



What's Next for Emergency Contraception? How Policymakers Can Improve Women's Access to Emergency Contraception

Emergency contraception (EC) holds tremendous potential for reducing the number of unintended pregnancies. Since the FDA first approved the emergency contraceptive Plan B® in 1999, there has been a tenuous path toward improved access:¹

- In 2006, after stalling for more than three years, the FDA approved Plan B® for over-the-counter (OTC) sales for individuals ages 18 and older.² While the medication was available to some without a prescription, because of the age restriction, it was kept behind the pharmacy counter which affected all purchasers.
- In April 2009, the FDA announced that it would comply with a federal court ruling calling for the agency to allow 17-year-olds to have OTC access to EC and to reconsider its policy on age restrictions.³
- In June 2009, the FDA approved Next Choice®, the first-ever generic version of Plan B®, for prescription use for individuals ages 17 and under.⁴ Two months later, the FDA approved the generic medication for over-the-counter use for individuals 17 and over.⁵
- In 2010, the FDA approved the emergency contraceptive ella® for use in the United States. Available only by prescription, ella® is safe and effective for use up to five days (120 hours) after sex.⁶
- In 2011, Teva, the manufacturer of Plan B® and the one-dose version, Plan B One-Step®, filed an application with the FDA requesting that the contraceptives be made available OTC for women of all ages.⁷
- Unfortunately, in December 2011, in response to Teva's application the Department of Health and Human Services (HHS) overruled a recommendation from the FDA to eliminate the age restriction on over-the-counter access to emergency contraceptives Plan B® and Plan B One-Step®.⁸
- In February 2012, the 2005 case against the FDA for imposing unnecessary age restrictions on EC was reopened and HHS then-Secretary Kathleen Sebelius was added as a defendant.⁹
- In July 2012, the FDA approved Next Choice ONE DOSE™, a generic version of Plan B One-Step®.¹⁰
- In April 2013, a federal judge ruled that HHS and FDA must lift all age or point-of-sale restrictions placed on levonorgestrel-based EC and make the medication available OTC. The judge added that Secretary Sebelius' decision to overrule the FDA's recommendation was "politically motivated, scientifically unjustified, and contrary to agency precedent."¹¹

- Also in April 2013, HHS announced that it had approved an amended application from Teva thereby lowering the age restriction on this particular type of EC to those younger than 15. The medication would be allowed to be on the shelf, but would include a “proof of age” requirement to be triggered at the cash register. Additionally, the medication would only be sold on the shelf at stores that include a retail pharmacy.¹²
- The very next day, the Department of Justice (DOJ) filed an appeal to challenge the court decision.¹³ The judge in the case refused to grant DOJ a stay, stating that the appeal “is frivolous and is taken for the purpose of delay.” However, he did allow DOJ to seek a stay from the court of appeals before the order went into effect.¹⁴ DOJ appealed the decision and a federal appeals court temporarily granted a stay.¹⁵
- Before a decision was handed down, however, the Obama administration agreed to drop its appeal to the federal court judge’s ruling that all age restrictions on EC be lifted. With that decision, Teva and the FDA reached a compromise that Plan B One-Step® would be available OTC without an age restriction. However, an age restriction for those 16 and younger remained in place for all other brands of EC.
- Several months later, the FDA announced its intention to remove age restrictions on generic EC, but also announced that the labels for the medication would continue to state they were intended only for women ages 17 and older – leading to significant confusion on the part of pharmacists and customers.¹⁶
- On April 30, 2016, Teva’s market exclusivity – a market protection that allowed it to be the only brand of EC available on the shelves – expired, allowing all generics to also be available on the shelves, to any person regardless of age or point-of-sale restriction.¹⁷

Emergency Contraception Availability¹⁸

Product	Product Placement	Age Restriction
Plan B One-Step and generic Take Action	OTC - on shelves	No age restriction. No ID check required.
Other generic one-pill Levonorgestrel EC product(s)	OTC - on shelves	No age restriction. No ID check required.
ellaOne	Prescription only - behind pharmacy counter	Prescription-only for all ages.

