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TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY,
DEANS – SCHOOLS AND COLLEGES OF PHARMACY

FROM: Carmen A. Catizone, Executive Director/Secretary

DATE: October 8, 2015

RE: MPJE Program Notification

In 2014, the National Association of Boards of Pharmacy® (NABP®) facilitated a review of the Multistate Pharmacy Jurisprudence Examination® (MPJE®) competency statements to ensure that the content areas represented are current and relevant to the application of pharmacy law in practice. The review resulted in modifications and additions to the content areas and these outcomes were included in a national survey of pharmacy regulators earlier this year. The survey yielded information regarding the importance of each of the content areas in practice which in turn produced weights for the MPJE blueprint.

Following the survey, NABP conducted an evaluation of the passing standard for the MPJE. The purpose of the MPJE passing standard meeting is to make a recommendation regarding the level of demonstrable performance that is necessary to pass the examination. To support the validation of a passing (cut) score recommendation and decision, standard setting meetings are held with subject matter experts who understand the purpose of the examination, the content being tested, and characteristics of the examinees. The panel that participated in the MPJE standard setting process was composed of pharmacists from a variety of backgrounds and experiences – board of pharmacy affiliates (executives, members), active practitioners, inspectors/compliance officers, board counsel, and academicians. Collectively, the panel has the requisite expertise encompassing the scope of pharmacy practice and the capacity to recommend a minimum standard for the knowledge and skills necessary for licensure.

NABP is providing the following summary of updates to the MPJE program to provide timely information to the boards of pharmacy participating in the MPJE program and to the schools and colleges of pharmacy. The implementation of the MPJE program changes will be effective April 2016.

- The MPJE will be assembled under the new (updated) competency statements and content area domain allocations (see accompanying attachment).
- The number of examination items will increase from 90 to 120. Of the 120 items, 100 will be used to produce a score for the MPJE and 20 will non-scored or pretest items. The increase in the number of questions will ensure testing across all of the content areas.

- Maximum testing time for the examination will increase from two hours to two and a half hours. The appointment time with the vendor, Pearson VUE, will be three hours to allow for time to read and agree to the confidentially/non-disclosure agreement, tutorial, and post-exam survey. To account for the additional seat time and exam development, the MPJE registration fee will increase from $210 to $250.
- A new passing standard for the MPJE will be implemented on April, 2016; however, the scaled score required to pass will remain at 75. It is typical to see variations in the pass rates after a new standard is in place.

If you have any questions regarding the updates to the MPJE program, please contact Maria Incrocci, competency assessment senior manager at [redacted].

cc: Lucinda Maine, American Association of Colleges of Pharmacy
Peter Vlasses, Accreditation Council for Pharmacy Education
NABP Executive Committee
NABP Advisory Committee on Examinations
NABP MPJE Review Committee
Carmen A. Catizone, Executive Director/Secretary

Multistate Pharmacy Jurisprudence Examination

Competency Statements
(to be implemented April 2016)

Area 1 Pharmacy Practice (83%)

1.1 Legal responsibilities of the pharmacist and other pharmacy personnel

1.1.1 Unique legal responsibilities of the pharmacist-in-charge (or equivalent), pharmacists, interns, and pharmacy owners

Responsibilities for inventory, loss and/or theft of prescription drugs, the destruction/disposal of prescription drugs and the precedence of Local, State, or Federal requirements

1.1.2 Qualifications, scope of duties, and conditions for practice relating to pharmacy technicians and all other non-pharmacist personnel

Personnel ratios, duties, tasks, roles, and functions of non-pharmacist personnel

1.2 Requirements for the acquisition and distribution of pharmaceutical products, including samples

1.2.1 Requirements and record keeping in relation to the ordering, acquiring, and maintenance of all pharmaceutical products and bulk drug substances/excipients

Legitimate suppliers, pedigrees and the maintenance of acquisition records

1.2.2 Requirements for distributing pharmaceutical products and preparations, including the content and maintenance of distribution records

Legal possession of pharmaceutical products (including drug samples), labeling, packaging, repackaging, compounding, and sales to practitioners

1.3 Legal requirements that must be observed in the issuance of a prescription/drug order

1.3.1 Prescription/order requirements for pharmaceutical products and the limitations on their respective therapeutic uses

Products, preparations, their uses and limitations applicable to all prescribed orders for both human and veterinary uses

1.3.2 Scope of authority, scope of practice, and valid registration of all practitioners who are authorized under law to prescribe, dispense, or administer pharmaceutical products, including controlled substances

Federal and State registrations, methadone programs, office-based opioid treatment programs, regulations related to retired or deceased prescribers, Internet prescribing, limits on jurisdictional prescribing

1.3.3 Conditions under which the pharmacist participates in the administration of pharmaceutical products, or in the management of patients' drug therapy

Prescriptive authority, collaborative practice, consulting, counseling, medication administration (including immunization, vaccines), ordering labs, medication therapy management, and disease state management

1.3.4 Requirements for issuing a prescription/order

Content and format for written, telephonic voice transmission, electronic facsimile, computer and Internet, during emergency conditions, and tamper-resistant prescription forms.

