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**MAP Advisory Group Meeting**

**Massachusetts Department of Public Health**

**March 16, 2017**

Mary Rota DPH Clinical Reviewer; Medication Administration Program; Drug Control Program

James Lavery, JD Director Bureau of Health Professions Licensure

Lauren B. Nelson, Esq. Director of Policy and Regulatory Affairs; Bureau of Health Care Safety and Quality

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New Location

Executive Office of Health & Human Services

Department of Public Health

Bureau of Health Professions Licensure 239 Causeway Street, Boston, MA

Drug Control Program

Medication Administration Program (MAP)

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MAP Policy - Background

The Medication Administration Program (MAP) is authorized by chapter 94C of the General Laws, *The Controlled Substance Act,* pursuant to:

105 CMR 700.000, *Implementation of M.G.L. c. 94C,* and The appropriate regulations of: The Department of Mental Health in 104 CMR 28.06: *Medication*,

The Department of Developmental Services in 115 CMR 5.15: *Medication*, or

The Department of Children and Families in 110 CMR 11.00: *Medical Authorizations*.

MAP Registered sites must follow these regulations, statutes and the MAP Policy Manual, drafted thereunder.

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MAP Policy – Development

Issue brought to DPH attention

Discussion MAP Administrators

Develop, modify, remove policy

Discussion/Feedback MAP Coordinators

MAP Work Group (Operational) “Help Make it Work”

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MAP Policy – Development

Pilot (if necessary)

Feedback (tweak)

Forwarded to MAP Advisory Group for Feedback (tweak again)

Implemented

Letter Sent to Service Providers

Policy Posted to DCP/MAP Website

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MAP Policy
Proposed Revisions

**MAP Policy Manual**

Version 2010 9-01

Revised xx/xx/17

The policies in this Manual, some of which are revisions of existing policies, supersede all other policies on these topics previously issued by the Departments

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Definitions

MAP Advisories: Information regarding certain medication related issues that are not regulated by MAP. Advisories may also be used to inform MAP program sites about changes to MAP procedures in the interim until the policy can be updated or created.

Administrative Staff: A person who is not assigned to work within the program site, who has managerial responsibilities for the agency/service provider. The position that satisfies this role may vary based upon the appropriate title used by the agency/service provider.

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Policy 02-1(7)

7. Staff have six months from the date of successful completion of the MAP Certification Training to attempt to pass the MAP Certification Test.

* + 1. If the staff does not pass the MAP Certification Test within six months, he/she must again complete the full MAP Certification Training.

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Policy 02-1 (9)

9. MAP Certification is valid for two years from the last day of the month in which the test was passed. For example, if a staff person passes the MAP Certification Test on 1/12/17 and another staff person passes the test on 1/28/17; the expiration date in both cases is 1/31/19.

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Policy 03-4 (New) Revocation of MAP Trainer Approval Status

1. The Department of Public Health may revoke a MAP Trainer’s Approval Status if the MAP Trainer:

a. fails to attend scheduled MAP Trainer meetings/webinars (*See Policy 03-1 for Trainer Requirements*);

b. fails to complete the required number of yearly trainings (*See Policy 03-1 for Trainer Requirements);*

c. fails to conduct trainings in accordance with current MAP training standards;

c. falsifies any of the certifications or other documentation associated with MAP Trainings; or

e. commits an infraction of M.G.L. c. 94C, The Controlled Substances Act.

1. The Service Provider shall be responsible for notification of their MAP regional/area Coordinator(s) regarding any actions or concerns involving employees in these areas.
2. Trainers who have missed scheduled MAP Trainer meetings/webinars, or who have not met the requirements to remain current, may contact their DMH/DCF Area or DDS Regional MAP Coordinator for guidance on how to regain approval to provide MAP Training.

