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Women's Preventive Services Guidelines



On December 20, 2016, HRSA updated the HRSA-supported Women's Preventive Services Guidelines. Read the most current version.

Non-grandfathered plans and coverage (generally, plans or policies created or sold after March 23, 2010, or older plans or policies that have been changed in certain ways since that date) are required to provide coverage without cost sharing consistent with these guidelines beginning with the first plan year (in the individual market policy year) that begins on or after December 20, 2017. Before that time, non-grandfathered plans are generally required to provide coverage without cost sharing consistent with the 2011 guidelines.

The HRSA-supported Women's Preventive Services Initiative recently released the Well Woman Chart , a resource that includes age-based preventive service recommendations for women from adolescence to maturity. The intent of the chart is to provide clarity for patients and providers, with the goal of improving women's health across the life span.

Affordable Care Act Expands Prevention Coverage for Women's Health and Well-Being

The Affordable Care Act – the health insurance reform legislation passed by Congress and signed into law by President Obama on March 23, 2010 – helps make prevention affordable and accessible for all Americans by requiring health plans to cover preventive services and by eliminating cost sharing for those services. Preventive services that have strong scientific evidence of their health benefits must be covered and plans can no longer charge a patient a copayment, coinsurance or deductible for these services when they are delivered by a network provider.

Women's Preventive Services Guidelines Supported by the Health Resources and Services Administration

Under the Affordable Care Act, women's preventive health care – such as mammograms, screenings for cervical cancer, prenatal care, and other services – generally must be covered with no cost sharing. However, the law recognizes and HHS understands the need to take into account the unique health needs of women throughout their lifespan.

The HRSA-supported health plan coverage guidelines, developed by the Institute of Medicine (IOM), will help ensure that women receive a comprehensive set of preventive services without having to pay a co-payment, co-insurance or a deductible. HHS commissioned an IOM study to review what preventive services are necessary for women's health and well-being and therefore should be considered in the development of comprehensive guidelines for preventive services for women. HRSA is supporting the IOM's recommendations on preventive services that address health needs specific to women and fill gaps in existing guidelines.

Health Resources and Services Administration Women's Preventive Services Guidelines

Non-grandfathered plans (plans or policies created or sold after March 23, 2010, or older plans or policies that have been changed in certain ways since that date) generally are required to provide coverage without cost sharing consistent with these guidelines in the first plan year (in the individual market, policy year) that begins on or after August 1, 2012.

Type of Preventive Service	HHS Guideline for Health Insurance Coverage	Frequency
Well-woman visits.	Well-woman preventive care visit annually for adult women to obtain the recommended preventive services that are age and developmentally appropriate, including preconception care and many services necessary for prenatal care. This well-woman visit should, where appropriate, include other preventive services listed in this set of guidelines, as well as others referenced in section 2713.	Annual, although HHS recognizes that several visits may be needed to obtain all necessary recommended preventive services, depending on a woman's health status, health needs, and other risk factors.* (see note)
Screening for gestational diabetes.	Screening for gestational diabetes.	In pregnant women between 24 and 28 weeks of gestation and at the first prenatal visit for pregnant women identified to be at high risk for diabetes.
Human papillomavirus testing.	High-risk human papillomavirus DNA testing in women with normal cytology results.	Screening should begin at 30 years of age and should occur no more frequently than every 3 years.
Counseling for sexually transmitted infections.	Counseling on sexually transmitted infections for all sexually active women.	Annual.
Counseling and screening for human immune-deficiency virus.	Counseling and screening for human immune-deficiency virus infection for all sexually active women.	Annual
Contraceptive methods and counseling. ** (see note)	All Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity.	As prescribed
Breastfeeding support, supplies, and counseling.	Comprehensive lactation support and counseling, by a trained provider during pregnancy and/or in the	In conjunction with each birth

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	postpartum period, and costs for renting breastfeeding equipment.	
Screening and counseling for interpersonal and domestic violence.	Screening and counseling for interpersonal and domestic violence.	

^{*} Refer to guidance issued by the Center for Consumer Information and Insurance Oversight entitled Affordable Care Act Implementation FAQs, Set 12, Q10.

