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Interim Director

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



EDMUND G. BROWN JR.
Governor

April 12, 2011

AFL 11-31

TO: Skilled Nursing Facilities

SUBJECT: Questions and Answers about Informed Consent

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

On January 7, 2011, the Department issued AFL 11-08 regarding verification of informed consent for psychotherapeutic drugs, physical restraints, and the prolonged use of a device that may lead to the inability to regain use of a normal bodily function. The Department has received a number of questions which have been gathered and are being released as a set of questions and answers. The Q&A document is attached. These questions and answers will also be posted on the Licensing & Certification website and updated on the website as needed.

If you have any questions regarding the Informed Consent Q&A's, please contact Edwin Hoffmark, RN Unit Chief at:

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Sincerely,

Original Signed by Pamela Dickfoss

Pamela Dickfoss
Acting Deputy Director
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Attachment



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Questions & Answers Regarding Informed Consent

For purposes of this FAQ “resident” means the same as “patient”

1. What is a preexisting order?

A preexisting order is an order of the attending licensed healthcare practitioner acting within the scope of his or her professional licensure written prior to the admission and encompassing the admission of a patient to a skilled nursing facility (SNF) in accordance with the following regulations from the California Code of Regulations (CCR) Title 22 Sections 72303, 72307(a), 72515, 72521(c)(2), 72521(c)(3), 72523(c)(1)(B), 72527, and 72528.

Every patient admitted or accepted for care by the SNF shall be under the care of a physician selected by the patient or the patient’s authorized representative (CCR Title 22 Section 72303(a)). There should be no period of time in which a patient is not under the care of a physician. Each patient admitted to the SNF shall be under the continuing supervision of a physician who evaluates the patient as needed and at least every 30 days unless there is an alternate schedule (CCR Title 22 Section 72307(a)).

Physician orders written prior to the admission of a patient to a SNF shall conform to the regulatory guidance in CCR Title 22, Division 5, Chapter 3 for their use in a SNF. The location or place where the preexisting orders were written should have no bearing on the care and treatment of a patient in a SNF.

2. What is “Physician assessment”?

CCR Title 22, Section 72303(b) states:

“Physician services shall mean those services provided by physicians responsible for the care of individual patients in the facility. Physician services shall include but are not limited to:

- (1) Patient evaluation including a written report of a physical examination within 5 days prior to admission or within 72 hours following admission.

(2) An evaluation of the patient and review of orders for care and treatment on change of attending physicians.”

This requirement allows facilities to obtain an evaluation including a written report of a physical examination within 5 days prior to the admission or within 72 hours following admission. The majority of patients admitted to a SNF could fall within the 72 hours following admission category. There will be some patients that will need an evaluation either prior to or immediately following admission. Those patients that require informed consent may require that an evaluation be performed prior to or immediately after admission which is allowed for by the regulation.

CCR Title 22 Section 72527(a) states:

“Patients have the rights enumerated in this section and the facility shall ensure that these rights are not violated. The facility shall establish and implement written policies and procedures which include these rights and shall make a copy of these policies available to the patient and to any representative of the patient. The policies shall be accessible to the public upon request. Patients shall have the right:

(1) To be fully informed, as evidenced by the patient's written acknowledgement prior to or at the time of admission and during stay, of these rights and of all rules and regulations governing patient conduct.

(3) To be fully informed by a physician of his or her total health status and to be afforded the opportunity to participate on an immediate and ongoing basis in the total plan of care including the identification of medical, nursing and psychosocial needs and the planning of related services.

(4) To consent to or to refuse any treatment or procedure or participation in experimental research.

(5) To receive all information that is material to an individual patient's decision concerning whether to accept or refuse any proposed treatment or procedure. The disclosure of material information for 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 shall include the disclosure of information listed in CCR Title 22 Section 72528(b).”

If a SNF is unable to verify that the patient or their authorized representative has given informed consent for the above listed therapies, the facility should have policies and procedures required under CCR Title 22 Section 72527(a)(5) to cover that contingency. If the facility is unable to verify informed consent or is unable to obtain the services of the licensed healthcare practitioner that ordered the above listed therapies to obtain informed consent from the patient or the patient's authorized representative, then the facility should determine if the facility can safely provide adequate care for the patient.

CCR Title 22 Section 72515(b) states:

“The licensee shall:

(b) Accept and retain only those patients for whom it can provide adequate care.”

A SNF is deemed out of compliance with CCR Title 22 Section 72528(c) when the SNF has failed to verify that the patient's medical record contains documentation that a patient or patient's authorized representative has given informed consent prior to administration of psychotherapeutic drugs in the SNF or physical restraints in the SNF or the prolonged use of a device in the SNF that may lead to the inability to regain use of a normal bodily function.

