

1 **RESOLUTION NO. 501 (California A)**

2  
3 **Endorse Access Without Age Restriction to Over-the-Counter Oral Contraceptive Pills**

4  
5 Introduced by the California Chapter

6  
7 Referred to the Reference Committee on Advocacy

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9  
10 WHEREAS, Unintended pregnancy remains a major public health problem in the United States<sup>1</sup>,  
11 and

12  
13 WHEREAS, access and cost issues are common reasons why women either do not use  
14 contraception or have gaps in use<sup>2</sup>, and

15  
16 WHEREAS, eighty-two percent of adolescent pregnancies are unplanned, accounting for one-fifth  
17 of all unintended pregnancies in the United States<sup>3</sup>, and

18  
19 WHEREAS, teenagers experience disproportionately high rates of unintended pregnancy and face  
20 unique challenges accessing contraceptives<sup>4</sup>, and

21  
22 WHEREAS, the American Academy of Family Physicians has previously endorsed contraceptive  
23 access as an important public health measure<sup>4</sup>, including over-the-counter (OTC) availability of  
24 oral contraceptive pills (OCPs)<sup>5</sup>, and

25  
26 WHEREAS, California approved behind-the-counter access to OCPs without an age restriction in  
27 2015<sup>6</sup>, and

28  
29 WHEREAS, surveys indicate that most women in the United States, as well as pharmacists, look  
30 favorably upon the OTC accessing to OCPs and only a minority of women support an age  
31 restriction for OTC OCPs<sup>7</sup>, and

32  
33 WHEREAS, contraindications to oral contraceptives are more prevalent among women 35 years  
34 and older compared with younger women<sup>8</sup>, and

35  
36 WHEREAS, young adolescents do not increase their sexual risk behavior with increased access to  
37 contraception<sup>9</sup>, and

38  
39 WHEREAS, OCPs are the most commonly used hormonal contraceptive method among United  
40 States teens<sup>10</sup>, now, therefore, be it

41  
42 RESOLVED, That the American Academy of Family Physicians write to the U.S. Food and Drug  
43 Administration (FDA) to urge that all adolescents be included in the over-the-counter (OTC) oral  
44 contraceptives studies required by the FDA (e.g., label comprehension study, actual use study) to  
45 determine whether OTC access is appropriate for this population.

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47 (Received 04/14/16)

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49 **Fiscal Impact:** None

1 **AAFP Background**

2 Oral contraceptives have been determined to be safe and effective for use by adolescents. The  
3 AAFP has advocated on coverage of over-the-counter (OTC) contraception and insurance  
4 coverage. The AAFP sent a [letter](#) to the Centers for Medicare & Medicaid Services (CMS) asking  
5 them to review and revise the coverage of contraceptive options. The AAFP encouraged CMS to  
6 expand coverage of contraceptive options to all FDA-approved contraceptive options for men and  
7 women of reproductive age enrolled in Medicare and Medicaid. The AAFP also sent a [letter](#) to  
8 Senator Patty Murray in support of legislation on OTC access and insurance coverage regardless  
9 of prescription status.

10  
11 All Medicaid programs must cover family planning services; providers and pharmacies are not  
12 permitted to charge cost-sharing for benefits. Family planning is considered a “mandatory” benefit  
13 under Medicaid, but states have discretion in identifying the specifics of inclusion in the program.  
14 Sec. 1905(a)(4)(C) of the Social Security Act provides: family planning services and supplies  
15 furnished (directly or under arrangements with others) to individuals of child-bearing age (including  
16 minors who can be considered sexually active) who are eligible under the State plan and who  
17 desire such services and supplies. Contraception is one of the primary services of family planning  
18 and many states offer broad coverage. There are a number of state Medicaid programs that  
19 currently cover OTC and/or prescriptions for emergency contraception.

20  
21 When pharmaceutical companies wish to switch a drug to an over-the-counter status, the Food  
22 and Drug Administration (FDA) may ask for additional studies, such as label comprehension  
23 studies, self-selection studies, and actual use studies. Label comprehension studies are meant to  
24 ensure that consumers can understand the information on the label. Self-selection studies  
25 determine if consumers can make a correct decision about whether the medication is appropriate  
26 for them after reading the indications and warnings provided. Actual use studies determine if the  
27 medication will be used properly, safely, and effectively in the OTC setting.

