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DIVISION OF MENTAL HEALTH AND ADDICTION SERVICES
ADMINISTRATIVE BULLETING TRANSMITTAL MEMORANDUM

TO: Chief Executive Officers

FROM: Lynn A. Kovich, Assistant Commissioner
Division of Mental Health and Addiction Services

DATE: June 1, 2012 **EFFECTIVE DATE: June 4, 2012**

SUBJECT: **Administrative Bulletins 5:04, 5:04A and 5:04B**
This Bulletin replaces AB 78-3- dated 10/1/82, and AB 5:04 dated 9/15/83
And AB 5:04 revised dated September 1, 2011

Attached is the Administrative Bulletin that replaces the above referenced bulletin AB 5:04. Please distribute to staff as appropriate. The enclosed administrative bulletin is separated into three separate, discrete, stand-alone policies. All of the required forms necessary for implementation of each of the separate policies are attached and shall be distributed contemporaneously with these new bulletins. The above policies address informed consent, administration of psychotropic medication to adult voluntary and involuntary patients at state psychiatric hospitals. The policies are as follows:

- **AB 5:04** is the informed consent policy
- **AB 5:04A** is the policy that creates the protocols for the involuntary emergency administration of psychotropic medication.
- **AB 5:04B** is the policy that creates the protocols for the administration of non-emergent involuntary administration of psychotropic medication.

Informed Consent

The informed consent policy confirms the requirement that medicating any person in any setting requires, where possible, informed consent. Additionally, if a patient has a guardian for medical informed consent or if someone holds a durable power of attorney for medical decisions, or if an advance psychiatric directive is in effect, the patient still should be informed as much as s/he is able, but the consent if given is by the guardian or representative.

AB 5:04A Emergency Medication

The protocols attached to AB 5:04A for the emergent administration of psychotropic medication have not been revised from the September 1, 2011 policy. AB 5:04A confirms the following process: that prior to involuntary medication for an emergency circumstance, less restrictive alternatives must be attempted and documented. Further, an emergency as defined in the policy is for a discrete period of time; one 72 hour period of medication is permitted for each emergency; additionally, 24 hour reviews continue during the emergency period to reassess if the situation remains emergent and the hospital Medical Director and Client Service Representative (CSR) must review every emergency medication event.

AB 5:04B: Non-Emergent Administration of Medication

The changes in AB 5:04B are for the protocols for the non-emergent administration of psychotropic medication for both patients who refuse medication and for those patients who cannot consent to medication.

Under the new policy, prior to administration of medication to individuals who have the capacity to consent but choose to refuse medication (formerly referred to as refusal requiring the 3 step process) or for individuals who cannot consent (formerly functionally incompetent), the prescriber must document that all less restrictive alternatives to forced medication have been considered. After such alternative treatments are exhausted or ruled out, the procedure in paragraph IV of the new policy must be followed before medication can be administered unless there is an emergency or the patient becomes willing and able to consent.

AB 5:04B requires new clinical staff, a Client Services Advocate (CSA) in addition to the Client Services Representative (CSR), to monitor the administration of non-emergent medication through the process of medication review hearings. For those individuals who cannot consent, the CSA will assist him/her throughout the medication review hearing which is administrative and clinical in nature.

The medication review hearing is before a three person panel: a non-treating psychiatrist as the panel chair, an administrator (Program Coordinator or above) as a panel member and another non-treating clinician. None of the panel members can be currently involved in the patient's treatment. Section IV C and D.

The panel will convene and hold a medication review hearing within the timeframes in AB 5:04B. Panel members will review the Involuntary Medication Administration Report (IMAR), which has been completed by the prescriber, approved by the Medical Director, and explained to the patient by the CSA. A three person panel will convene, will hold a hearing according to the process in the policy and render a decision. The patient may appeal this decision according to the process set forth within the policy at section IV paragraphs O through Q.

The policy is effective on June 4, 2012.

DIVISION OF MENTAL HEALTH AND ADDICTION SERVICES
ADMINISTRATIVE BULLETIN 5:04

Effective Date: June 4, 2012

Note: This bulletin replaces A.B. 78-3 dated 10/1/82 and A.B. 5:04 dated 9/15/83, and A.B. 5:04 dated 9/1/11

SUBJECT: MEDICATION INFORMED CONSENT POLICY

I. Policy

A. Title 30 of the New Jersey Statutes provides that every individual who has a mental illness is entitled to medical care and other professional services in accordance with accepted standards, and that patients in the care of the State have the right to participate in planning for their own treatment to the extent that their conditions permit. Voluntary and involuntary patients are presumed competent.