As of November 2016

Emergency Contraception and the Affordable Care Act

Additionally, under the Affordable Care Act (ACA), all health plans must cover EC (among all FDA-approved contraception) without a copay or deductible.¹⁹ The administration has explicitly exempted religious houses of worship. Religiously affiliated non-profit employers and closely held, for-profit companies are eligible for an accommodation, which allows them to

register their objection to providing contraceptive coverage; in these cases, the benefit is delivered directly to employees through the insurance company or third-party administrator.

Strategies for Improving Access to Emergency Contraception¹

These decisions are a big step forward for women's reproductive health and privacy – but in order to realize emergency contraception's full potential to prevent unintended pregnancy, policymakers need to take several additional steps:

1. **Educate Women and Doctors About EC** - Even though EC is available now without a prescription, a major hurdle remains to its use: too few women (and even doctors!) know what it is, how it works, and how to use it correctly. The **21st Century Women's Health Act** (S.674) would fund public-education campaigns to inform women and health-care professionals that EC is available, safe, and effective at preventing pregnancy.²⁰ Similarly, states can fund outreach programs to doctors, pharmacists, and women to increase their awareness about this underutilized medication.
2. **Protect Women From Pharmacists Who Oppose Birth Control** - Since some women still have to obtain EC directly from a pharmacy, it's as important as ever to ensure that rogue pharmacists aren't allowed to stand between women and their medications. Additionally, under the ACA, health-care plans must cover all FDA-approved contraceptives, including EC. That's why Congress must pass the **Access to Birth Control Act** S.2625/H.R.728 (last introduced in the 113th Congress) – a bill that would ensure that a woman receives EC and other forms of birth control without harassment, lectures, or delay.²¹ And if Congress fails to act, state legislatures and governors should take the lead by implementing a statewide policy that requires pharmacies to provide women with the birth-control medication they need, as has been done in states across the country.²²
3. **Inform Rape Survivors About EC** - Each year, thousands of women in the United States become pregnant as a result of sexual assault – but unbelievably, many hospitals fail (or refuse) to discuss emergency contraception with patients. Even though the medication is now available without a prescription, it is crucial that hospitals inform patients about EC – otherwise, women may not know about it, or won't be able to get it in time. Policymakers can, and should support legislation to improve this situation. The **21st Century Women's Health Act** (S.674) (introduced in the 114th Congress), the **Emergency Contraception Access and Education Act** in the Senate (S.2876) and the **Compassionate Assistance for Rape Emergencies Act** in the House (last introduced in the 112th Congress as H.R.1724) would ensure that, among other things, sexual-assault

¹ In addition to this list of suggested policy actions, lawmakers also can improve U.S. servicewomen's access to EC. For information on that issue, please see the related fact sheet, *Support U.S. Servicewomen's Access to Emergency Contraception*.

survivors learn about EC in hospital emergency rooms and are provided the medication upon request.²³ If Congress refuses to act, state “EC in the ER” laws can accomplish the same goal. To date, 17 states and the District of Columbia already have taken action to make EC or information about the medication available in hospital emergency rooms.²⁴

4. Insurance Coverage of EC –

- Under the Affordable Care Act, all health plans must cover EC without a copay or deductible.²⁵ In 2011, as part of its implementation of Section 2713(a)(4) of the health-care law, which requires health plans to cover—at no cost—certain preventive-health services that are specific to women, HHS appointed an Institute of Medicine (IOM) panel to recommend which services should be defined as preventive care. The IOM panel recommended that the full range of FDA-approved contraceptive methods, including EC, be covered.²⁶ In August 2011, HHS adopted this recommendation in full.²⁷ In August 2012, all newly issued health plans were required to cover the full range of FDA-approved methods of contraception, including EC. The policy explicitly exempts religious houses of worship. Religiously affiliated non-profit employers and closely held, for-profit companies are eligible for an accommodation, which allows them to register their objection to providing contraceptive coverage; in those cases, then the benefit is delivered directly to employees through the insurance company or third party administrator.