28  
29 The process of transferring FDA-approved prescription medications to nonprescription, over-the-  
30 counter (OTC) status is known as “Rx-to-OTC switch.” This process provides consumers with  
31 convenient, cost-effective access to safe and effective medicines without the required assistance  
32 of a healthcare provider. When an ingredient is first introduced as an OTC medicine, it typically  
33 has been marketed by a manufacturer as a prescription medicine first. Then, after a sufficient  
34 amount of time has passed to enable the manufacturer to gather appropriate scientific information  
35 on the product, the manufacturer may elect to submit a new drug application, or NDA, to FDA so  
36 that it may be considered for OTC status. FDA experts review the application and determine if that  
37 product has a high enough safety profile and if labeling can be developed so that the medicine can  
38 be marketed safely and effectively as an OTC medicine.

39  
40 While drug user-fee schedules do apply, each case is handled on its own merits and actually may  
41 take longer than the predetermined 10-month targeted timeframe. There are a number of reasons  
42 that the approval process may be delayed. For example, FDA may ask a manufacturer to provide  
43 additional data on the safety, effectiveness, or use of the product. The agency also may ask a  
44 manufacturer to modify a product’s labeling so that it is more understandable. The important thing  
45 to remember is that each switch application is considered on its own merits.  
46 <http://www.chpa.org/SwitchFAQs.aspx>([www.chpa.org](http://www.chpa.org))

47  
48 The FDA has drafted Guidance for Industry E11 Clinical Investigation of Medicinal Products in the  
49 Pediatric Population.  
50 <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073>  
51 [143.pdf](http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073)([www.fda.gov](http://www.fda.gov))

1 The FDA also provides guidance to clinical investigators on including adolescents in studies.  
2 Moreover, when children are to be included as subjects in a study, the parent or guardian must  
3 provide permission in accordance with requirements for informed consent.  
4 [http://www.fda.gov/RegulatoryInformation/Guidances/ucm404975.htm#children\(www.fda.gov\)](http://www.fda.gov/RegulatoryInformation/Guidances/ucm404975.htm#children(www.fda.gov))

5  
6 The following article provides a good overview on this topic. "A Difficult Proposition: Oral  
7 Contraceptives' Switch from Prescription to Over-the-counter Status."  
8 [https://dash.harvard.edu/bitstream/handle/1/8965575/Ada\\_Dekhtyar.pdf?sequence=1\(dash.harvard.edu\)](https://dash.harvard.edu/bitstream/handle/1/8965575/Ada_Dekhtyar.pdf?sequence=1(dash.harvard.edu))

## 11 **Current Policy**

### 13 [Over-the-Counter Oral Contraceptives](#)

### 15 [Contraception Methods for Medicare Patients](#)

### 17 [Coverage, Patient Education, and Counseling for Family Planning, Contraceptive Methods, and Sterilization Procedures](#)

## 20 **Prior Congress Action**

### 22 **Resolution No. 503 from the 2011 COD (Not Adopted):**

23 RESOLVED, That the American Academy of Family Physicians (AAFP) urge the U.S.  
24 Congress and federal and state agencies to provide federal and state Medicaid coverage for  
25 all family planning drugs and supplies that are FDA-approved for sale over-the-counter, and  
26 not require a prescription for such coverage, and be it further

27  
28 RESOLVED, That the American Academy of Family Physicians (AAFP) urge health insurers  
29 and managed care organizations participating in Medicaid and the private insurance market  
30 to include in their insurance products coverage for all family planning drugs and supplies that  
31 are FDA-approved for sale over-the-counter, and not require a prescription for such  
32 coverage.

33 **Please see Page 258-262 in the [2011 Transactions](#) for details.**

### 35 **Resolution No. 504 from the 2011 COD (Not Adopted):**

36 RESOLVED, That the American Academy of Family Physicians support congress and  
37 federal and state agencies to enact legislation and policies that to provide federal and state  
38 Medicaid coverage for all oral contraceptive pills that are FDA-approved for sale over-the-  
39 counter, and not to require a prescription for such coverage and be it further

40  
41 RESOLVED, That the American Academy of Family Physicians (AAFP) urge health insurers  
42 and managed care organizations participating in Medicaid and the private insurance market  
43 to include in their insurance products coverage for all oral contraceptive pills that are FDA-  
44 approved for sale over-the-counter, and not to require a prescription for such coverage.

45 **Please see Pages 258-262 in the [2011 Transactions](#) for details.**

### 47 **Substitute Resolution No. 503 from the 2011 COD (Substitute Adopted):**

48 RESOLVED, That the American Academy of Family Physicians (AAFP) support policies and  
49 legislation that would require public and private insurance plans to provide coverage for  
50 family planning drugs and supplies that are FDA approved, including those for sale over-the-  
51 counter.

