PHARM TECH BASICS · ONE-PAGER

Poison Prevention Packaging Act: Child-Resistant Containers

The 1970 Act and CPSC rules, how a package passes, when a non-child-resistant container is allowed, exempt drugs, inpatients, reuse and OTC packaging

14 sources + more detail
pharmtechbasics.com/sheets/pharm-pppa-packaging.html
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1 The law in brief

POINT	RULE
Law	Poison Prevention Packaging Act (PPPA), signed December 30, 1970
Agency	Consumer Product Safety Commission (CPSC) since 1973; FDA before that
Regulations	16 CFR part 1700; the list of products is 16 CFR 1700.14
Goal	Packaging that is significantly difficult for children under 5 to open, and not difficult for adults to use
Covers	Almost every oral prescription drug; every oral controlled substance, OTC included; listed OTC products (aspirin, acetaminophen over 1 g, iron 250 mg or more, and others)
Responsible at the counter	The dispensing pharmacist; the technician who fills the vial follows the same rule

EXAM TIP Child-resistant, not childproof: the law's definition does not require that every child be kept out, and a passing package may still be opened by up to 20% of test children.

2 How a package passes

TEST	WHO AND HOW	PASS MARK
Child test	Children 42–51 months old, in pairs: 5 minutes, one demonstration, 5 more minutes	At least 85% cannot open it before the demonstration, 80% after
Unit dose (blister)	Same children; a failure is more than 8 units or a harmful amount, whichever is lower	At least 80% kept out
Senior adult test	100 adults aged 50–70: open and close it in 5 minutes, then again in 1 minute	At least 90% succeed
Younger adult test	Adults 18–45; only for aerosols and products that need metal containers	At least 90% succeed

3 When a non-child-resistant container is allowed

WHO ASKS	WHAT IT COVERS
Prescriber, on the prescription	That prescription and its refills only
Patient, for one prescription	That prescription only; not a standing request
Patient, for all prescriptions (blanket request)	Every prescription until the patient changes it; get it in writing and record it in the profile
Pharmacist or technician, on their own	Never: you may tell the patient the option exists, but the choice is the patient's

EXAM TIP Only the patient can make a blanket request. A prescriber's request covers one prescription and its refills; a new prescription goes back into a child-resistant vial.

SAFETY Before using an easy-open cap, check the profile for a recorded request. Federal law does not demand a written request, but CPSC staff recommend one, and your pharmacy or state board of pharmacy may require a signature.

4 Exempt prescription drugs (examples)

- Sublingual nitroglycerin (fast access in chest pain; keep it in its original glass bottle)
- Sublingual and chewable isosorbide dinitrate, 10 mg or less
- Oral contraceptives in the maker's memory-aid packs; estrogen- or progestogen-only hormone therapy; medroxyprogesterone tablets
- Methylprednisolone tablets, 84 mg or less per package; prednisone tablets, 105 mg or less
- Unit-dose potassium supplements, 50 mEq or less per unit
- Cholestyramine and colestipol powders, pancrelipase, erythromycin ethylsuccinate within package limits

SAFETY An exemption has limits. A 21-tablet pack of methylprednisolone 4 mg (84 mg) is exempt; a bottle of 30 tablets (120 mg) is not.

5 Settings and containers

SITUATION	CHILD-RESISTANT NEEDED?
Hospital inpatient, doses given by staff	No
Traditional nursing home, staff give the doses	No
Discharge or outpatient prescription; assisted living where residents keep their drugs	Yes: the test is whether the package will go into a home
Mail order	Yes: the vial inside the mailer must be child-resistant
Refill in the patient's old plastic vial	No reuse: wear weakens the closure
Glass container	CPSC staff do not object to reuse with a new closure
Vial from one maker, cap from another	Avoid: they may not work together

6 Exam pearls

EXAM TIP Agency: CPSC. Age protected: under 5. Classic exemption: sublingual nitroglycerin. Blanket waiver: patient only. Inpatients: exempt; discharge prescriptions: not. Plastic vials: never reused. OTC makers may sell one non-child-resistant size labeled 'This Package for Households Without Young Children'; prescription drugs have no such size.

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