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Policy 04-1 Advisory Ruling Number 9401

 **Massachusetts Board of Registration in Nursing**

 Advisory Ruling on Nursing Practice

**Title:**  The Role of the Licensed Nurse in the Department of Public Health Medication Administration Program

 **Advisory Ruling Number:** 9401

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Policy 06-2 (1)

1. Health Care Provider orders for all PRN medications must have specific target signs/symptoms and instruction(s) for their use (e.g., Tylenol 325 mg by mouth every 6 hours as needed for a fever above 101.)

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Proposed Changes

Remove Policy 06-6 Over-the-Counter Medications and Preparations

Supplement with two new Policies

06-6 Over-the-Counter Medications

06-7 Dietary Supplements

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Policy 06-6 (Revision) 06-6 Over the Counter Medications

1. With the exception of sunscreen, insect repellant, and personal hygiene cleansing products, all Over-the Counter medications (OTCs) require a Health Care Provider’s order.

a. Over-the-Counter (OTC) medications have fewer regulatory controls than prescription medications, but they may have significant medical impact especially when an individual is taking prescription medications along with OTC medications.

2. Over-the-Counter medications (OTCs) ordered by a Health Care Provider require labeling whereby a label is applied by the pharmacy as prescription medications are labeled.

a. Certified and licensed staff working at a DPH MAP Registered site may only administer Over-the-Counter (OTC) medications ordered by a Health Care Provider that are labeled by the pharmacy.

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Proposed Changes-Over-the-Counter (OTC)

Remove ‘Preparations’ from policy

Remove OTC ‘Method B’ from policy

Require that all Over-the-Counter Medications:

Have a HCP order

Have a pharmacy label

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Policy 06-7 (New) Dietary Supplements

1. All Dietary Supplements\* *(\*Congress defined the term ‘dietary supplement’ in the Dietary Supplement Health and Education Act (DSHEA) of 1994. A ‘dietary supplement’ is a product taken by mouth that contains a ‘dietary ingredient’ intended to supplement the diet. The ‘dietary ingredients’ in these products may include: vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites*) require a Health Care Provider’s order.

a. Dietary Supplements have fewer regulatory controls than prescription medications, but they may have significant medical impact especially when an individual is taking prescription and/or Over-the-Counter medications along with Dietary Supplements.

2. All Dietary Supplements require labeling whereby a label is applied by the pharmacy as prescription and Over-the-Counter medications are labeled.

a. Certified and licensed staff working at a DPH MAP Registered site may only administer Dietary Supplements that are labeled by the pharmacy.

i. If best efforts to have the Dietary Supplement labeled by the pharmacy have been exhausted, a *Dietary Supplement Labeling Exemption* may be utilized.

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Proposed Changes-Dietary Supplement

Dietary Supplement Policy will Require that all Dietary Supplements:

Have a HCP order

Have a pharmacy label

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Proposed Changes-Dietary Supplement

Dietary Supplement Labeling Exemption

May be exercised if best efforts to have the dietary supplement labeled have been exhausted

When exemption in place, a Verification Procedure by a licensed professional must be completed

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Policy 07-3 (1) (c)

The ‘pill-organizer’ must be marked with individual’s name.

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Policy 08-2 (2)

2. Unless the form(s) cataloged above is/are being photocopied, the allergy list can be formatted to assist in readily identifying the allergies, (e.g., circling the list with a red pen).

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Policy 08-5 (4)(b)(ii)(2)(a)

2. If a second staff person is not available, the medication may still be administered.

(a) A  may be used in the medication grid on the medication sheet to indicate ‘second staff person is not available’.

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Policy 08-5 Sample Warfarin Medication Sheet

CODES

* -Second Staff Not Available

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Policy 08-6 (2)(a)(ii)(1) and (4)(b)(iii) and (iv)

ii. procedures for safe administration of Clozapine, including but not limited to:

When transcribing Clozapine onto the medication sheet, the next date for the upcoming Absolute Neutrophil Count (ANC) lab draw must be indicated on the medication sheet.

