

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 Title 22 California Code of Regulations (CCR) 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 (Title 22 CCR 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 (Title 22 CCR Section 72307(a)).

Physician orders written prior to the admission of a patient to a SNF shall conform to the regulatory guidance in Title 22 CCR 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 a “Physician assessment”?

Title 22 CCR 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.
- (3) Patient diagnoses.
- (4) Advice, treatment and determination of appropriate level of care needed for each patient.
- (5) Written and signed orders for diet, care, diagnostic tests and treatment of patients by others. Orders for restraints shall meet the requirements of Section 72319(b).
- (6) Health record progress notes and other appropriate entries in the patient’s health records.
- (7) Provision for alternate physician coverage in the event the attending physician is unavailable.”

Those patients that require informed consent may require that an evaluation be performed prior to or immediately after admission which is allowed under the regulation.

Title 22 CCR Section 72307(a) states:

“Each patient admitted to the skilled nursing facility 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, and who documents the visits in the patient health record.”

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 Title 22 CCR 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.

Nurse practitioners or physician assistants who have standardized procedures and protocols and the delegated authority that includes prescriptive authority from a collaborating physician may prescribe psychotherapeutic medications. It is not necessary to specifically list the individual psychotherapeutic medication separately in the protocol. Informed consent must be obtained regardless if a nurse practitioner, physician assistant, physician, or surgeon prescribes the psychotherapeutic medication.

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, including a nurse practitioner or physician assistant with delegated authority from a physician and surgeon, 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 for whom they cannot provide adequate care, including a patient requiring a therapy for 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 Title 22 CCR 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 patient's 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?

An advanced practice nurse or physician assistant whose scope of practice allows the prescribing of drugs may obtain informed consent if that nurse practitioner or physician assistant prescribed the drug. A nurse practitioner or physician assistant must have standardized procedures and protocols established with a supervising physician or surgeon before obtaining informed consent from the resident. There should be documentation of standardized procedures and protocols between the nurse practitioner or physician assistant and supervising physician and surgeon readily available.

8. Can a facility, using an approved form, fill the form out for a physician or other delegated authority (without the physician or the nurse practitioner or physician assistant 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?

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 Title 22 CCR 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 Title 22 CCR Section 72528(c) below).

How the facility verifies the content of informed consent is up to the facility [see Title 22 CCR 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 Title 22 CCR Section 72527 and Section 72528, with special emphasis on Title 22 CCR Section 72528(b) in regard to documenting informed consent in the patient's medical record.

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

Title 22 CCR Section 72052, which states:

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 Title 22 CCR Sections 72527(a)(5) and 72528.

Title 22 CCR Section 72092, which states:

Psychotherapeutic drug means a medication to control behavior or to treat thought disorder processes.

Title 22 CCR Section 72527(a)(5), which 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).

Title 22 CCR Section 72527(e)(1), which 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.

Title 22 CCR Section 72528, which 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 Title 22 CCR Section 72527(a)(5) and Title 22 CCR 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 Title 22 CCR 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 Title 22 CCR 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 Title 22 CCR 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 Title 22 CCR 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 Title 22 CCR Section 72528; one in paragraph (e) and two in paragraph (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.

Title 22 CCR 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 Title 22 CCR Section 72527(a)(5) and Title 22 CCR 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?

Prior to 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, Title 22 CCR Section 72528(b) requires the licensed healthcare practitioner to disclose at least the following information:

- (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.

Subsection (c) indicates that before commencing any of the treatment options under subsection (b), informed consent must be documented in the medical record. Taken together, these subsections require that the medical record contains documentation that

all enumerated requirements listed under subsection (b) have been shared with the patient, that the patient has consented to the treatment, and that this sharing and ultimate approval of the procedure by the patient is memorialized in the medical record prior to the initiation of treatment.

While the regulation does not specify the exact language used to reflect the informed consent disclosures, each facility should ensure that it has a policy and procedure in place that complies with the disclosure requirements set forth above.

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 Title 22 CCR Section 72515(b) if they accept the patient for whom they cannot provide care.

Title 22 CCR 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 Title 22 CCR Section 72527(e)(1).

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

Title 22 CCR 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 regulation does not state how the obtained informed consent is documented in the medical record, only that before initiating the therapy, facility staff must ensure that the medical record contains documentation that informed consent had been obtained.