- **(I)(a) Objecting entities—religious beliefs.
- (1) These Guidelines do not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, and thus the Health Resources and Service Administration exempts from any Guidelines requirements issued under 45 CFR 147.130(a)(1)(iv) that relate to the provision of contraceptive services:
- (i) A group health plan and health insurance coverage provided in connection with a group health plan to the extent the non-governmental plan sponsor objects as specified in paragraph (I)(a)(2) of this note. Such non-governmental plan sponsors include, but are not limited to, the following entities:
- (A) A church, an integrated auxiliary of a church, a convention or association of churches, or a religious order;
- (B) A nonprofit organization;
- (C) A closely held for-profit entity;
- (D) A for-profit entity that is not closely held; or
- (E) Any other non-governmental employer;
- (ii) An institution of higher education as defined in 20 U.S.C. 1002 in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (I)(a)(2) of this note. In the case of student health insurance coverage, section (I) of this note is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to "plan participants and beneficiaries" will be interpreted as references to student enrollees and their covered dependents; and
- (iii) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (I)(a)(2) of this note. Where a health insurance issuer providing group health insurance coverage is exempt under this paragraph (I)(a)(1)(iii), the plan remains subject to any requirement to provide coverage for contraceptive services under these Guidelines unless it is also exempt from that requirement.
- (2) The exemption of this paragraph (I)(a) will apply to the extent that an entity described in paragraph (I)(a)(1) of this note objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services, based on its sincerely held religious beliefs.

 (b) Objecting individuals—religious beliefs. These Guidelines do not provide for or support the requirement of coverage or
- payments for contraceptive services with respect to individuals who object as specified in this paragraph (I)(b), and nothing in 45 CFR 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a) (1)(iv), or 29 CFR 2590.715-2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate benefit package option, or a separate policy, certificate or contract of insurance, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs.
- (II)(a) Objecting entities—moral convictions.
- (1) These Guidelines do not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, and thus the Health Resources and Service Administration exempts from any Guidelines requirements issued under 45 CFR 147.130(a)(1)(iv) that relate to the provision of contraceptive services:

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- (i) A group health plan and health insurance coverage provided in connection with a group health plan to the extent one of the following non-governmental plan sponsors object as specified in paragraph (II)(a)(2) of this note:
- (A) A nonprofit organization; or
- (B) A for-profit entity that has no publicly traded ownership interests (for this purpose, a publicly traded ownership interest is any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934);
- (ii) An institution of higher education as defined in 20 U.S.C. 1002 in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (II)(a)(2) of this note. In the case of student health insurance coverage, section (I) of this note is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to "plan participants and beneficiaries" will be interpreted as references to student enrollees and their covered dependents; and
- (iii) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (II)(a)(2) of this note. Where a health insurance issuer providing group health insurance coverage is exempt under this paragraph (II)(a)(1)(iii), the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under these Guidelines unless it is also exempt from that requirement.
- (2) The exemption of this paragraph (II)(a) will apply to the extent that an entity described in paragraph (II)(a)(1) of this note objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage or payments for some or all contraceptive services, or for a plan, issuer, or third party administrator that provides or arranges such coverage or payments, based on its sincerely held moral convictions.
- (b) Objecting individuals—moral convictions. These Guidelines do not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (II)(b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a) (1)(iv), or 29 CFR 2590.715-2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held moral convictions.
- (III) Definition. For the purposes of this note, reference to "contraceptive" services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of these Guidelines.

See Federal Register Notice: <u>Religious Exemptions and Accommodations for Coverage of Certain Preventive Services under the Affordable Care Act</u> (PDF - 488 kb).

HRSA, in concert with an external review committee, will review, and continually update, the Women's Preventive Services' Guidelines.

Date Last Reviewed: September 2018

Learn More

- Women's Preventive Services Initiative Report №
- 2011 IOM Report Clinical Preventive Services For Women: Closing The Gaps &
- US Preventive Services Task Force

Advisory Committee On Immunization Practices &

For Further Information

Contact wellwomancare@hrsa.gov.