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Evaluation Tool for Clozapine Therapy (5), (6), (7), (10), and (20)

5. Knows regular blood testing monitoring for the Absolute Neutrophil Count (ANC) is required for the pharmacy to dispense Clozapine.

6. Knows the pharmacy must be supplied with a current blood work (ANC count) result (drawn within 7 days, irrespective of monitoring frequency) prior to dispensing Clozapine. If lab draw date is more than 7 days old, the Clozapine cannot be dispensed by the pharmacy.

7. Knows if the ANC counts are older than 7 days (from when the Clozapine prescription is to be filled), another blood draw must be done.

10. Knows that the Health Care Provider can prescribe the Clozapine (including refills) but the pharmacist cannot dispense the Clozapine without the current acceptable ANC counts.

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Policy 08-6 Sample Clozapine Medication Sheet

**BLOODWORK**

**NEXT ANC BLOODWORK**

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Policy 08-7 (2)(a.) and (2)(a.)(i)(1.)

a. The buprenorphine/naloxone has been prescribed by a qualifying medication assisted treatment (MAT) prescriber. The pharmacist can only dispense buprenorphine/naloxone when it is prescribed by qualifying medical doctor, nurse practitioner, or physician assistant who is specially trained and registered, known as a DATA (Drug Addiction Treatment Act) 2000 waived prescriber.

 i. Assure that the MAT prescriber’s order indicates the need for administration of buprenorphine/naloxone:

 1. This should specify narcotic treatment, opioid addiction therapy or other similar term as the purpose for buprenorphine/naloxone.

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Policy 08-7

 a. The buprenorphine/naloxone has been prescribed by a qualifying medication assisted treatment (MAT) prescriber. The pharmacist can only dispense buprenorphine/naloxone when it is prescribed by qualifying medical doctor, nurse practitioner, or physician assistant who is specially trained and registered, known as a DATA (Drug Addiction Treatment Act) 2000 waived prescriber.

 i. Assure that the MAT prescriber’s order indicates the need for administration of buprenorphine/naloxone:

i. Whenever a Health Care Provider prescribes a new medication or the dosage of a previously prescribed medication is changed, the MAT prescriber who prescribed the buprenorphine/naloxone must be consulted.

1. The site must maintain documented verification that the MAT prescriber who prescribed the buprenorphine/naloxone was consulted.

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Policy 09-6 (9) (a.) (ii) and (iii)

9. The supervisor should then review the MOR and complete *Section F*.

a. To complete *Section F*, the Supervisor should review the factors involved in the occurrence.

i. A listing is provided in *Section F* of the most common factors that contribute to Medication Occurrences. The site supervisor should review the factors involved in the occurrence and select all those that apply.

ii. If no contributing factors listed on the form are involved, then ‘8’ ‘other’ should be selected.

iii. The supervisor may comment, as he/she deems necessary and appropriate in the narrative section. If other is selected, the Narrative Section must be completed.

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Policy 09-7 MOR Form

8. Other-(Narrative Required)

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Policy 09-7 MOR Form-Contact List

Contacts

DMH/DCF Area MAP Coordinators

Contact Information

DDS Regional MAP Coordinators

Contact Information

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Policy 10-1 (3) (f)

f. Agency specific medication policies (when applicable), e.g., Warfarin sodium; Dietary Supplement Labeling Exemption; Clozapine; Medications Requiring Additional Monitoring of An Individual; Buprenorphine/Naloxone, etc.;

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Policy 10-1 (4)

4. With the exception of the Agency colors chosen for posting and verifying (see Policy 13-1 *Transcription, Posting Verifying of Health Care Provider’s Orders)*, all MAP associated documentation must be done in black or blue ink. The use of a Highlighter is prohibited on all MAP associated documentation. However, the use of a Highlighter may be used on the Index page of the Countable Controlled Substance Book to designate that a medication has been removed from ‘Count’ or the row is inactive (i.e., the page has been transferred and a new count row started), and as a communication aide to the Health Care Provider for HCP related forms (e.g., HCP to sign here).