Ensure Medicaid Coverage of Emergency Contraception

- While the FDA’s approval of generic EC and over-the-counter sale of EC marked significant steps forward in advancing women’s access to contraception, the medication’s retail cost is too expensive for many women. In many states, women eligible for Medicaid need to obtain a prescription in order to have the cost of the medication covered. Because EC is effective only if used within a very brief time period, going to a physician to obtain a prescription for the medication hinders timely access to the medication. Accordingly, state efforts to provide Medicaid coverage of EC without a prescription are critical to ensuring access to the medication.
- Medicaid coverage of EC is particularly important for women of color, who disproportionately work in low-wage jobs that do not offer benefits²⁸ and therefore turn at higher rates to public programs such as Medicaid to access affordable health care.

January 1, 2017

Notes:

- ¹ Press Release, Women’s Capital Corporation, *A New Generation of Emergency Contraception Has Arrived* (July 28, 1999).
- ² Press Release, Barr Pharmaceuticals, Inc., *FDA Grants OTC Status to Barr’s Plan B® Emergency Contraceptive* (Aug. 26, 2006); Press Release, U.S. Food and Drug Administration, *FDA Approves Over-the-Counter Access for Plan B for Women 18 and Older, Prescription Remains Required for Those 17 and Under* (Aug. 24, 2006).
- ³ Press Release, Reproductive Health Technologies Project, *FDA revises restriction on over-the-counter access to Plan B emergency contraception to women 17 and over* (Apr. 22, 2009).
- ⁴ Press Release, Food and Drug Administration, *FDA Approves Generic Prescription-Only Version of Plan B Emergency Contraception for Women Ages 17 and Under* (Jun. 24, 2009) at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm168870.htm> (last Dec. 11, 2015).
- ⁵ Emergency Contraception: A Guide for Pharmacies and Retailers (October 2014), at http://americansocietyforec.org/uploads/3/2/7/0/3270267/pharmacy_ec_access_overview.pdf (last visited Dec. 11, 2015).
- ⁶ Press Release, Food and Drug Administration, *FDA approves ella™ tablets for prescription emergency contraception* (Aug. 13, 2010) at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm222428.htm> (last visited Dec. 11, 2015).
- ⁷ Center for Reproductive Rights, *The Center Takes the FDA Back to Court*, at <http://reproductiverights.org/en/feature/the-center-takes-the-fda-back-to-court> (last visited Dec. 11, 2015).
- ⁸ Press Release, U.S. Department of Health and Human Services, *A Statement by U.S. Department of Health and Human Services Secretary Kathleen Sebelius* (Dec. 7, 2011) at <http://wayback.archive-it.org/3926/20140108161943/http://www.hhs.gov/news/press/2011pres/12/20111207a.html> (last visited Dec. 11, 2015).
- ⁹ Press Release, Center for Reproductive Rights, *The Center Takes the FDA Back to Court*, at <http://reproductiverights.org/en/feature/the-center-takes-the-fda-back-to-court> (last visited Dec. 11, 2015).
- ¹⁰ PR Newswire, *Watson’s Generic Version of Plan B One-Step® Receives FDA Approval* (July 2012) at [http://www.prnewswire.com/news-releases-test/watsons-generic-version-of-plan-b-one-step-receives-fda-approval-162337006.html](http://www.prnewswire.com/news-releases/test/watsons-generic-version-of-plan-b-one-step-receives-fda-approval-162337006.html) (last visited Dec. 11, 2015).
- ¹¹ Press Release, Center for Reproductive Rights, *Federal Judge Orders FDA to Broaden Access to Emergency Contraception* (Apr. 5, 2013) at <http://reproductiverights.org/en/press-room/federal-judge-orders-fda-to-broaden-access-to-emergency-contraception> (last visited Dec. 11, 2015).
- ¹² Press Release, U.S. Food and Drug Administration, *FDA Approves Plan B One-Step Emergency Contraceptive Without a Prescription for Women 15 Years of Age and Older* (Apr. 30, 2013) at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm350230.htm> (last visited Dec. 11, 2015).
- ¹³ Pam Belluck & Michael Shear, *U.S. to Defend Age Limits on Morning-After Pill Sales*, N.Y. TIMES, May 1, 2013, at http://www.nytimes.com/2013/05/02/health/us-will-appeal-order-on-morning-after-pill.html?_r=0 (last visited Dec. 11, 2015). Reid Epstein, *President Obama Defends Plan B Appeal*, POLITICO, May 2, 2013, at <http://www.politico.com/story/2013/05/obama-plan-b-90877.html> (last visited Dec. 11, 2015).
- ¹⁴ *Tummino v. Hamburg*, 12-CV-763 (E.D.N.Y. May 10, 2013).
- ¹⁵ Larry Neumeister, *Judge in NYC Refuses to Suspend His Plan B Ruling*, HUFFINGTON POST, May 10, 2013, at http://www.huffingtonpost.com/huff-wires/20130510/us-morning-after-pill/?utm_hp_ref=arts&ir=arts (last visited Dec. 11, 2015).
- ¹⁶ Kaiser Family Foundation, *Emergency Contraception* (Oct. 2014) at <http://kff.org/womens-health-policy/fact-sheet/emergency-contraception/> (last visited Nov. 2, 2015); Letter to NDA/ANDA Applicant – Reference ID 3460250,