52 **Please see Pages 258-262 from the [2011 Transactions](#) for details.**

1 Please see Page 174 from the [2012 Transactions](#) for follow-up details.

2  
3 **Resolution No. 504 from the 2013 COD (Referred to the BOD):**

4 RESOLVED, That the American Academy of Family Physicians endorse the policy that oral  
5 contraceptive pills be made available over-the-counter, weighing the risks versus the benefits  
6 based on currently available data, and be it further

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8 RESOLVED, That the American Academy of Family Physicians endorse the policy that oral  
9 contraceptive pills be included among Food and Drug Administration-approved over-the-  
10 counter contraceptive methods and supplies covered by insurers and Medicaid.

11 Please see Pages 310-313 in the [2013 Transactions](#) for details.

12 Please see [Resolution No. 504](#) on the AAFP website for follow-up details.

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14 **Resolution No. 505 from the 2013 COD (Referred to the BOD):**

15 RESOLVED, That the American Academy of Family Physicians adopt policy recommending  
16 that oral contraceptives be made available for retail sale without a prescription.

17 Please see Pages 310-313 in the [2013 Transactions](#) for details.

18 Please see [Resolution No. 505](#) on the AAFP website for follow-up details.

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20 **Resolution No. 506 from the 2013 COD (Referred to the BOD):**

21 RESOLVED, That the American Academy of Family Physicians write to the U.S. Food and  
22 Drug Administration (FDA) to urge that oral contraceptive pills (OCPs) be made available  
23 without a prescription and with coverage by the Centers for Medicare and Medicaid Services  
24 and commercial insurers, and be it further

25  
26 **References:**

- 27 1. Finer LB, Zolna MR. Unintended pregnancy in the United States: incidence and disparities, 2006.  
28 Contraception. 2011;84:478-85.
- 29 2. Frost JJ, Singh S, Finer LB. U.S. women's one-year contraceptive use patterns, 2004. Perspect Sex  
30 Reprod Health 2007;39:48-55.
- 31 3. Birth Control: Choosing the method that's right for you. American Academy of Family Physicians.  
32 Updated March 2005.
- 33 4. Adolescents and long-acting reversible contraception: implants and intrauterine devices. American  
34 College of Obstetricians and Gynecologists. Committee Opinion No. 539. Obstet Gynecol.  
35 2012;120:983-988.
- 36 5. AAFP COD 2011 – Advocacy Item 3 Adopted.
- 37 6. §1746.1 of Article 5 of Division 17 of Title 16 of the California Code of Regulations: Protocol for  
38 Pharmacists Furnishing Self-Administered Hormonal Contraception.
- 39 7. Grindlay K, Grossman D. Women's Perspectives on Age Restriction for Over-the-Counter Access to  
40 Oral Contraceptives. Grindlay K, Grossman D. J of Adol Health. 56 (2015) 38-43.
- 41 8. Grossman D, Fernandez L, Hopkins K, Amastae J, Garcia SG, Potter JE. Accuracy of self-screening for  
42 contraindications to combined oral contraceptive use. Obstet Gynecol. 2008;112(3):572-578.
- 43 9. Harper CC, Cheong M, Rocca CH, Darney PD, Raine TR. The effect of increased access to emergency  
44 contraception among young adolescents. Obstet Gynecol. 2005;106(3):483-491.
- 45 10. Upadhyia, Krishna. Contraception for adolescents. Pediatrics in review [0191-9601] yr:2013 vol:34 iss:9  
46 pg:384 -94.

1 11. RESOLVED, That the American Academy of Family Physicians endorse making oral  
2 contraceptive pills (OCPs) available without a prescription, with coverage by insurers and the  
3 Centers for Medicare and Medicaid Services.

4 **Please see Pages 310-313 in the [2013 Transactions](#) for details.**

5 **Please see [Resolution No. 506](#) on the AAFP website for follow-up details.**

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7 **Prior Board Action**

8 Approval of a recommendation from the Commission on Health of the Public and Science that  
9 the new statement "[Over-the-Counter Oral Contraceptives](#) be approved as AAFP policy.

10 B2014, July 30-August 1, pp. 10-11.

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12 Approval of a [letter](#) of support for the Affordability is Access Act (S. 1532).

13 BC1:12015, July 15, p. 1.

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