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

GAVIN NEWSOM
Governor

February 28, 2024

AFL 24-07

TO: Skilled Nursing Facilities (SNFs)
Intermediate Care Facilities (ICFs)
Hospices

SUBJECT: Assembly Bill (AB) 48 - Nursing Facility Resident Informed Consent Protection Act of 2023

AUTHORITY: Health and Safety Code (HSC) sections 1599.1 and 1599.15

All Facilities Letter (AFL) Summary

- This AFL notifies SNFs, ICFs and hospices of the passage of AB 48 (Chapter 794, Statutes of 2023) that codifies current regulations related to a patient's right to be free from psychotherapeutic drugs and, to provide informed consent before treatment with psychotherapeutic drugs and clarifies applicable federal regulations.
- Facilities must obtain a resident's written informed consent for treatment using psychotherapeutic drugs, and consent renewal every six months.
- The California Department of Public Health (CDPH) must consult with interested stakeholders to develop a standardized informed consent form specific to psychotherapeutic drugs by December 1, 2025.

Effective January 1, 2024, AB 48 codifies existing regulations that state residents have the right to be free of psychotherapeutic drugs when used for the purpose of resident discipline or staff convenience and to be free from psychotherapeutic drugs used as a chemical restraint. “Chemical restraint" is a drug used to control behavior and used in a manner not required to treat the resident's medical symptoms. “Psychotherapeutic drug" is a drug to control behavior or to treat thought disorder processes, excluding antidepressants. CDPH has the authority to implement, clarify and make specific this law by means of an AFL.

Written Informed Consent and Information Disclosure

AB 48 requires the facility to obtain written informed consent and specifies that the disclosure of material information for proper informed consent for a prescription for psychotherapeutic drugs must include:

- Possible nonpharmacologic approaches that could address the resident's needs.
- Whether the drug has a current boxed warning label along with a summary of, and information about how to find, the contraindications, warnings, and precautions required by the United States Food and Drug Administration (FDA).
- Whether the proposed drug is being prescribed for a purpose that has or has not been approved by the United States FDA.
- Possible interactions with other drugs the resident is receiving.
- How the facility and prescriber will monitor and respond to any adverse side effects and inform the resident of side effects

Examination and Signatures

Before prescribing a psychotherapeutic drug, the prescriber must personally examine the resident and obtain informed written consent signed by the resident or the resident's representative along with, the signature of the health care professional declaring the required material information has been provided. If the resident or resident's representative cannot sign the form, a licensed nurse can sign the form and document the name of the person who gave consent and the date. The personal exam and the signatures of the prescriber, resident, or representative can be completed and signed using remote technology.

The resident and representative have a right to receive the written disclosure in a language they understand. If that is not possible, the facility may provide a version of the written disclosure in English, along with an oral explanation in a language the resident and their representative understand. If the resident is hearing or vision impaired, the facility is responsible for supplying the material information and written consent form in an accessible format the resident can understand. Copies of the signed written consent must be given to the resident and their representative.

Medical Records

The signed written consent must be recorded in the resident's medical record. Before initiating treatment with psychotherapeutic drugs, facility staff must verify that the resident's health record contains written informed consent with the required signatures. For a prescription written prior to facility admission, the facility staff must verify that the resident or the resident's representative gave informed consent and make a notation in the resident's records. The record does not need to be checked every time the drug is administered.

Renewals of Informed Consent

Facilities must renew the written informed consent every six months. At that time, the facility must provide the resident with any recommended dosage adjustments and the option of revoking consent. If the resident decides to discontinue using the drug, the prescriber is responsible for planning any necessary, gradual dose reduction, as well as possible behavioral interventions.

Policies and Procedures (P&Ps)

Facilities must review and revise their P&Ps to ensure compliance with the new law. The P&Ps must specifically consider and plan for how the facility will verify that the resident provided informed consent or refused treatment or a procedure pertaining to the administration of psychotherapeutic drugs.

Standardized Form Development

CDPH along with stakeholders will begin developing a standardized informed consent form specifically for psychotherapeutic drugs. CDPH must distribute the form on or before December 31, 2025.

Updates to Federal Regulations for SNFs, ICFs, and Hospices

AB 48 updates references to federal regulations found in HSC section 1599.1(i)(2). The updated references align with the 2017 version of Title 42 of the Code of Federal Regulations (CFR).

Additionally, SNFs, ICFs, and hospices must follow the appeal process provided in Title 42 CFR section 483.204 in the event of an appeal for an involuntary transfer or discharge, regardless of a resident's payment source or the Medi-Cal or Medicare certification status.

Facilities are responsible for following all applicable laws. CDPH's failure to expressly notify facilities of statutory or regulatory requirements does not relieve facilities of their responsibility for following all laws and regulations. Facilities should refer to the full text of all applicable sections of the HSC and Title 22 of the CCR.

If you have any questions about this AFL, please contact your local district office.

If you have questions about the development of the standardized form, please contact the CHCQ Regulation Development Section at CHCQRegulations@cdph.ca.gov.

Sincerely,

Original signed by Cassie Dunham

Cassie Dunham

Deputy Director

Resources:

- AFL 09-12 Informed Consent for Antipsychotic Medication
- AFL 11-08 Informed Consent
- AFL 11-31 Questions and Answers about Informed Consent
- AFL 12-56 California Forging Major Campaign to Improve Dementia Care and Reduce Unnecessary Antipsychotic Drug Use in Nursing Homes
- AFL 14-11 Informed Consent – Physician Assistants

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Page Last Updated : February 28, 2024