Food and Drug Administration (Feb. 25, 2014) at <http://www.hpm.com/pdf/blog/PLAN%20B%20-%20FDA%20Exclusivity%20&%20Carve-Out%20Determination.pdf> (last visited Nov. 2, 2015).

¹⁷ Frequently Asked Questions: Emergency Contraception and Age Restrictions, Reproductive Health Technologies Project at <http://www.rhtp.org/contraception/emergency/documents/FrequentlyAskedQuestions-EmergencyContraceptionandAgeRestrictions.pdf> (last visited May 10, 2016).

¹⁸ Emergency Contraception: A Guide for Pharmacies and Retailers (October 2014), at http://americansocietyforec.org/uploads/3/2/7/0/3270267/pharmacy_ec_access_overview.pdf (last visited Dec. 11, 2015).

¹⁹ P.L. 111-148, 111th Cong. (2010) § 2713(a)(4).

²⁰ 21st Century Women's Health Act of 2015, S.674, 114th Cong. (2015).

²¹ Access to Birth Control Act, H.R.728, 113th Cong. (2013); S.333, 113th Cong. (2013).

²² Guttmacher Institute, *State Policies in Brief: Emergency Contraception* (December 2015), available at http://www.guttmacher.org/pubs/spib_EC.pdf (last visited Nov. 20, 2015).

²³ 21st Century Women's Health Act of 2015, S.674, 114th Cong. (2015); Compassionate Assistance for Rape Emergencies Act of 2011, H.R.1724, 112th Cong. (2011).

²⁴ NARAL Pro-Choice America & NARAL Pro-Choice America Foundation, *Who Decides? The Status of Women's Reproductive Rights in the United States* (24th ed. 2015), available at www.WhoDecides.org.

²⁵ P.L. 111-148, 111th Cong. (2010) § 2713(a)(4).

²⁶ INSTITUTE OF MEDICINE, CLINICAL PREVENTIVE SERVICES FOR WOMEN: CLOSING THE GAPS (2011).

²⁷ Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 76 Fed. Reg. 149 (proposed August 3, 2011) (to be codified at 45 C.F.R. pt. 147).

²⁸ Kaiser Family Found., *Racial and Ethnic Disparities in Women's Health Coverage and Access to Care: Findings from the 2001 Kaiser Women's Health Survey 2* (Mar. 2004), at http://mhrc.dopm.uab.edu/resources_new/Racial-disparities-in-Women.pdf (last visited Dec. 11, 2015).