

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 518
(A-22)

Introduced by: American College of Obstetricians and Gynecologists

Subject: Over-the-Counter Access to Oral Contraceptives

Referred to: Reference Committee E

1 Whereas, The benefits of contraception, named as one of the 10 great public health
2 achievements of the 20th century by the Centers for Disease Control and Prevention, are widely
3 recognized and include improved health and well-being, reduced global maternal mortality,
4 health benefits of pregnancy spacing for maternal and child health, female engagement in the
5 work force, and economic self-sufficiency;¹ and
6

7 Whereas, Contraception can be lifesaving for people with serious medical conditions like heart
8 disease, cancer or diabetes for whom an unplanned pregnancy can worsen preexisting health
9 conditions; and
10

11 Whereas, Oral contraceptives can have important non-contraceptive benefits, including
12 decreasing risk of endometrial and ovarian cancer, treating heavy menstrual bleeding and
13 dysmenorrhea, and reducing pelvic pain due to endometriosis;² and
14

15 Whereas, Barriers to access are one reason for inconsistent or nonuse of contraception and
16 the requirement for a prescription can be an obstacle for some contraceptive users; and
17

18 Whereas, A national survey of 1,385 women reported that among the 68% of individuals who
19 had ever tried to obtain a prescription for hormonal contraception, 29% had problems
20 accessing the initial prescription or refills, reporting obstacles including challenges in obtaining
21 an appointment or getting to a clinic, the health care provider requiring a clinic visit,
22 examination, or Pap test, and not having a regular physician or clinic;³ and
23

24 Whereas, Surveys repeatedly have demonstrated interest among adolescents and adult
25 women in over-the-counter access to oral contraceptives,⁴⁻⁶ including a 2011 national survey
26 about views on over-the-counter oral contraceptives,⁷ a nationally representative, cross-
27 sectional online survey of approximately 2,500 females (aged 15–44 years),⁸ and focus group
28 data from adolescent females and adult women;⁹⁻¹⁰ and
29

30 Whereas, Progestin-only emergency contraception (EC) is already available without a
31 prescription for people of all ages in the United States; and
32

33 Whereas, Pelvic and breast examinations, cervical cancer screening, and sexually transmitted
34 infection screening are not required before initiating hormonal contraception;¹¹⁻¹⁴ and
35

36 Whereas, Studies have shown that women can accurately use checklists to determine if they
37 have contraindications to hormonal contraception; in one study, 96% of cases evaluated
38 demonstrated agreement between a women's assessment of her contraindications using a
39 checklist and a clinician's independent evaluation, and women often take a more conservative
40 approach compared with clinicians;¹⁵⁻¹⁶ and

1 Whereas, Data support that progestin-only hormonal methods are generally safe and carry no
2 or minimal risk of venous thromboembolism (VTE);¹⁷ and

3
4 Whereas, The VTE risk with combined oral contraceptive use is small compared with the
5 increased risk of VTE during pregnancy and the postpartum period;¹⁸ and

6
7 Whereas, Oral contraceptive pills are safe and effective for adolescent users, there is no
8 scientific rationale for limiting access to a future over-the-counter oral contraceptive product by
9 age, and over-the-counter access to hormonal contraception has the potential to reduce barriers
10 and increase hormonal contraceptive use for adolescents;¹⁹ and

11
12 Whereas, An Oral Contraceptives Over-the-Counter Working Group was formed in 2004 with
13 the aims “to improve access to contraception and reduce disparities in reproductive health
14 outcomes by making a low-cost oral contraceptive product available OTC in the United States;”
15 and

16
17 Whereas, Over 100 organizations have signed onto the Oral Contraceptives Over-the-Counter
18 Working Group’s statement of purpose, including the American Academy of Pediatrics, ACOG,
19 the National Hispanic Medical Association, the North American Society for Pediatric and
20 Adolescent Gynecology, and the Society for Adolescent Health and Medicine;²⁰ and