3. What constitutes confirmation of informed consent?

The regulations do not require any particular type of documentation to be in the medical record to indicate informed consent was given. Therefore state surveyors will accept documentation that shows informed consent was obtained by the prescribing licensed healthcare practitioner acting within his/her scope of professional licensure. The documentation must conform to the facility's established policies and procedures regarding how such information will be memorialized within the medical record. These policies and procedures are required under CCR Title 22 Section 72527(e)(1).

4. Initiating vs. continuing orders for therapy.

Once a patient has been admitted to a SNF all orders on admission are new orders for the skilled nursing facility and the SNF initiates all legally prescribed orders. A SNF is therefore initiating these admission orders. Continuation of those orders may occur on a monthly basis with no need for renewal of informed consent unless there is a change in the material circumstances or risks for the patient. There is no requirement for a facility to renew informed consent if the dosage or therapy is being decreased. There is no requirement to obtain a new informed consent if the patient is transferred to a hospital and returns with no change in orders so far that none of the material circumstances or risks have changed **and** the facility has a copy of the informed consent in the patient's medical record.

The one exception to these requirements concerns antipsychotic medications. Health and Safety Code (HSC) Section 1418.9(a) states:

"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.
- (2) Seek the consent of the resident to notify the resident's interested family member, as designated in the medical record. If the resident consents to the notice, the physician and surgeon shall make reasonable attempts, either personally or through a designee, to notify the interested family member, as designated in the medical record, within 48 hours of the prescription, order, or increase of an order."

5. If a patient is admitted to a SNF with an order for a psychotherapeutic drug, physical restraint, and/or device whose prolonged use may lead to the inability to regain use of a normal bodily function, how long does the SNF have to obtain informed consent?

The SNF shall verify informed consent prior to the administration of psychotherapeutic drugs in the SNF, use of physical restraints in the SNF, or the prolonged use of a device in the SNF that may lead to the inability to regain use of a normal bodily function. The SNF can either have the licensed healthcare practitioner who ordered the therapy obtain the informed consent from the patient or obtain a copy of the current informed consent from the facility where the therapy was started. The SNF should not admit any patient they cannot care for; that includes a patient who requires a therapy in which informed consent is required by law or regulation and the SNF is unable to either obtain a current copy of the informed consent or is unable to arrange for a licensed healthcare practitioner who ordered the therapy to obtain the informed consent prior to initiating the therapy in the SNF.

6. What agents may obtain informed consent?

The Department's plain understanding of CCR Title 22 Section 72528 is that it is the responsibility of the attending licensed healthcare practitioner acting within the scope of his or her professional licensure to determine what information a reasonable person in the patient's condition and circumstances would consider material to a decision to accept or refuse a proposed treatment or procedure. The disclosure of the material information and obtaining informed consent is the responsibility of the licensed healthcare practitioner who, acting within the scope of his or her professional licensure, performs or orders the procedure or treatment for which informed consent is required. In other words: The person who orders the therapy shall obtain the patient's or patients authorized representative's informed consent prior to the initiation of therapy.

7. Can a physician delegate his responsibility to obtain informed consent for a psychotherapeutic medication to a nurse?

Because prescribing the drug would not be in the scope of the nurse's licensure, the physician cannot delegate the responsibility to obtain the consent. An advanced practice nurse whose scope of practice allows the prescribing of drugs may obtain informed consent if the nurse prescribed the drug.

8. Can a facility, using an approved form, fill the form out for a physician (without the physician discussing the issue with the patient) and have a patient

(or the responsible party if the patient is without the capacity to provide consent) sign the form and then send the form to the physician for signature.

The answer to that question is No. The requirement in both statute and regulation requires that an attending licensed healthcare practitioner acting within the scope of his or her professional licensure shall discuss with the patient or their authorized representative the information material for a patient or their authorized representative to make an informed decision regarding proposed therapy (please refer to CCR Title 22 Section 72528(b)).

Once the licensed healthcare practitioner has obtained the informed consent of the patient or their authorized representative, the fact that informed consent has been obtained must be recorded in the medical record (please read CCR Title 22 Section 72528(c) below).

How the facility verifies the content of informed consent is up to the facility [see CCR Title 22 Section 72527(e)(1)]. The facility must ensure it meets all statutory and regulatory requirements. The Department suggests that a facility establish and implement policies and procedures by following the guidance under all of CCR Title 22 Section 72527 and Section 72528, with special emphasis on CCR Title 22 Section 72528(b) in regards to documenting informed consent in the patient's medical record.

