



State of California—Health and Human
Services Agency
**California Department of
Public Health**



January 7, 2011

AFL 11-08

TO: Skilled Nursing Facilities

SUBJECT: Informed Consent

AUTHORITY: California Code of Regulations, Title 22 Section 72528(c)

The purpose of this letter is to notify California Skilled Nursing Facilities (SNF) of a change in guidance regarding Title 22 Section 72528(c).

Title 22 Section 72528(c) states: Before initiating the administration of psychotherapeutic drugs, or physical restraints, or the prolonged use of a device that may lead to the inability to regain use of a normal bodily function, facility staff shall verify that the patient's health record contains documentation that the patient has given informed consent to the proposed treatment or procedure. The facility shall also ensure that all decisions concerning the withdrawal or withholding of life sustaining treatment are documented in the patient's health record.

In the past, the Department has issued guidance to Surveyors and SNF that when admitting a patient to a SNF with unchanged, preexisting orders for psychotherapeutic drugs, or physical restraints, or the prolonged use of a device that may lead to the inability to regain use of a normal bodily function, the patient's medical record only had to contain documentation that the drug, restraint or device had been initiated prior to admission to the SNF in order to be in compliance with this regulation. The Department has not historically confirmed whether the SNF verified that informed consent was obtained and the documentation was in the patient's medical record.

As part of the Licensing & Certification's continuing process to optimize the health and well-being of people who receive care in licensed health facilities, the Department has reviewed the above guidance regarding Section 72528(c). The Department has determined that in order to verify compliance with Section 72528(c), surveyors must confirm that health records contain documentation that the patient gave informed consent for the treatments listed in the regulation for all residents, including those admitted with preexisting orders.

Therefore, effective immediately, all SNF shall verify that the patient's health record contains documentation that the patient has given informed consent to the proposed treatment or procedure as written in Section 72528(c).

In order for SNF to be in full compliance with this regulation, the Department suggests a few methods that are permitted under current regulations and/or statutes.

1. Obtain documentation that informed consent had been obtained from the patient for the proposed therapy and is in the patient's medical record.
2. Obtain new informed consent as described in Section 72528(c) and place the informed consent documentation in the patient's medical record.

If you have any questions, please contact Edwin Hoffmark, RN Unit Chief at:

California Department of Public Health
Licensing & Certification Program
P.O. Box 997377, MS 3201
Sacramento, CA 95899-7377
Fax: (916) 324-4820
Email: RNUnit@cdph.ca.gov
Phone: 1-800-236-9747

Sincerely,

Original Signed by Pamela Dickfoss

Pamela Dickfoss
Acting Deputy Director

Center for Health Care Quality, MS 0512 . P.O. Box 997377 . Sacramento, CA
95899-7377
(916) 324-6630 . (916) 324-4820 FAX
Department Website (cdph.ca.gov)



Page Last Updated : November 3, 2017