Informed consent to treatment, including the administration of psychotropic medication, by a competent adult or an appropriate proxy is the norm. Patients are to be encouraged to participate in treatment decisions, and will be given a meaningful opportunity to invite a person of their choice, for example, a family member or Client Services Advocate, to any treatment team meeting where medication is discussed. Details of any patient treatment preferences communicated to the team through writing, through a psychiatric advance directive, or verbally will be documented in team notes, along with a rationale for deviation from these preferences if the patient's preferred mode of treatment is not implemented.

B. This bulletin provides guidelines to state psychiatric hospital staff on informed consent for treatment that will:

1. Fulfill ethical, professional and legal responsibilities to provide treatment in conformity with the best practices known at the time the treatment is required and with the goal of promoting the wellness and recovery of every consumer of the state's mental health services;

2. Enhance the ability of consumers, while they are patients in the state psychiatric hospitals, to direct their own treatment through their engagement in a collaborative treatment planning process when they are capable of participating, and, when they are not capable of direct participation, by the engagement of guardians or mental health care representatives guided by advance directives for mental health treatment that will promote their recovery; and

3. Protect the rights of patients to give or withhold consent to the administration of medications.

II. Responsibilities

A. The Medical/Clinical Director is responsible for oversight of clinical decision-making under this bulletin at each psychiatric hospital, for reviewing the decisions of the prescribers, for supporting the actions of the Client Service Advocates at the hospital level, and for correcting any deviations from the policy by prescribers through counseling, using the PAR/PES system for evaluation of professional performance, and where necessary invoking discipline through A.O.4:08 and the appropriate licensing board.

B. The CEO or Deputy CEO of each hospital must appoint and directly supervise a Client Services Advocate and provide staff and resources sufficient to implement this bulletin, including making administrators and clerical and clinical staff available for any hearings convened pursuant to A.B. 5:04 B.

C. The Client Services Advocate at each hospital is responsible for reviewing the chart of each patient who is prescribed psychotropic medication and for reporting, both on a monthly basis and as needed and appropriate, any departures from the bulletin to the hospital's Medical/Clinical Director and the DMHAS Medical Director. S/he, or, if unavailable, his/her designee shall meet with the hospital's Medical Director and other medical staff weekly to review difficult cases and any current medication issues. S/he also has the responsibility to ensure that those patients who consent to medication have done so voluntarily, and that those who are medicated without consent are medicated in accordance with the policy. The Client Services Advocate shall have access to all charts and prescribers, and shall ensure that the hospital provides an orientation for new patients that includes information about their medication rights.

D. Each prescriber is required to become familiar with the procedures in this bulletin and to conform his or her prescribing activity to its standards.

E. All direct care and nursing staff are to report observed side effects of medications to the prescriber, to inquire about an involuntarily medicated patient's willingness to accept medication on a regular basis, to observe and report any change in a patient's ability or willingness to consent to medication, and to monitor the proper administration of medication.

F. All staff are responsible for participating in treatment activities as appropriate to their title, and doing so in a way that encourages shared decision-making and patients' wellness and recovery.

.III. Definitions

Client Services Advocate (CSA) – is a licensed prescriber or Master's-prepared psychiatric nurse who directly reports to the CEO or Deputy CEO of each hospital and has a reporting relationship to the DMHAS Medical Director through the Coordinating Chief of CSAs (hereinafter Coordinator) and whose primary responsibility is to evaluate individuals receiving treatment with psychotropic medication. The CSA accomplishes this by individual patient assessment, consultation with the treatment team, and participation in the Medication Review Hearings process, as ongoing assessment and oversight to ensure that medication is only continued if that medication is the least restrictive alternative and appropriately approved. The CSA is responsible for developing and providing orientation and training programs on these procedures for staff and patients. The CSA may delegate non-clinical monitoring and patient communication and education activities to appropriate staff including Client Services Representatives.