Title 22 regulations that must be taken into consideration when developing policies and procedures for obtaining informed consent include:

CCR Title 22 Section 72052

Informed Consent means the voluntary agreement of a patient or a representative of an incapacitated patient to accept a treatment or procedure after receiving information in accordance with CCR Title 22 Sections 72527(a)(5) and 72528.

CCR Title 22 Section 72527(a)(5) states:

(a) Patients have the rights enumerated in this section and the facility shall ensure that these rights are not violated. The facility shall establish and implement written policies and procedures which include these rights and shall make a copy of these policies available to the patient and to any representative of the patient. The policies shall be accessible to the public upon request.

Patients shall have the right:

(5) To receive all information that is material to an individual patient's decision concerning whether to accept or refuse any proposed treatment or procedure. The disclosure of material information for 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 shall include the disclosure of information listed in Section 72528(b).

CCR Title 22 Section 72527(e)(1) states:

(e) Patients' rights policies and procedures established under this section concerning consent, informed consent and refusal of treatments or procedures shall include, but not be limited to the following:

(1) How the facility will verify that informed consent was obtained or a treatment or procedure was refused pertaining to the administration of psychotherapeutic drugs or physical restraints or the prolonged use of a device that may lead to the inability of the patient to regain the use of a normal bodily function.

CCR Title 22 Section 72528. states:

(a) It is the responsibility of the attending licensed healthcare practitioner acting within the scope of his or her professional licensure to determine what information a reasonable person in the patient's condition and circumstances would consider material to a decision to accept or refuse a proposed treatment or procedure. Information that is commonly appreciated need not be disclosed. The disclosure of the material information and obtaining informed consent shall be the responsibility of the licensed healthcare practitioner who, acting within the scope of his or her professional licensure, performs or orders the procedure or treatment for which informed consent is required.

(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.

(c) 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.

9. If the responsible party is not available [physically], is it acceptable to document on the informed consent that consent has been given via phone conversation.

Based on the facility's policies and procedures established and implemented in accordance with CCR Title 22 Section 72527(a)(5) and CCR Title 22 Section 72527(e)(1), how the attending licensed healthcare practitioner, acting within the scope of his or her professional licensure, decides to inform the patient or their authorized representative is up to the attending licensed healthcare practitioner. How the facility chooses to document the informed consent is up to the facility. Please read the statutory and regulatory requirements.

The purpose of obtaining informed consent is not simply one of documentation. The purpose is to ensure that a patient or his/her authorized representative has been given all the material information necessary (see CCR Title 22 Section 72528(b)) to make a decision regarding therapy from the attending licensed healthcare practitioner acting within the scope of his or her professional licensure and that the resulting decision made by the informed patient or his/her authorized representative is documented in the medical record.

10. We need clarification regarding CCR Title 22 Section 72528 (c) "on the prolonged use of a device that may lead to the inability to regain use of a normal bodily function." Could we have an explanation of what is prolonged use and to which device(s) does the regulation refer?

The terms used under CCR Title 22 Section 72528(c) regarding: the "prolonged" use of a "device" that may lead to the "inability to regain" use of a "normal bodily function" are not defined in either statute or regulation. Discussions at the time of promulgation of this requirement did not specify any specific device or device category since there was not sufficient evidence in medical literature at that time that any commonly used devices (i.e.; nasogastric tubes, indwelling catheters, gastrostomy tubes) would lead to the inability to regain use of a normal bodily function. The Department has not issued guidance specifying any current device or device category that would meet the informed consent requirements under CCR Title 22 Section 72528(c) "on the prolonged use of a device that may lead to the inability to regain use of a normal bodily function". With the advancement of medical technology, there may be future devices which fit this description. If this occurs, specific instructions will be provided to providers. Facilities are free to define in their policies and procedures such devices they feel may meet the

criteria, based upon the clinical expertise of the professional staff and current standards, and therefore may require informed consent prior to use.

11. What exceptions are there to the informed consent requirement?

There are three exceptions to the informed consent requirement found in CCR Title 22 Section 72528. One in (e) and two in (f). It is important to note that there must be documentation in the clinical record of the circumstances that allow these exceptions to be used.

CCR Title 22 Section 72528(e) & (f) state [emphasis added]:

(e) “There shall be no violation for initiating treatment without informed consent if there is documentation within the patient's health record that an emergency exists where there is an unanticipated condition in which immediate action is necessary for preservation of life or the prevention of serious bodily harm to the patient or others or to alleviate severe physical pain, and it is impracticable to obtain the required consent, and provided that the action taken is within the customary practice of licensed healthcare practitioners of good standing acting within the scope of their professional licensure in similar circumstances.