21
22 Whereas, Policy statements from the American Academy of Family Physicians (AAFP), the
23 American College of Obstetricians and Gynecologists (ACOG), and American Public Health
24 Association (APHA) support OTC oral contraceptive access;²¹⁻²³ and

25
26 Whereas, In December 2016, Ibis Reproductive Health announced a partnership with HRA
27 Pharma to conduct the research needed and submit an application to the FDA to bring a
28 progestin-only oral contraceptive pill to the United States OTC market;²⁴ and

29
30 Whereas, Current AMA Policy directs our AMA to encourage manufacturers of oral
31 contraceptives to submit the required application and supporting evidence to the US Food and
32 Drug Administration for the Agency to consider approving a switch in status from prescription
33 to over-the-counter for such products; and

34
35 Whereas, HRA Pharma completed its final testing phase in 2021 on a progestin-only oral
36 contraceptive and is expected to file a formal application for over-the-counter approval with the
37 U.S. Food and Drug Administration before the end of 2022;²⁵ therefore be it

38
39 RESOLVED, That our American Medical Association amends policy D-75.995, “Over-the-
40 Counter Access to Oral Contraceptives,” by addition and deletion to read as follows:

41
42 Our AMA:

- 43 1. Encourages ~~manufacturers of oral contraceptives to submit the required~~
44 ~~application and supporting evidence to the US Food and Drug Administration for the~~
45 ~~Agency to consider approving a~~ to swiftly review and approve a switch in status from
46 prescription to over-the-counter for ~~such products~~ oral contraceptives, without age
47 restriction.
48 2. Encourages the continued study of issues relevant to over-the-counter access for
49 oral contraceptives.
50 3. Will work with expert stakeholders to advocate for the availability of hormonal
51 contraception as an over-the-counter medication. (Modify Current HOD Policy)

Fiscal Note: Not yet determined

Received: 05/11/22

References:

1. Sonfield A, Hasstedt K, Kavanaugh ML, Anderson R. The social and economic benefits of women's ability to determine whether and when to have children . New York (NY): Guttmacher Institute; 2013. Available at: <http://www.guttmacher.org/pubs/social-economic-benefits.pdf> . Retrieved August 4, 2014.]
2. Noncontraceptive uses of hormonal contraceptives. Practice Bulletin No. 110. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2010;115:206–18.
3. Grindlay K, Grossman D. Prescription Birth Control Access Among U.S. Women at Risk of Unintended Pregnancy. *J Womens Health (Larchmt)* 2016;25:249–54.
4. Landau SC, Tapias MP, McGhee BT. Birth control within reach: a national survey on women's attitudes toward and interest in pharmacy access to hormonal contraception. *Contraception* 2006;74:463–70.
5. Grossman D, Fernández L, Hopkins K, Amastae J, Potter JE. Perceptions of the safety of oral contraceptives among a predominantly Latina population in Texas. *Contraception* 2010;81:254–60.
6. Manski R, Kottke M. A survey of teenagers' attitudes toward moving oral contraceptives over the counter. *Perspect Sex Reprod Health* 2015;47:123–9.
7. Grossman D, Grindlay K, Li R, Potter JE, Trussell J, Blanchard K. Interest in over-the-counter access to oral contraceptives among women in the United States. *Contraception* 2013;88:544–52.
8. Grindlay K, Grossman D. Interest in over-the-counter access to a progestin-only pill among women in the United States. *Womens Health Issues* 2018;28:144–51.
9. Dennis A, Grossman D. Barriers to contraception and interest in over-the-counter access among low-income women: a qualitative study. *Perspect Sex Reprod Health* 2012;44:84–91.
10. Baum S, Burns B, Davis L, Yeung M, Scott C, Grindlay K, et al. Perspectives among a diverse sample of women on the possibility of obtaining oral contraceptives over the counter: a qualitative study. *Womens Health Issues* 2016;26:147–52.
11. Curtis KM, Jatlaoui TC, Tepper NK, Zapata LB, Horton LG, Jamieson DJ, et al. U.S. selected practice recommendations for contraceptive use, 2016. *MMWR Recomm Rep* 2016;65(RR-4):1–66.
12. Access to contraception. Committee Opinion No. 615. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2015;125:250–5.
13. Tepper NK, Curtis KM, Steenland MW, Marchbanks PA. Physical examination prior to initiating hormonal contraception: a systematic review. *Contraception* 2013;87:650–4.
14. Tepper NK, Steenland MW, Marchbanks PA, Curtis KM. Laboratory screening prior to initiating contraception: a systematic review. *Contraception* 2013;87:645–9.
15. Grossman D, Fernandez L, Hopkins K, Amastae J, Garcia SG, Potter JE. Accuracy of Self-Screening for Contraindications to Combined Oral Contraceptive Use. *Obstet Gynecol.* 2008;112(3):572-578.
16. Shotorbani S, Miller L, Blough DK, Gardner J. Agreement between women's and providers' assessment of hormonal contraceptive risk factors. *Contraception.* 2006;73(5):501-506.
17. Tepper NK, Whiteman MK, Marchbanks PA, James AH, Curtis KM. Progestin-only contraception and thromboembolism: A systematic review. *Contraception* 2016;94:678–700.
18. U.S. Food and Drug Administration. FDA Drug Safety Communication: updated information about the risk of blood clots in women taking birth control pills containing drospirenone . Silver Spring (MD): FDA; 2012. Available at: <https://www.fda.gov/Drugs/DrugSafety/ucm299305.htm> .
19. Upadhyia KK, Santelli JS, Raine-Bennett TR, Kottke MJ, Grossman D. Over-the-counter access to oral contraceptives for adolescents. *J Adolesc Health* 2017;60:634–40.
20. Oral Contraceptives Over-the-Counter Working Group. Statement of Purpose. <http://ocsotc.org/statement-of-purpose/>. Accessed May 11, 2022.
21. American Academy of Family Physicians. Over-the-Counter Oral Contraceptives. 2014; <https://www.aafp.org/about/policies/all/otc-oral-contraceptives.html>. Accessed May 11, 2022.
22. Over-the-counter access to hormonal contraception. ACOG Committee Opinion No. 788. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2019;134:e96–105.
23. American Public Health Association. Improving Access to Over the Counter Contraception by Expanding Insurance Coverage (Policy Number 20111). 2011; <https://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-database/2014/07/24/10/31/improving-access-to-over-the-counter-contraception-by-expanding-insurance-coverage>. Accessed May 12, 2022.
24. Ibis Reproductive Health. Ibis announces groundbreaking partnership with HRA Pharma to move a birth control pill over the counter. 2016; <https://ibisreproductivehealth.org/news/ibis-announces-groundbreaking-partnership-hra-pharma-move-birth-control-pill-over-counter>
25. Draft abortion opinion renews urgency on over-the-counter birth control, Politico. <https://www.politico.com/news/2022/05/05/draft-abortion-opinion-scotus-over-the-counter-birth-control-00030157>

RELEVANT AMA POLICY

Over-the-Counter Access to Oral Contraceptives D-75.995

Our AMA:

1. Encourages manufacturers of oral contraceptives to submit the required application and supporting evidence to the US Food and Drug Administration for the Agency to consider approving a switch in status from prescription to over-the-counter for such products.
2. Encourages the continued study of issues relevant to over-the-counter access for oral contraceptives.

Citation: Sub. Res. 507, A-13; Modified: BOT Rep. 10, A-18

Development and Approval of New Contraceptives H-75.990

Our AMA: (1) supports efforts to increase public funding of contraception and fertility research; (2) urges the FDA to consider the special health care needs of Americans who are not adequately served by existing contraceptive products when considering the safety, effectiveness, risk and benefits of new contraception drugs and devices; and (3) encourages contraceptive manufacturers to conduct post-marketing surveillance studies of contraceptive products to document the latter's long-term safety, effectiveness and acceptance, and to share that information with the FDA.