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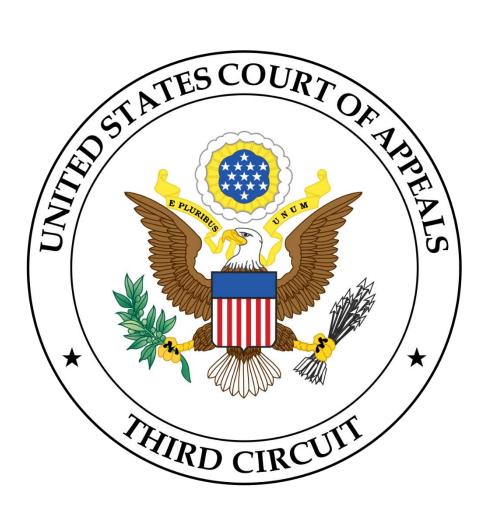
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FAQS ABOUT AFFORDABLE CARE ACT IMPLEMENTATION PART 36



U.S. Department of Labor Employee Benefits Security Administration January 9, 2017

Set out below is an additional Frequently Asked Question (FAQ) regarding implementation of the Affordable Care Act. This FAQ has been prepared jointly by the Departments of Labor (DOL), Health and Human Services (HHS), and the Treasury (collectively, the Departments). Like previously issued FAQs (available at www.dol.gov/ebsa/healthreform/index.html and www.cms.gov/cciio/resources/fact-sheets-and-faqs/index.html), this FAQ answers a question from stakeholders to help people understand the law and benefit from it, as intended.

COVERAGE OF PREVENTIVE SERVICES

Section 2713 of the Public Health Service Act (PHS Act), as added by the Affordable Care Act and incorporated into the Employee Retirement Income Security Act (ERISA) and the Internal Revenue Code (the Code), requires that non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage provide coverage of certain specified preventive services without cost sharing.

As originally drafted, the bill that became the Affordable Care Act would not have covered additional preventive services that "many women's health advocates and medical professionals believe are critically important" to meeting women's unique health needs. 155 Cong. Rec. 28,841 (2009) (Sen. Boxer). To address that concern, the Senate adopted a "Women's Health Amendment," adding a new category of preventive services specific to women's health. This provision requires coverage without cost sharing of preventive care and screenings for women provided for in comprehensive guidelines supported by the Health Resources and Services Administration (HRSA). Supporters of the Women's Health Amendment emphasized that it would reduce unintended pregnancies by ensuring that women receive coverage for "contraceptive services" without cost-sharing. 155 Cong. Rec. at 29,768 (Sen. Durbin).

On August 1, 2011, the Departments issued amended regulations requiring coverage of women's preventive services provided for in the HRSA guidelines,² and HRSA adopted and released such guidelines, which were based on recommendations of the independent organization, the National Academy of Medicine (formerly Institute of Medicine).³ The preventive services identified in the HRSA guidelines include all Food and Drug Administration (FDA)-approved contraceptives, sterilization

See also, e.g., 155 Cong. Rec. at 28,841 (Sen. Boxer) ("family planning services"); id. at 28,843 (Sen. Gillibrand) ("family planning"); id. at 28,844 (Sen. Mikulski) (same); id. at 28,869 (Sen. Franken) ("contraception"); id. at 29,070 (Sen. Feinstein) ("family planning services"); id. at 29,307 (Sen. Murray) (same).

² 26 CFR 54.9815-2713, 29 CFR 2590.715-2713, 45 CFR 147.130.

The 2011 amended regulations were issued and effective on August 1, 2011, and published on August 3, 2011 (76 FR 46621).

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procedures, and patient education and counseling for women with reproductive capacity, as prescribed by a health care provider (collectively, contraceptive services).⁴ Under the regulations issued in August 2011 and the contemporaneously issued HRSA guidelines, group health plans of "religious employers" (organizations that are organized and operate as nonprofit entities and are referred to in section 6033(a)(3)(A)(i) or (iii) of the Code) are exempt from the requirement to provide contraceptive coverage. That exemption reflects "the longstanding governmental recognition of a particular sphere of autonomy for houses of worship." 80 FR 41318, 41325 (July 15, 2015); see 26 U.S.C. 6033(a)(3)(A)(i) or (iii) (referring to "churches, their integrated auxiliaries, conventions or associations of churches, and the exclusively religious activities of any religious order").

