MPJE Federal-Core Reference Study Sheet

Controlled substances & DEA · FDA & labeling · OBRA '90 · HIPAA · USP compounding

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SCOPE OF THIS SHEET

Federal law only — the shared core every jurisdiction's MPJE draws on; state statutes and board rules are covered in each state's own program. Administered by the National Association of Boards of Pharmacy (NABP) at Pearson VUE: 120 questions (100 scored + 20 pretest), 2.5 hours, reported pass/fail. Passing standards are set by each jurisdiction — no single score applies, so none is printed here.

CONTROLLED SUBSTANCES & DEA

Topic	Federal rule
Schedules	five; Schedule I: no accepted medical use; Schedule II: highest abuse potential with a medical use
Schedule II refills	none, ever; a prescriber may issue several prescriptions at once covering up to a 90-day supply, each with a "do not fill until" date; an emergency oral authorization requires the written/electronic prescription within 7 days, and DEA is notified if it never arrives
Schedule III / IV refills	up to 5 refills within 6 months; Schedule V as authorized
Schedule II partial fills	stock short: remainder within 72 hours or the balance is void, prescriber notified · terminal illness / long-term care: partial fills over 60 days
Transfers	Schedule III–V may transfer, pharmacist-to-pharmacist; Schedule II never
Schedule II changes	after consulting the prescriber: date, dosage form, strength, quantity, directions · never: patient name, drug name, prescriber signature
Valid prescription elements	patient name/address, date, drug name/strength, dosage form, quantity, directions, prescriber name/address/signature; DEA number for controlled substances; a faxed Schedule II is not the original, except LTC, hospice, and home-infusion patients

Topic	Federal rule
Corresponding responsibility	valid only if issued for a legitimate medical purpose in the usual course of practice; pharmacist shares responsibility
DEA pharmacy registration	renewed every 3 years; DEA may deny or revoke; a power of attorney may authorize CSOS / order-form signers, revocable in writing
Ordering	Schedule II via Form 222 or CSOS; III–V on invoices; EPCS permitted with two-factor authentication
Inventory	initial inventory when controlled-substance activity begins; biennial within 2 years of the previous; Schedule II exact count; III–V estimated unless a container holds over 1,000 units
Records	kept at least 2 years (federal floor); Schedule II records separate; III–V separate or readily retrievable
Theft / significant loss	DEA notified in writing within one business day of discovery; Form 106 completed; breakage/spillage documented in pharmacy records, not on Form 106
Disposal	Form 41 for registrant disposal; reverse distributors and take-back collectors are routes; on-site destruction must render product non-retrievable

FDA, LABELING & COMPOUNDING

Topic	Federal rule
Adulterated drug	contaminated or decomposed, prepared under insanitary conditions, or strength/quality differing from compendial standards
Misbranded drug	false or misleading labeling, missing required label information, or (OTC) no adequate directions for use
Generic substitution	an FDA-approved generic equivalent may be dispensed unless the prescriber prohibits it (DAW); an AB rating in the Orange Book means therapeutically equivalent
Child-resistant packaging (PPPA)	most oral prescriptions in child-resistant containers unless the patient or prescriber requests otherwise; exceptions include nitroglycerin and oral contraceptives in mnemonic packs

Recall classes	Class I: reasonable probability of serious harm or death · Class II: temporary or reversible harm · Class III: harm unlikely; recalled stock is quarantined, never dispensed
Section 503A compounding	patient-specific prescriptions only, no office-use supply; state-board regulated; limited anticipatory compounding permitted from a history of valid prescriptions; copies of commercial drugs prohibited absent a documented clinical difference or shortage listing
Section 503B outsourcing facilities	FDA-registered and CGMP-compliant; may supply office stock without patient-specific prescriptions
USP <795> beyond-use dates (defaults)	non-preserved aqueous: 14 days refrigerated · preserved aqueous: 35 days · non-aqueous liquids: 90 days · solids: 180 days
USP <797> categories	Category 1: ISO 5 primary engineering control in a segregated compounding area; beyond-use limits 12 hours room temperature, 24 hours refrigerated · Category 2: cleanroom suite, longer beyond-use dates
USP <800> hazardous drugs	NIOSH list identifies hazardous drugs; containment controls, closed-system transfer devices, PPE, deactivation/decontamination

OBRA '90, HIPAA & FEDERAL AUTHORITY

Topic	Federal rule
Prospective DUR	before dispensing; screens duplication, interactions, incorrect dosage/duration, allergy, abuse/misuse, age/gender contraindications; the patient profile holds name, address, DOB/age, gender, medication history, allergies, conditions
Counseling offer & content	for Medicaid patients, an offer to counsel is federally required; counseling or refusal is documented; content: drug name/description, form/route, duration, special directions, precautions, side effects, storage, refill information, missed-dose action; only the pharmacist (or a supervised intern) may counsel — technicians may offer it but may not counsel
Adverse-event reporting	drug adverse events via FDA MedWatch (Form 3500); vaccine adverse events via VAERS
Permitted uses of PHI	treatment, payment, and health care operations without patient authorization; most other uses require written authorization; patients may access/copy records and request amendments, an accounting of disclosures, and restrictions; the minimum-necessary standard applies to payment and operations, not to treatment
Safeguards & breaches	administrative, physical, and technical safeguards (access controls, encryption); incidental disclosures permitted with reasonable safeguards; on a breach, affected individuals notified generally within 60 days of discovery and HHS notified
Federal vs. state authority	DEA registration is federal; pharmacy permits, pharmacist licenses, and technician registration come from the state board of pharmacy

WHAT THIS SHEET DOESN'T COVER

- Your jurisdiction's law: state statutes, board rules, and state-specific dispensing requirements — roughly half of every MPJE is jurisdiction law, covered in the state program.
- Blueprint-weighted scenario application: pharmacy-practice situations, not just reference facts.
- Timed, full-length exam simulation.
- An explanation for every answer — why the right answers are right and the wrong ones are wrong.
- A fresh set of questions on every attempt, so practice never repeats itself.

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Federal facts are those used across the PassProfessor MPJE question banks' verified explanations (shared federal core, dual-tagged to the current Competency Statements and the March 1, 2027 Content Outline).