Citation: BOT Rep. O, I-91; Reaffirmed: Sunset Report, I-01; Modified: CSAPH Rep. 1, A-11; Modified: CSAPH Rep. 1, A-21

Opposition to HHS Regulations on Contraceptive Services for Minors H-75.998

(1) Our AMA continues to oppose regulations that require parental notification when prescription contraceptives are provided to minors through federally funded programs, since they create a breach of confidentiality in the physician-patient relationship. (2) The Association encourages physicians to provide comparable services on a confidential basis where legally permissible.

Citation: (Sub. Res. 65, I-82; Reaffirmed: CLRPD Rep. A, I-92; Reaffirmed: BOT Rep. 28, A-03; Reaffirmed: Res. 825, I-04; Reaffirmed: CMS Rep. 1, A-14)

Coverage of Contraceptives by Insurance H-180.958

1. Our AMA supports federal and state efforts to require that every prescription drug benefit plan include coverage of prescription contraceptives.
2. Our AMA supports full coverage, without patient cost-sharing, of all contraception without regard to prescription or over-the-counter utilization because all contraception is essential preventive health care.

Citation: Res. 221, A-98; Reaffirmation A-04; Reaffirmed: CMS Rep. 1, A-14; Reaffirmation: I-17; Modified: BOT Rep. 10, A-18

Reducing Unintended Pregnancy H-75.987

Our AMA: (1) urges health care professionals to provide care for women of reproductive age, to assist them in planning for pregnancy and support age-appropriate education in esteem building, decision-making and family life in an effort to introduce the concept of planning for childbearing in the educational process; (2) supports reducing unintended pregnancies as a national goal; and (3) supports the training of all primary care physicians and relevant allied health professionals in the area of preconception counseling, including the recognition of long-acting reversible contraceptives as efficacious and economical forms of contraception.

Citation: Res. 512, A-97; Reaffirmed: CSAPH Rep. 3, A-07; Reaffirmation A-15; Appended: Res. 502, A-15; Reaffirmation I-16

Access to Emergency Contraception H-75.985

It is the policy of our AMA: (1) that physicians and other health care professionals should be encouraged to play a more active role in providing education about emergency contraception, including access and informed consent issues, by discussing it as part of routine family planning and contraceptive counseling; (2) to enhance efforts to expand access to emergency contraception, including making emergency contraception pills more readily available through pharmacies, hospitals, clinics, emergency rooms, acute care centers, and physicians' offices; (3) to recognize that information about emergency contraception is part of the comprehensive information to be provided as part of the emergency treatment of sexual assault victims; (4) to support educational programs for physicians and patients regarding treatment options for the emergency treatment of sexual assault victims, including information about emergency contraception; and (5) to encourage writing advance prescriptions for these pills as requested by their patients until the pills are available over-the-counter.

Citation: (CMS Rep. 1, I-00; Appended: Res. 408, A-02; Modified: Res. 443, A-04; Reaffirmed: CSAPH Rep. 1, A-14)

Access to Emergency Contraception D-75.997

1. Our AMA will: (a) intensify efforts to improve awareness and understanding about the availability of emergency contraception in the general public; and (b) support and monitor the application process of manufacturers filing for over-the-counter approval of emergency contraception pills with the Food and Drug Administration (FDA).
2. Our AMA: (a) will work in collaboration with other stakeholders (such as American College of Obstetricians and Gynecologists, American Academy of Pediatrics, and American College of Preventive Medicine) to communicate with the National Association of Chain Drug Stores and the National Community Pharmacists Association, and request that pharmacies utilize their web site or other means to signify whether they stock and dispense emergency contraception, and if not, where it can be obtained in their region, either with or without a prescription; and (b) urges that established emergency contraception regimens be approved for over-the-counter access to women of reproductive age, as recommended by the relevant medical specialty societies and the US Food and Drug Administration's own expert panel.

Citation: CMS Rep. 1, A-00; Appended: Res. 506, A-07; Reaffirmed: CMS Rep. 01, A-17