The physician is responsible for obtaining informed consent, as provided in HSC Section 1418.9(a). If the supervising physician has established standard protocols and procedures and has delegated prescribing authority for psychotherapeutic drugs to a collaborating nurse practitioner or physician assistant whose scope of practice allows the prescribing of drugs, the nurse practitioner or physician assistant may obtain informed consent if that nurse practitioner or physician assistant prescribed the drug. The licensed health practitioner that obtains the informed consent must document the informed consent in the chart. Title 22 CCR Section 72528(c) requires facility staff to verify that the patient's health record contains such documentation prior to initiating the therapy.

17. There is nothing in the progress notes or written orders regarding informed consent, but the printed recapitulation of orders indicates that the consent was obtained by the doctor, nurse practitioner, or physician assistant. Is this acceptable?

Each facility is permitted to create its own documentation policy that conforms to the informed consent requirements. As discussed above, Title 22 CCR Section 72528(c) does not specify how the obtained informed consent must be documented in the medical record. The facility staff must confirm that informed consent documentation exists in the medical record prior to initiating treatment in order for the facility will be in compliance with the regulation.

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, nurse practitioner, or physician assistant 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 Title 22 CCR 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 by a physician, nurse practitioner or physician assistant acting within the scope of his/her professional licensure prior to initiating therapy described in Title 22 CCR Section 72528 (excepting the provisions stated in Title 22 CCR Section 72528(e)). It is a facility's responsibility under Title 22 CCR 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 Title 22 CCR 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 review Title 22 CCR Sections 72052, 72527, 72528, and HSC Section 1418.9(a).

19. Shouldn't informed consent be physician, nurse practitioner, or physician assistant 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 Title 22 CCR Section 72528(a). The nurse practitioner or physician assistant must have standard protocols and procedures and prescribing authority, as delegated by a supervising physician and surgeon, in order to prescribe psychotherapeutic drugs or obtain informed consent.

Nevertheless, Title 22 CCR 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 doctor, nurse practitioner, or physician assistant 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.

Title 22 CCR Section 70707(b)(5) & (6) provides that patients have the right to:

(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 non-treatment 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 medication is increased?

It depends on the type of medication prescribed, the changing material circumstances of the dosage range, and if the dosage range has changed from the original consent by the patient or the patient's representative. Specific requirements under HSC Section 1418.9(a) stipulate that a physician and 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..." If the nurse practitioner/physician assistant and physician and surgeon have listed antipsychotic drugs in the standardized agreement then the nurse practitioner/physician assistant can prescribe these types of medications.

You need to obtain informed consent:

- If the material circumstances which originally warranted the use of the psychotropic medication have changed or if the original informed consent had a dosage range and the new order would exceed that range. See Title 22 CCR Section 72528(d).

Otherwise, you do not need to obtain informed consent:

- If the increase in dosage is within the parameters listed on the informed consent and the material circumstances of the patient have not changed. See Title 22 CCR Section 72528(d).

23. Should nurse practitioners/physician assistants and supervising physicians and surgeons have standardized agreements for prescribing psychotherapeutic or antipsychotic prescriptions?

Yes. According to Business and Professions Code (BPC) Section 2836.1(a) and (c)(1), nurse practitioners must have documented standard protocol and procedures that include which medications can be prescribed with the approval of a supervising physician. Typically this is not a specific list of individual drugs, rather a list of drug classes.

Further, pursuant to BPC Section 3502.1, physician assistants must have documented standard protocol and procedures that include which medications can be prescribed with the approval of a supervising physician. Again, typically, this is not a specific list of individual drugs, rather a list of drug classes.

These standardized agreements may not contain standing orders, which are written orders that are used or are intended to be used in the absence of a specific order for a specific patient provided by a licensed healthcare practitioner acting within the scope of his or her professional licensure. Title 22 CCR Section 72317 dictates that standing orders shall not be used in skilled nursing facilities.

24. What should a standardized agreement look like for the nurse practitioner?

According to BPC Section 2836.1 (c)(1), the standardized procedure and protocol should specify which drugs or devices may be prescribed and under what circumstances, the extent of the physician's supervision for the furnishing of the prescriptions, the method of periodic review of the nurse practitioner's competency, including peer review and the review of protocols and procedures.

25. What should a standardized agreement look like for the physician assistant?

According to BPC Section 3502.1, the standardized procedure and protocol should specify which drugs or devices may be prescribed and under what circumstances, the extent of the physician's supervision for the furnishing of the prescriptions, the method of periodic review of the physician assistant's competency, including peer review and the review of protocols and procedures.