1.3.5 Requirements for the issuance of controlled substance prescriptions/orders

Content and format for written, telephonic voice transmission, electronic facsimile, computerized and Internet, during emergency conditions, conditions for changing a prescription, time limits for dispensing initial prescriptions/drug orders, and requirements for multiple Schedule II orders

1.3.6 Limits of a practitioner's authority to authorize refills of a pharmaceutical product, including controlled substances

1.4 Procedures necessary to properly dispense a pharmaceutical product, including controlled substances, pursuant to a prescription/drug order

1.4.1 Responsibilities for determining whether prescriptions/orders were issued for a legitimate medical purpose and within all applicable legal restrictions

Corresponding responsibility, maximum quantities, restricted distribution systems, red flags/automated alerts, controlled substances, valid patient / prescriber relationship, and due diligence to ensure validity of the order

1.4.2 Requirements for the transfer of existing prescription/order information from one pharmacist to another

1.4.3 Conditions under which a prescription/order may be filled or refilled

Emergency fills or refills, partial dispensing of a controlled substance, disaster or emergency protocol, patient identification, requirement for death with dignity, medical marijuana, and conscience /moral circumstances

1.4.4 Conditions under which prospective drug use review is conducted prior to dispensing

Patient specific therapy and requirements for patient specific documentation

1.4.5 Conditions under which product selection is permitted or mandated

Consent of the patient and/or prescriber, passing-on of cost savings, and appropriate documentation

1.4.6 Requirements for the labeling of pharmaceutical products and preparations dispensed pursuant to a prescription/order

Generic and therapeutic equivalency, formulary use, auxiliary labels, patient package inserts, FDA medication guides, and written drug information

1.4.7 Packaging requirements of pharmaceutical products, preparations, and devices to be dispensed pursuant to a prescription/order

Child-resistant and customized patient medication packaging

1.4.8 Conditions under which a pharmaceutical product, preparation, or device may not be dispensed

Adulteration, misbranding, and dating

1.4.9 Requirements for compounding pharmaceutical products

Environmental controls, release checks and testing, beyond use date (BUD), initial and ongoing training

1.4.10 Requirements for emergency kits

Supplying, maintenance, access, security, and inventory

1.4.11 Conditions regarding the return and/or reuse of pharmaceutical products, preparations, bulk drug substances/excipients, and devices

Charitable programs, cancer or other repository programs, previously dispensed, and from ""will call"" areas of pharmacies

1.4.12 Procedures and requirements for systems or processes whereby a non-pharmacist may obtain pharmaceutical products, preparations, bulk drug substances/excipients, and devices

Pyxis (vending), after hour's access, telepharmacies, and secure automated patient drug retrieval centers

1.4.13 Procedures and requirements for establishing and operating central processing and central fill pharmacies

Remote order verification

1.4.14 Requirements for reporting to PMP, accessing information in a PMP and the maintenance of security and confidentiality of information accessed in PMPs

1.4.15 Requirements when informed consent must be obtained from the patient and/or a duty to warn must be executed

Collaborative practice and investigational drug therapy

1.5 Conditions for making an offer to counsel or counseling appropriate patients, including the requirements for documentation

1.5.1 Requirements to counsel or to make an offer to counsel

1.5.2 Required documentation necessary for counseling

1.6 Requirements for the distribution and/or dispensing of non-prescription pharmaceutical products, including controlled substances

1.6.1 Requirements for the labeling of non-prescription pharmaceutical products and devices

1.6.2 Requirements for the packaging and repackaging of non-prescription pharmaceutical products and devices

1.6.3 Requirements for the distribution and/or dispensing of poisons, restricted, non-prescription pharmaceutical products, and other restricted materials or devices

Pseudoephedrine, dextromethorphan, emergency contraception, and behind the counter products as appropriate

1.7 Procedures for keeping records of information related to pharmacy practice, pharmaceutical products and patients, including requirements for protecting patient confidentiality

