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| To: | California Mental Health Services Authority |
| From: | Manatt, Phelps & Phillips, LLP |
| Date: | January 22, 2023 |
| Subject: | Psychiatric Medication Consent Recommendations |

The California Mental Health Services Authority (hereinafter "CalMHSA") requested that Manatt, Phelps & Phillips, LLP (hereinafter "Manatt") research whether California statutes and regulations require mental health care providers to obtain any specific informed consent from patients before prescribing or initiating treatment with psychotropic and antipsychotic medications ("Specific Medications"). This research was intended to support CalMHSA in the development of a broadly applicable written medication consent templates for Specific Medications, which may be used by the Counties utilizing CalMHSA's SmartCare EHR platform. CalMHSA used this information to develop mediation consent templates for the Specific Medications. Manatt has reviewed the proposed medication consent templates and believe they incorporate the results of our research.

The medication consent templates for Specific Medications are not meant to address all situations in which a provider may want or be required to obtain general or specific informed consent before prescribing or commencing other types of medications or treatments. In addition, the templates for the Specific Medications cannot be used in lieu of any specific FDA consent form that must be used by providers for medications covered under the Risk Evaluation and Mitigation Strategy (REMS) program.

A summary of our research is below.

- Manatt reviewed the California Department of Health Care Services' Annual Review Protocol for Specialty Mental Health Services and Other Funded Services (hereinafter "Guidance")[1] . The Guidance document listed general informed consent requirements for "psychiatric medications."[2] We then verified the specific medication consent requirements utilizing the below WestLaw search.

- Manatt utilized the legal search tool WestLaw to determine the instances in which the following terms or phrases were used in California statutes and regulations:

[1] Note this Guidance document is no longer effective as changes to the Lanterman-Petris-Short Act—for which this guidance is associated—took effect in 2023, making it outdated. We note the use of this Guidance simply as a starting point for our research.

[2] We note that the Guidance document and other documents, such as the contract between the Counties and the Department of Health Care Services uses the term "psychiatric medications" generally. However, for the purposes of the memorandum we use the term "antipsychotic medications" as it is the term used in California law and regulations. *See* Cal. Wel. & Inst. Code § 5325.3; 9 CCR § 851.

- "Antidepressant medication" and "antidepressants"
- "Antianxiety medication" and "antianxiety"
- "Psychotropic medication"
- "Psychiatric medication"
- "Opioid Use Disorder"
- "Medication-Assisted Treatment"

We reviewed any laws and regulations where such terms were used to assess their applicability to the development of the medication consent templates for the Specific Medications. We identified specific consent requirements for "antipsychotic" medications, "psychotropic" medications, and "opioid use disorder" medications generally and specifically when used by a minor. We found that there are laws and regulations in California that regulate medication consent for "psychotropic" medications—a broader class of medications that include "antipsychotic" medications. Under the Lanterman-Petris-Short Act (LPS Act), providers treating *voluntary* patients in facilities governed by the LPS Act[3] who prescribe "antipsychotic" medications must note in the patient's medical record that they discussed "the information about informed consent for antipsychotic medications" with the patient and include a "notation that the patient understands the nature and effect of the antipsychotic medications and consents to the administration of those medications."[4]

**Conclusion**

Based on our research as described above, we find that CalMHSA's template medication consents should meet the specific informed consent documentation requirements for the Specific Medications under federal and state law and regulation. Where the laws and regulations were silent with regard to specific requirements related to changes to a medication regimen of a Specific Medication -- for example, change to the medication dose, medication titration, and switching medications from brand name to generic or from generic to brand name -- we have assumed there is no specific written informed consent that must be used; in such instance, as in all other instances of prescribing medications or commencing treatments, providers may use their professional medical judgment to determine whether documenting a standalone informed consent in the record versus a notation in the medical record is necessary.

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[3] *See* California Behavioral Health Information Notice No. 23-065 (Nov. 15, 2023) (the facilities include, mental health rehabilitation centers, community treatment facilities, social rehabilitation facilities/programs, short-term residential therapeutic programs, children's crisis residential programs, crisis stabilization units, psychiatric health facilities, acute psychiatric hospitals, general acute care hospitals, and correctional treatment centers), https://www.dhcs.ca.gov/provgovpart/Documents/BHIN-23-065.pdf.

[4] *See* Cal. Wel. & Inst. Code § 5325.3(a), (b).