerations

- Evaluate informed consent policies and procedures:
  - Are they realistic?
  - Can they be consistently applied?
- Ensure all licensed nursing staff and physicians are able to explain facility informed consent process.

Who May Give Consent

- Determination of who has legal authority to consent is based on:
  - Patient's legal status (e.g., adult, emancipated minor, minor)
  - Patient's physical and mental condition
- If the patient has capacity, then he/she has the right to consent.
- If the patient lacks capacity, then someone else must consent to the treatment on their behalf except in an emergency situation.



Challenges

- Determining whether patient has an advance directive or durable power of attorney for health care
- In cases of incapacity and no advance directive, dealing with:
  - Finding family or friends willing to make health care decisions
  - Dueling family members
  - Delays in getting conservator

Compliance Considerations

- Documentation on admission, during care planning meetings that indicates resident/family is fully informed about care and treatment. (F 156)

- Document periodic communication with resident/family to probe if there are questions and confirm understanding of care approaches, including use of medication.

Use of the Interdisciplinary Team in the SNF Setting

- **<u>Health and Safety Code section 1418.8</u> allows the SNF's interdisciplinary team to authorize medical treatment ordered by physician that requires informed consent if there is no:**
  - Available family member willing to make health care decisions;
  - Conservator of the person, and
  - Other person with legal authority to make health care decisions.

Interdisciplinary Team Process

- Attending physician determines lack of capacity.
- Attending physician determines that there is no person with legal authority to make health care decisions (e.g., power of attorney, guardian, conservator or kin).
- Except in an emergency, facility holds interdisciplinary team review of the medical intervention that includes:
  - **Review of physician's patient assessment;**
  - **Reason for proposed medical intervention;**
  - **Discussion of patient's desires if known (interviews with patient, family members, friends, review of medical records);**
  - **Review of type of medical intervention;**
  - **Probable impact on patient's condition with/without medical intervention;**
  - **Alternative medical intervention considered or utilized and reason for discontinuance or inappropriateness; and**
  - **Evaluation by interdisciplinary team of prescribed medical intervention at least quarterly and upon significant change in patient's medical condition.**

Interdisciplinary Team Process

- **Interdisciplinary team must oversee care using team approach**
  - Participants include attending physician, RN with patient responsibility; and other appropriate staff depending on patient's needs
  - Must include a patient representative when practical (e.g., family member or friend who can't take full responsibility for health care decisions; public guardian or ombudsman)
- All determinations and the reasons must be documented in the medical record.
- Not subject to administrative sanction if the physician or other health care provider believes in good faith that actions consistent with Health and Safety Code 1418.8, desires of patient if known, or the best interests of the patient.

Informed Consent Enforcement Focus CMP Issuance

Consider issuance of a civil money citation for one or more of the following non-compliance(s):

- *Resident/RP indicates (on interview) required material information (as defined in T22 Section 72528 (1-6)) was not received in order to make an informed decision prior to receipt of the antipsychotic medication.*
- *Physician did not obtain informed consent from the resident (the process of informed consent was delegated to licensed nursing staff, ward clerk, etc.).*
- *Facility failed to develop and implement patients' rights policies and procedures, in accordance with state laws and regulations, related to psychotherapeutic informed consent.*

Are You Prepared?
Taking the Necessary Steps

- **Identify on admission if the patient has an advance directive.**
- **Identify if the patient has capacity or lacks capacity to make health care decisions. Make sure it is clearly documented in the medical record and known to facility staff.**
- **Maintain open lines of communication with the patient and family members concerning consent issues.**
- **Address any and all consent issues with the attending physician.**
- **Draft policies and procedures to ensure compliance with laws/regulatory requirements.**
- **Develop all necessary Informed Consent forms and maintain practices consistent with law.**
- **Make sure that compliance with Interdisciplinary Team Meetings held pursuant to Health and Safety Code 1418.8 is well documented in the medical record.**
  - **Consider drafting a form to memorialize the meetings.**
- **Continually educate staff on policies and procedures regarding consent issues.**
- **Create and implement a process for monitoring compliance with consent issues.**
- **Consult legal counsel when necessary.**

Resources

- AHCA Quality Initiative - http://www.ahcancal.org/quality_improvement/qualityinitiative/Pages/default.aspx
- CAHF Quality Initiative - http://www.cahf.org
- CAHF Person Centered Behavior Management Tool Kit - http://www.cahfdownload.com/cahf/nurses/2011BestPractices_PersonCenteredBehaviorMgmt_Toolkit.pdf
- CDPH Surveyor Tool and Antipsychotic Collaborative Report - http://member.cahf.org/Operations/SurveyEnforcement.asp
- Improving Antipsychotic Appropriateness in Dementia Patients (IA-ADAPT website) - https://www.healthcare.uiowa.edu/igec/IAADAPT

THANK YOU!

Questions?