(f) Notwithstanding CCR Title 22 Section 72527(a)(5) and CCR Title 22 Section 72528(b)(4), disclosure of the risks of a proposed treatment or procedure may be withheld if there is documentation of one of the following in the patient's health record:

- (1) That the patient or patient's representative specifically requested that he or she not be informed of the risk of the recommended treatment or procedure. This request does not waive the requirement for providing the other material information concerning the treatment or procedure.
- (2) That the licensed healthcare practitioner acting within the scope of his or her professional licensure relied upon objective facts, as documented in the health record, that would demonstrate to a reasonable person that the disclosure would have so seriously upset the patient that the patient would not have been able to rationally weigh the risks of refusing to undergo the recommended treatment and that, unless inappropriate, a patient's representative gave informed consent as set forth herein.”

12. Should the documentation of informed consent include options discussed?

The regulation does not require that the documentation indicate what information the physician provided prior to obtaining the informed consent. The regulation states the facility staff shall verify the health record contains documentation that the patient has given informed consent. We cannot require facilities to verify the content of the discussion between the healthcare provider acting within the scope of his/her professional license and the patient or the representative of the patient. How facilities

ensure they are meeting the requirements of CCR Title 22 Section 72528(b) is up to them and should be part of their policies and procedures.

13. What can I do if a facility tells me or my loved one if we do not consent to the use of a psychotropic medication then I or my loved one will need to leave the facility?

If facilities are using the threat of requiring the patient to leave the facility if the patient or his/her responsible party does not agree to the use of a psychotropic medication, then this is something that would need to be reported to the Department and investigated for a potential violation of regulations.

14. Must a facility accept a patient from an acute care hospital with orders for a psychotherapeutic medication without informed consent?

If a facility is unable to have an attending licensed healthcare practitioner, acting within the scope of his or her professional licensure, obtain informed consent either prior to admission or prior to the administration of the first dose of the medication and the acute care hospital has not obtained informed consent then the skilled nursing facility would be in violation of CCR Title 22 Section 72515(b) if they accept the patient for whom they cannot provide care.

CCR Title 22 Section 72515(b) states:

“The licensee shall:

(b) Accept and retain only those patients for whom it can provide adequate care.”

Once informed consent has been obtained by either an attending licensed healthcare practitioner, acting within the scope of his or her professional licensure, at the acute care hospital or if the attending licensed healthcare practitioner acting within the scope of his or her professional licensure deems that the patient no longer requires the medication and discontinues the medication, then the facility may accept the patient in accordance with all applicable regulations.

15. What type of documentation will L&C staff consider proof of informed consent?

The regulations do not require any particular type of documentation to be in the medical record to indicate informed consent was given. Therefore state surveyors will accept documentation that shows informed consent was obtained by the prescribing licensed healthcare practitioner acting within his/her scope of professional licensure prior to the administration or initiation of the treatment. The documentation must conform to the facility's established policies and procedures regarding how such information will be

memorialized within the medical record. These policies and procedures are required under CCR Title 22 Section 72527(e)(1).

16. Does there need to be a document signed by the physician and patient or RP that indicates informed consent on the chart? Some facilities stated that it's the physician's responsibility; therefore, they assume it is done.

CCR Title 22 Section 72528(c) indicates that, "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 physician is responsible for obtaining informed consent, as provided, for example, in HSC Section 1418.9(a). Nevertheless, CCR Title 22 Section 72528(c) requires facility staff to verify that the patient's health record contains such documentation.

17. There is nothing in the progress notes or written orders, but the printed orders have that the consent was obtained by the doctor. When we ask the physician and patient/family they say yes. Is this acceptable?

This question states that there was no documentation in the patient's medical record prior to the initiation of therapy, only that the printed recapitulation of the physician orders signifies that informed consent had been obtained. This would not meet the requirements of CCR Title 22 Section 72528, since the facility staff could not verify that informed consent had been obtained prior to start of therapy.

The requirements in CCR Title 22 Section 72528 do not state how the obtained informed consent is documented in the medical record, only that the medical record contains documentation that informed consent had been obtained prior to initiating therapy as described in CCR Title 22 Section 72528. It should be noted that the original order from the prescribing licensed healthcare practitioner acting within his/her scope of professional licensure signed prior to the administration of psychotherapeutic medication or initiation of the treatment would need to be readily available, such as being retained in the active medical record, as proof that there was documentation relied upon by facility staff for purposes of verifying informed consent prior to therapy. The requirement in CCR Title 22 Section 72528 is one of verifying that the medical record contains evidence that informed consent had been obtained prior to start of therapy.