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10-2 (6) and (6) (a)

6. Each individual program should have available a back-up key that is kept in a separate locked location. The knowledge of this location shall be restricted to the agency administrative staff.

a. The position that satisfies the agency administrative staff role may vary based upon the appropriate title used by the agency/service provider.

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Policy 10-3 (1) Schedule II-V

1. Medication counts are to be conducted with two Certified and/or licensed staff whenever control of the medication key is passed.

a. DPH recognizes that there are some situations where two licensed and/or Certified staff are not available at every change of shift. In those instances, the single licensed/Certified staff person coming on or off shift/assignment must conduct a count and sign the Countable Controlled Substance Book. At the first opportunity for a two-person count, the count must be conducted.

i. Under no circumstances should a two-person count be conducted less than once every twenty-four hours.

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Policy 10-3 (3)

3. In addition to contacting the Program Supervisor and/or on-call manager, any discrepancy noted in the count should be reported to the Department of Public Health within 24 hours of discovery of the discrepancy *(see Policy No.* 10*-7 and Policy No.* 17-1*)*.

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Policy 10-4 (3)

3. The program must maintain a record of when a prescription is filled and the quantity of medication dispensed by the pharmacy. Medication dispensed by the pharmacy, for use in a DPH MAP Registered site, must be received directly from the pharmacy. Only MAP Certified or licensed staff may receive medications dispensed by the pharmacy.

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Policy 10-7 (3) (a)

a. Medication losses must be reported to the Drug Control Program (DCP) at DPH within twenty-four hours after discovery [105 CMR 700.003(F)(1)(e)].

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Policy 13-2 (2)(g)(i)

g. reason for medication being administered;

i. the reason the medication is prescribed must be obtained from and documented by the prescribing Health Care Provider (HCP). If the reason continues to be appropriate, historical Health Care Provider documentation in the individual’s medical record is acceptable as long as the reason was obtained from the HCP.

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Policy 13-5 (2)(b)

b. provide authentication of the signature such as is required by HIPAA regulations and 21 CFR Part 11.

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Policy 14-2 Epinephrine Administration via Auto-Injector Device(s)

 See forms and instructions on following pages.

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Policy 14-2 (4)(a)(iv)

iv. demonstration of the correct technique used to administer epinephrine via the pre-filled auto-injector, including the specific auto-injector that has been prescribed for the individual.

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Policy 14-2 (8)

8. Any changes, in the Health Care Provider order for epinephrine use, including a change in the type of auto-injector, require a review. This review, according to the Service Provider’s policy, must be done prior to allowing administration of epinephrine via pre-filled auto-injector device by approved staff.

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Policy 14-4 Gastrostomy/Jejunostomy Registration Form

Gastrostomy/Jejunostomy Management Form

Complete and keep in individual’s medical record

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Policy 16-2

Document to be removed from the MAP Policy Manual

‘Sealed Hospice Emergency Starter Kit Count Sheet’

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Policy 17-1 Contacts

DMH/DCF Area MAP Coordinators

Contact Information

DDS Regional MAP Coordinators

Contact Information

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Section 18 MAP Advisories

Current Advisories added to MAP Policy Manual

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New MAP Advisory Waiver Provision

**Medication Administration Program (MAP)**

**Advisory Ruling**

**Waiver Requirements-Medication Administration Program Sites**

The Department of Public Health (DPH) may waive the applicability of one or more of the MAP Policy requirements to a specific DPH MAP Registered site upon finding that:

1. Compliance would cause undue hardship to the DPH MAP Registered site;
2. That non-compliance does not jeopardize the health or safety of the individuals supported by the site; and
3. The Service Provider has instituted compensating features that are acceptable to the DPH Drug Control Program.

The Service Provider must provide the DPH Drug Control Program with sufficient written documentation to support its request for a waiver. Waiver requests should be submitted, via postal mail, to the *Drug Control Program Director* for the Department of Public Health.

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Discussion