Client Services Representative (CSR) – is a hospital employee who reports to the hospital's CSA and who is responsible to ensure compliance with due process procedures when a patient will not or cannot provide informed consent for psychotropic medication in non-emergent situations. The CSR will meet with patients to understand their concerns, inform patients of their rights to least restrictive effective treatments, and explain their right to give informed consent and the circumstances under which that right can be overridden by their need for treatment. The CSR shall document side effects as reported by the patient or as noted in the record, and report side effects or other events to the CSA. The CSR shall conduct record reviews, follow-up with the teams when procedural discrepancies occur, compile monthly reports, collect other data as required by the CSA, and shall meet with the CSAs and Coordinator as needed to assure conformity across the system with the standards in this policy.

Coordinating Chief of Client Services Advocates / Coordinator ("Coordinator") - is an employee of the Division qualified by education and experience to clinically guide the CSAs who reports to the Division Medical Director. He/she shall provide guidance to the CSAs, review their reports and assist with quality improvement. The Coordinator shall work with the CEOs in establishing work duties of the CSAs, selecting qualified candidates, providing input into their performance evaluations, and ensuring coverage for all of the hospitals. The Coordinating Chief shall also assist the Division Medical Director in arranging for independent, non-treating psychiatrists for Medication Review Hearings and for providing for their orientation and training. S/he shall meet regularly with the CSAs and the CSRs.

Decision-making capacity - is the ability to understand and appreciate the nature and consequences of mental health care decisions, including the benefits and risks of each, and alternatives to any proposed mental health care, and to reach an informed decision. A patient's decision-making capacity is evaluated by a licensed professional relative to the demands of a particular mental health care decision.

Division - means the Division of Mental Health and Addiction Services (DMHAS) in the New Jersey Department of Human Services.

Division Medical Director - refers to the Medical Director for the Division of Mental Health and Addiction Services.

Incapacity - means the state in which a person is generally unable to govern or manage his or her affairs, including medical decisions; this determination can be made only by a court, and a person who is incapacitated has a legal guardian. However, a person who is generally competent can be found to lack capacity to make a particular decision so that his or her advance directive for mental health care becomes operative and serves as authority to treat.

Medical Director – means the Hospital Medical Director, as referenced throughout this policy. Each of the State psychiatric hospitals has its own Medical Director. Whenever the Medical Director is referenced in this policy it allows for the Medical Director or hospital CEO to appoint a clinical designee at the Director or Supervisory level to perform functions where appropriate.

Mental Health Care Representative - means the individual designated by a declarant pursuant to the proxy directive part of an advance directive for mental health care for the purpose of making mental health care decisions on the declarant's behalf, and includes an individual designated as an alternate mental health care representative who is acting as the declarant's mental health care representative in accordance with the terms and order of priority stated in an advance directive for mental health care.

Mental illness - means any current substantial disturbance of thought, mood, perception or orientation which significantly impairs judgment, functioning, capacity to control behavior or capacity to recognize reality caused by any organic, mental or emotional impairment.

Prescriber - means a professional licensed in New Jersey to prescribe or renew a prescription for psychotropic medication.

State - means the state of New Jersey.

IV. Consent

A. Upon admission and on an ongoing basis:

All hospital staff shall ensure that consent to medication in a non-emergent situation is informed and voluntary for all patients who have the capacity and the will to give consent. Each patient will be informed of the rights, benefits, and risks of medication that are prescribed for that patient, and will be given the opportunity to consent to take the prescribed medication or refuse to

consent.

B. Procedure

1. In order to meet the requirements for informed consent for medication, an adult voluntary or involuntary patient must have decision-making capacity; shall have been informed in writing of the nature, benefits, and risks of the medications that are being recommended; and shall be informed that s/he has the right to refuse medication and given contact information for, and information about the role of, the Client Services Advocate. The prescriber shall provide the patient with information about the specific medication and the proposed dosage range, including the appropriate psychotropic medication fact sheet(s), which are available at http://www.state.nj.us/humanservices/DMHAS/news/publications/med_manual_nov2008.pdf, and shall review all information with the patient and offer to answer any questions that the patient may have about the medication(s) before the consent form is signed.

2. The prescriber shall ask a consenting patient/guardian/mental health care representative to sign the DMHAS Psychotropic Medication Informed Consent Form, which shall list the prescribed medication(s) and their formulations (oral vs. short or long acting injection). Use of dosages above the usual therapeutic maximum dose and the presence of other potential adverse reactions must be listed on the form and discussed with the patient, guardian, or mental health care representative.

3. If a patient capable of giving informed consent is willing to take a medication but not willing to sign a consent form, s/he may provide verbal consent. Two treatment team members (other than the prescriber) shall witness that the patient has consented, and this consent shall be documented on a consent form and in a progress note.