18. Is there any regulation that mandates that documentation of informed consent must include the signature of the patient or their proxy? My understanding has been that the physician must document from whom they obtained informed consent and the relationship if it was a proxy. This needs to be

in the medical record, and in our facility we use a form for that. What we don't do is ask for a signature other than the doctor getting consent.

The requirements in CCR Title 22 Section 72528 do not state how the obtained informed consent is documented in the medical record, only that the medical record contains documentation that informed consent had been obtained prior to initiating therapy described in CCR Title 22 Section 72528 (excepting the provisions stated in CCR Title 22 Section 72528(e)). It is a facility's responsibility under CCR Title 22 Section 72527(e)(1) to have policies and procedures for this. However, when you read the statutory language in the Health and Safety Code and the regulatory language in CCR Title 22, Division 5, Chapter 3, Skilled Nursing Facilities there are specific requirements. SNFs are to have policies and procedures in place to ensure they meet the statutory and regulatory requirements. We encourage you to reference CCR Title 22 Sections 72052, 72527, 72528, and HSC Section 1418.9(a).

19. Shouldn't informed consent be physician directed rather than facility directed?

The licensed healthcare practitioner who, acting within the scope of his/her professional licensure, ordered the treatment is responsible for obtaining informed consent, as provided, in CCR Title 22 Section 72528(a). Nevertheless, CCR Title 22 Section 72528(c) requires facility staff to verify that the patient's health record contains such documentation. Facilities should reference all applicable statutes and regulations as discussed previously in this document.

20. If the MD does not direct and complete the informed consent right away and the facility has medication orders [that require informed consent], then they cannot dispense the medication, correct?

That is correct. The facility has the responsibility to ensure that the patient/responsible party has given informed consent prior to the start of therapy at the facility. Thus, the facility should have policies and procedures in place to ensure timely administration of medications ordered by the licensed healthcare practitioner.

21. Verification of the informed consent from the hospital, do hospitals have a requirement to obtain informed consent?

While acute care hospitals have a requirement to obtain informed consent, this requirement is not as specific as the requirement for skilled nursing facilities.

CCR Title 22 Section 70707(b)(5) & (6) states:

(5) Receive as much information about any proposed treatment or procedure as the patient may need in order to give informed consent or to refuse this course of treatment. Except in emergencies, this information shall include a description of the procedure or treatment, the medically significant risks involved in this treatment, alternate courses of treatment or nontreatment and the risks involved in each and to know the name of the person who will carry out the procedure or treatment.

(6) Participate actively in decisions regarding medical care. To the extent permitted by law, this includes the right to refuse treatment.

These acute care hospital requirements do not specify who must give informed consent nor do these acute care hospital requirements place an obligation upon the hospital to verify that informed consent had been obtained prior to the start of therapy, nor do they require any documentation be present in the acute care hospital medical record that the patient had given informed consent.

Skilled nursing facilities have a requirement to verify that the patient's SNF health record contains documentation that informed consent had been obtained by the attending licensed healthcare practitioner acting within the scope of his or her professional licensure from the patient or the patient's authorized representative prior to administration of psychotherapeutic drugs or physical restraints or the prolonged use of a device that may lead to the inability of the patient to regain the use of a normal bodily function for a patient in that skilled nursing facility.

22. Do we need to get a new consent if the dose for a psychotropic meds is increased?

The answer to this question is: maybe.

There is specific requirement under HSC Section 1418.9(a), stipulates that a physician or a surgeon shall obtain the informed consent of a resident "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 "

- This is a statute; it overrides regulations so in a SNF a Licensed Practitioner other than a physician can not order antipsychotic medications and you would need a physician or surgeon to obtain the informed consent.
- Note that Antipsychotic is defined as medication used to treat psychosis. HSC Section 1418.9(b)(3) "'Antipsychotic medication" means a medication approved by the United States Food and Drug Administration for the treatment of psychosis."

- HSC Section 1418.9(b)(4) ""Increase of an order" means an increase of the dosage of the medication above the dosage range stated in a prior consent from the resident."

If the medication is a psychotropic medication other than an antipsychotic then the attending licensed healthcare practitioner acting within the scope of his or her professional licensure must obtain informed consent from the patient or the patient's authorized representative if the material circumstances which originally warranted the use of the psychotropic medication has changed or if the original informed consent had a dosage range and the new order would exceed that range. Both of these cases would require a new informed consent. If the material circumstances of the patient have not changed, then no new informed consent is required. See CCR Title 22 Section 72528(d).