1.7.1 Requirements pertaining to controlled substance inventories

1.7.2 Content, maintenance, storage, and reporting requirements for records required in the operation of a pharmacy

Prescription filing systems, computer systems and backups, and prescription monitoring programs

1.7.3 Requirements for protecting patient confidentiality and confidential health records

HIPAA requirements and conditions for access and use of information

1.8 Requirements for handling hazardous materials such as described in USP <800>

1.8.1 Requirements for appropriate disposal of hazardous materials

1.8.2 Requirements for training regarding hazardous materials

Reverse distributors, quarantine procedures, comprehensive safety programs, Material Safety Data Sheets

1.8.3 Environmental controls addressing the proper storage, handling, and disposal of hazardous materials

Ventilation controls, personal protective equipment, work practices, and reporting

1.8.4 Methods for the compounding, dispensing and administration of hazardous materials

All hazardous materials including sterile and non-sterile compounding

Area 2 Licensure, Registration, Certification, and Operational Requirements (15%)

2.1 Qualifications, application procedure, necessary examinations, and internship for licensure, registration, or certification of individuals engaged in the storage, distribution, and/or dispensing of pharmaceutical products (prescription and non-prescription)

2.1.1 Requirements for special or restricted licenses, registration, authorization, or certificates

Pharmacists, pharmacist preceptors, pharmacy interns, pharmacy technicians, controlled substance registrants, and under specialty pharmacist licenses (Nuclear, Consultant etc.)

2.1.2 Standards of practice related to the practice of pharmacy

Quality assurance programs (including peer review), changing dosage forms, therapeutic substitution, error reporting, public health reporting requirements (such as notification of potential terrorist event, physical abuse, and treatment for tuberculosis), and issues of conscience and maintaining competency

2.1.3 Requirements for classifications and processes of disciplinary actions that may be taken against a registered, licensed, certified, or permitted individual

2.1.4 Requirements for reporting to, and participating in, programs addressing the inability of an individual licensed, registered, or certified by the Board to engage in the practice of pharmacy with reasonable skill and safety

Impairment caused by the use of alcohol, drugs, chemicals, or other materials, or mental, physical, or psychological conditions

2.2 Requirements and application procedure for the registration, licensure, certification, or permitting of a practice setting or business entity

2.2.1 Requirements for registration, license, certification, or permitting of a practice setting

In-state pharmacies, out-of-state pharmacies, specialty pharmacies, controlled substance registrants, wholesalers, distributors, manufacturers/repackagers, computer services providers, and internet pharmacies

2.2.2 Requirements for an inspection of a licensed, registered, certified, or permitted practice setting

2.2.3 Requirements for the renewal or reinstatement of a license, registration, certificate, or permit of a practice setting

2.2.4 Classifications and processes of disciplinary actions that may be taken against a registered, licensed, certified, or permitted practice setting

2.3 Operational requirements for a registered, licensed, certified, or permitted practice setting

2.3.1 Requirements for the operation of a pharmacy or practice setting that is not directly related to the dispensing of pharmaceutical products

Issues related to space, equipment, advertising and signage, security (including temporary absences of the pharmacist), policies and procedures, libraries and references (including veterinary), and the display of licenses

2.3.2 Requirements for the possession, storage, and handling of pharmaceutical products, preparations, bulk drug substances/excipients, and devices, including controlled substances

Investigational new drugs, repackaged or resold drugs, sample pharmaceuticals, recalls, and outdated pharmaceutical products

2.3.3 Requirements for delivery of pharmaceutical products, preparations, bulk drug substances/excipients, and devices, including controlled substances

Issues related to identification of the person accepting delivery of a drug, use of the mail, contract delivery, use of couriers, use of pharmacy employees, use of kiosks, secure mail boxes, script centers, use of vacuum tubes, and use of drive-up windows

Area 3 General Regulatory Processes (2%)

3.1 Application of regulations

3.1.1 Laws and rules that regulate or affect the manufacture, storage, distribution, and dispensing of pharmaceutical products, preparations, bulk drug substances/excipients, and devices, (prescription and non-prescription), including controlled substances

Food, Drug, and Cosmetic Act(s) and Regulations, the Controlled Substances Act(s) and Regulations, OBRA 90's Title IV Requirements, Practice Acts and Rules, other statutes and regulations, including but not limited to, dispensing of methadone, child-resistant packaging, tamper resistant packaging, drug paraphernalia, drug samples, pharmacist responsibilities in Medicare-certified skilled-nursing facilities, NDC numbers, and schedules of controlled substances