4. The prescriber is responsible for ensuring that the contents of the consent form and medication fact sheets are communicated to the patient/ guardian/ mental health care representative in his or her primary language or mode of communication. If communication is other than in English, or if provided other than through these documents, the nature and mode of communication shall be documented on the consent form by the prescriber.

5. A change in the dosage of a patient's medication does not require a new consent so long as it is within the usual therapeutic dose and for a use described in the appropriate literature provided by its manufacturer (for a list of maximum dosages of psychotropics, which are to be considered as a

guideline only, see the DMHAS Pharmacological Practice Guidelines for the Treatment of Schizophrenia in 2005). If the change would order a dose that is above the usual therapeutic dose or it is being given in a different formulation (e.g., oral, injection), a new consent, with the additional risks and benefits explained, must be obtained. If the patient will not consent to the new dose or medication, the procedures in A.B. 5:04B shall be completed before the medication order can be changed to the new dose or medication.

6. Consent will not be considered to be voluntary if it is given in response to coercion, such as when medication is tied to threats of forced medication, involuntary commitment, transfer to a more restrictive setting, or loss of privileges. Any allegation of the use of coercion or force reported to any Department of Human Services employee by the patient, another patient, a family member, or an advocate must be reported as abuse to the Department of Human Services and investigated either by the hospital risk manager or the Patient Services Compliance Unit, at the option of the DMHAS Medical Director.

7. The consent form shall be maintained in the patient's clinical record and shall be effective for one year, unless revoked by the patient, or where legally permissible by the consumer's guardian or mental health care representative. If new risks and benefits are identified during the year, the patient shall be informed in writing and offered the opportunity to revoke or revise his or her consent to the medication.

8. A patient/guardian/mental health care representative who has consented to medication may revoke consent at any time by stating or writing a desire to discontinue or change the medication; in addition, consent may be called into question by any behavior indicating an unwillingness to take the medication. Regular or repeated resistance to the administration of a medication will be discussed with the patient and the treatment team, and if the consent is considered revoked, the patient will be informed of treatment options and the limited right to refuse medication.

9. When a patient who has consented to medication refuses that medication consistently for 72 hours, his or her consent shall be considered revoked, "void" shall be written on the consent form, and the medication shall be discontinued in compliance with the standard of care. If the patient subsequently indicates a willingness to take the medication, he/she must sign a new consent form.

10. If a patient is being medicated pursuant to an instruction in an advance directive for mental health care, any medication refusal shall be evaluated as a request for modification or rescission of the advance directive, and the

refusal shall be effective only if the patient currently has the capacity to modify or rescind the advance directive. See N.J.S.A. 26:2H-106 f.

V. Exceptions to the requirement of informed consent

A. In an emergency, in A.B. 5:04A any patient can be medicated without informed consent with psychotropic medication for 72 hours using the procedure in AB 5:04A.

B. If the patient has not been declared legally incapacitated and is not refusing psychotropic medication but, in the prescriber's opinion, lacks decision-making capacity to consent to the administration of psychotropic medication the prescriber shall follow the procedures in A.B. 5:04B. The prescriber shall concurrently assess the need for the appointment of a guardian, and if a guardian is needed, shall take all actions necessary to initiate the process.

C. If the patient is refusing to consent to the administration of medication, whether or not she or he has decision-making capacity, the patient shall be evaluated for the appropriateness of overriding that refusal pursuant to A.B. 5:04B, but if the patient does not meet the standards in that section for involuntary administration of medication, s/he shall not be given that medication, and an alternative treatment plan shall be designed to address the mental health needs of the patient.

D. If the patient has been declared incapacitated and has a legal guardian, the latter shall be contacted and asked to meet with the team in order to receive this information and to sign the consent form. If, after being afforded reasonable notice of the proposed action and a request for consent, the patient's guardian does not either grant or deny consent, then the Chief Executive Officer may give written consent to the administration of the medication in accordance with NJSA 30: 4-7.2. If the guardian refuses consent and the prescriber still believes the patient is in need of medication as defined in this policy, the prescriber will follow the procedures in A.B. 5:04 B.

