



Plan B OTC: What will it look like?

On August 24, 2006, the Food and Drug Administration (FDA) announced it would allow over the counter (OTC) access to Plan B® emergency contraceptive pills for adults aged 18 and older. Women under the age of 18 will still have access to Plan B, with a prescription (Rx). What will change, on a practical level, for a woman in need of Plan B? Here are some answers we have found so far.

Where will Plan B OTC be sold?

Consumers will need to request Plan B at the pharmacy counter. Because Plan B has a “dual label” – it is OTC for consumers 18 and older but available by Rx only to those under 18 – it will be available only in retail outlets that have a pharmacy with licensed professionals. It will not be available in places that do not have a licensed prescriber or pharmacist on site – such as gas stations or convenience stores – nor is it likely to be available for purchase if a licensed pharmacist is off duty.

Will Plan B OTC be available in clinics?

Yes. Assuming they have a system in place for confirming age, health care clinics will be able to distribute Plan B OTC to women and men 18 and older. In addition, they will be able to continue to dispense Plan B to anyone who needs a prescription.

Will pharmacist technicians be able to dispense Plan B?

Individual pharmacies will have systems in place to confirm the age of Plan B customers. The FDA requires that a health care professional must be available to answer questions if needed, but anyone behind the pharmacy counter will be able to dispense Plan B OTC after seeing proof of age.

What kind of proof of age will be required for consumers 18 and older to purchase Plan B?

The FDA has not issued specific guidelines for proof of age. However, the Drug Enforcement Administration, which has recently introduced federal limits on the sale of cold medicines containing pseudoephedrine to adults 18 and older, has recently published a list of acceptable forms of ID to purchase that product. Pharmacies may decide to follow the same guidelines for proof of age to purchase Plan B OTC. (For the complete DEA list, please see the end of this document.)

How will the age restriction be monitored and enforced?

As part of its agreement with the FDA, Barr will conduct point of purchase monitoring at individual pharmacies; clinics and doctor offices will not be subject to this point of purchase monitoring. If a pharmacist sells Plan B to someone under the age of 18, Barr will “increase its educational efforts regarding the age restriction and focus on improving the level of understanding among pharmacists and pharmacy staff.” A second infraction will result in the pharmacist being reported to the State Board of Pharmacy.

Aside from the age restriction, has the FDA placed any other restrictions on the OTC sale of this product?

Barr has agreed to monitor public data for unwanted public health outcomes related to Plan B OTC sales. Furthermore, Barr has agreed to conduct a point of purchase monitoring program, to ensure that women under the age of 18 are not able to purchase Plan B OTC. Barr will report to the FDA on their findings twice a year.

Will men be able to buy Plan B?

Yes. The FDA approved OTC access for all *consumers* 18 and older. A man 18 years old or older intending to purchase Plan B will also have to request it from a pharmacy staffer or clinician and show proof of age.

When do we expect to see Plan B in stores, ready for purchase without a prescription?

Duramed, the subsidiary of Barr Laboratories that distributes Plan B expects to ship the new packages in early November. Qualified consumers should be able to purchase an OTC package of Plan B before the end of the month.

How much will Plan B cost OTC? Will insurance still cover Plan B for women (of any age) who have a prescription? Will Medicaid cover it?

These questions are still largely unknown. Barr has announced a tentative wholesale price of \$27. Individual insurance companies will determine their own policies for coverage. Additionally, because Medicaid policies differ in each individual state, there won't be one answer to this question. Right now, Medicaid covers no OTC product in approximately one third of states; some OTC products in one third of states, and several OTC products in the other third. However, many states with Medicaid coverage for OTC products require prescriptions for the OTC products. A group of advocacy organizations are working together to tackle this and other access issues for low-income women.

Can state governments attempt to further restrict OTC access to Plan B?

According to the Guttmacher Institute, it is possible, but it will be a challenge. While some states have enacted legislation restricting the sale of certain OTC products that are addictive or for which there is evidence of widespread misuse among consumers (including ephedra and pseudoephedrine), most states do not have policies that allow state agencies to regulate OTC products. Most states prohibit pharmacy boards and pharmacists from interfering with the sale of OTC products, and most states have laws

prohibiting agencies from adding non-narcotic OTC products to lists of controlled substances.

There are exceptions—some state agencies are able to ban or otherwise regulate non-narcotic OTC products that endanger public health or if a pattern of abuse develops. However, attempts to classify Plan B as dangerous or subject to abuse would go against both scientific literature and FDA findings, and any moves to do so would be strongly opposed by consumer product groups, who are against regulation of OTC products.

How will this decision affect collaborative practice agreements?

The FDA's decision has no bearing on collaborative practice agreements which allow health care providers to authorize pharmacists to dispense Plan B in nine states: Alaska, California, Hawaii, Maine, Massachusetts, New Hampshire, New Mexico, Vermont, and Washington. Women under the age of 18 will still be able to access Plan B directly from a pharmacist in these nine states. In Hawaii, those under 14 need parental consent to get Plan B through a pharmacist.

DEA approved proof of age for pseudoephedrine purchases:

An individual must present an identification card that includes a photograph and is issued by a State or the Federal government or a document considered acceptable under 8 CFR

274a.2(b)(1)(v)(A) and (B). Those documents currently include the following:

- United States passport (unexpired or expired).
- Alien Registration Receipt Card or Permanent Resident Card, Form I-551.
- An unexpired foreign passport that contains a temporary I-551 stamp.
- An unexpired Employment Authorization Document issued by the Immigration And Naturalization Service which contains a photograph, Form I-766; Form I-688, Form I-688A, or Form I-688B.
- In the case of a nonimmigrant alien authorized to work for a specific employer incident to status, an unexpired foreign passport with an Arrival-Departure Record, Form I-94, bearing the same name as the passport and containing an endorsement of the alien's nonimmigrant status, so long as the period of endorsement has not yet expired and the 14 proposed employment is not in conflict with any restrictions or limitations identified on the Form I-94.

For individuals 16 years of age or older:

- A driver's license or identification card containing a photograph, issued by a State or an outlying possession of the United States. If the driver's license or identification card does not contain a photograph, identifying information shall be included such as: name, date of birth, sex, height, color of eyes, and address.
- School identification card with a photograph.
- Voter's registration card.
- U.S. military card or draft record.

- Identification card issued by Federal, State, or local government agencies or entities. If the identification card does not contain a photograph, identifying information shall be included such as: name, date of birth, sex, height, color of eyes, and address.
- Military dependent's identification card.
- Native American tribal documents.
- United States Coast Guard Merchant Mariner Card.
- Driver's license issued by a Canadian government authority.