E. If the patient lacks decision-making capacity and has named a mental health care representative in an advance directive for mental health care, the prescriber shall give the information required in this section to that representative and to the patient to the extent s/he is able to participate, and shall obtain the mental health care representative's consent to the administration of the medication. If the patient has given instructions in an advance directive for mental health care that if the directive takes effect s/he consents to the medication, the prescriber shall document that fact, shall assure that the advance directive is in the chart, and shall authorize the administration of the medication. If the instructions or the mental health care representative direct refusal of the medication, the patient shall be treated as a refusing patient pursuant to A.B.5:04B

VI. Training: Appropriate annual and new employee training on the positive and negative potential effects of long-term use of antipsychotics, polypharmacy, and this policy shall be mandatory for all Client Services Advocates,prescribers, and other designated personnel, as appropriate.

Lynn A. Kovich, Assistant Commissioner

Appendices:
Informed consent form
5:04 A
5:04 B

N.J. DIVISION OF MENTAL HEALTH AND ADDICTION SERVICES
INSERT HOSPITAL NAME

PSYCHOTROPIC MEDICATION INFORMED CONSENT FORM

Patient Name:_____ Hospital #:_____

GENERAL INFORMATION:

If psychotropic medication (a medicine that changes your behavior or the way you think) is considered a necessary part of your treatment program, you will be given information about how the doctor, nurse, or team believes the medication will help you, and specific information about expected changes, both good and bad, that might happen to you if you take the medication. You will also receive this information in writing in the form of a Medication Fact Sheet that describes the purpose, benefits, side effects, and risks of each medication being prescribed to you.

If you are a voluntary patient, the staff may not give you ANY psychotropic medication without your consent unless there is an emergency (you are going to hurt yourself or someone else very soon) and no less drastic measures will stop the emergency. You can only be medicated in an emergency up to 72 hours.

If you are committed to the hospital, you still have the right not to sign the consent, and to refuse psychotropic medication, but the hospital staff can give you medication in an emergency, and can go through a process to determine if you can be given the medication(s) even though you don't consent.

A **Client Service Advocate (CSA)** and Client Services Representative are available to assist you if you have questions about your medication or if you want to refuse to take psychotropic medications, They are _____CSA and_____CSR, and they can be called toll free at _____

THE MEDICATIONS PRESCRIBED FOR YOU:

Medication Name	How medication(s) will be taken	Dosage Range

Additional information about the above medication(s) in you treatment (If applicable):

❑ The dose is higher than usual dose and this is why this is necessary:_____

_____

❑ There are specific side effects/medical risks for you (e.g., metabolic effects, TD):_____

_____

N.J. DIVISION OF MENTAL HEALTH AND ADDICTION SERVICES
INSERT HOSPITAL NAME

PSYCHOTROPIC MEDICATION INFORMED CONSENT FORM

PHYSICIAN'S CERTIFICATION: Please initial each section and sign below.

_____I have explained to this patient: the nature of his/her condition; the purpose, nature, dosage range and method of administration of the medication; the anticipated benefits, risks and side effects of the medication; his or her prognosis with and without medication; and whether or not there are any feasible alternative treatments. If the patient has offered to take different medications or consent to other less restrictive treatment, I have considered the patient's wishes and explained why I have concluded that the medication(s) that I have prescribed is a better choice.

_____I have given the patient copies of the appropriate Medication Fact Sheets, explained their contents in language and a manner that I think s/he can understand, and offered to answer any questions.

_____I have explained to the patient that even if s/he consents to medication, s/he may revoke consent at any time.

Based on my assessment of this patient, I have concluded that the patient is capable of providing consent to medication and is willing to do so.

Physician Print Name:_____Physician Signature:_____

Date:___/___/____ Time:___:___a.m. / p.m.

IF APPLICABLE:

Interpreter Print Name:_____Interpreter Signature:_____

Date:___/___/____ Time:___:___a.m. / p.m. Patient's primary language:_____

PATIENT'S CONSENT:

Based on my understanding of the benefits and risks of these medications and the choices that are available to me, I consent to taking the medication(s) listed on the front of the document.

Patient Signature_____ ❑ **Patient refused to sign** Date:___/___/___ Time:___:___a.m. / p.m.

_____ _____

Guardian or Mental Health Care Representative signature Date Time

Staff witness: I affirm that the patient or an authorized representative of the patient agreed in my presence to take the medication described on the front of this document.

_____ _____

Staff/Witness Signature Date Time

_____ _____

Staff/Witness Signature Date Time

Date: / / Time: : a.m. / p.m.

Copy to: Client Service Advocate
Patient