Subsequently, on July 2, 2013, the Departments published regulations that provide an accommodation for eligible organizations⁵ that object on religious grounds to providing coverage for contraceptive services, but are not eligible for the exemption for religious employers (78 FR 39870).⁶ Under the accommodation, an eligible organization is not required to contract, arrange, pay, or provide a referral for contraceptive coverage. At the same time, the accommodation generally ensures that women enrolled in the health plan established by the eligible organization, like women enrolled in health plans maintained by other employers, receive contraceptive coverage seamlessly—that is, through the same issuers or third party administrators that provide or administer the health coverage furnished by the eligible organization, and without financial, logistical, or administrative obstacles.⁷ Minimizing such obstacles is essential to achieving the purpose of the Affordable Care Act's preventive services provision, which seeks to remove barriers to the use of preventive services and to ensure that women receive full and equal health coverage appropriate to their medical needs.

In Burwell v. Hobby Lobby Stores, Inc., 134 S. Ct. 2751 (2014), which addressed claims brought under the Religious Freedom Restoration Act (RFRA), the Supreme Court held that the contraceptive-coverage requirement substantially burdened the religious exercise of the closely held for-profit corporations that had religious objections to providing contraceptive coverage, and that the accommodation was a less restrictive means of providing coverage to their employees. In light of the Hobby Lobby decision, the Departments extended the accommodation to closely held for-profit entities.⁸

⁴ On December 20, 2016, HRSA updated the women's preventive services guidelines, which go into effect for non-grandfathered group health plans and health insurance coverage for plan years (in the individual market, policy years) beginning on or after December 20, 2017. The HRSA guidelines exclude services relating to a man's reproductive capacity, such as vasectomies and male condoms.

An eligible organization, which may seek the accommodation based on its sincerely held religious objection to providing contraceptive coverage, is defined at 26 CFR 54.9815-2713A(a), 29 CFR 2590.715-2713A(a), and 45 CFR 147.131(b),

⁶ 26 CFR 54.9815-2713A, 29 CFR 2590.715-2713A, 45 CFR 147.131.

An accommodation is also available with respect to student health insurance coverage arranged by eligible organizations that are institutions of higher education. 45 CFR 147.131(f). For ease of use, this FAQ refers only to "employers" with religious objections to the contraceptive-coverage requirement, but references to employers with respect to insured group health plans should also be considered to include institutions of higher education that are eligible organizations with respect to student health insurance coverage.

⁸ 26 CFR 54.9815-2713A(b)(2)(ii); 29 CFR 2590.715-2713A(b)(2)(ii); 45 CFR. 147.131(b)(2)(ii).

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Under the accommodation, an eligible organization that objects to providing contraceptive coverage for religious reasons may either:

- (1) self-certify its objection to its health insurance issuer (to the extent it has an insured plan) or third party administrator (to the extent it has a self-insured plan) using a form provided by the Department of Labor (EBSA Form 700);⁹ or
- (2) self-certify its objection and provide certain information to HHS without using any particular form.¹⁰

In Zubik v. Burwell, 136 S. Ct. 1557 (2016), the Supreme Court considered claims by a number of employers that, even with the accommodation provided in the regulations, the contraceptivecoverage requirement violates RFRA. Following oral argument, the Court issued an order requesting supplemental briefing from the parties. The Court's order noted that under the existing regulations, an objecting employer with an insured plan that seeks to invoke the accommodation by contacting its issuer must use a form of written notice stating that the employer objects on religious grounds to providing contraceptive coverage.¹¹ The Court directed the parties to file supplemental briefs addressing "whether contraceptive coverage could be provided to [the objecting employers'] employees, through [the employers'] insurance companies, without any such notice."¹² After consideration of the supplemental briefing, the Supreme Court vacated the judgments of the lower courts and remanded Zubik and several other cases raising parallel RFRA challenges to the accommodation. 136 S. Ct. at 1560-1561. The Court emphasized that it "expresse[d] no view on the merits of the cases" and, in particular, that it did not "decide whether [the employers'] religious exercise has been substantially burdened, whether the Government has a compelling interest, or whether the current regulations are the least restrictive means of serving that interest." Id. at 1560. The Court, however, stated that in light of what it viewed as "the substantial clarification and refinement in the positions of the parties" in their supplemental briefs, the parties "should be afforded an opportunity to arrive at an approach going forward that accommodates [the objecting employers'] religious exercise while at the same time ensuring that women covered by [the employers'] health plans 'receive full and equal health coverage, including contraceptive coverage." Id. (citation omitted).¹³

The EBSA Form 700 serves as a certification that the organization is an "eligible organization" (as described in 26 CFR 54.9815-2713A(a), 29 CFR 2590.715-2713A(a), and 45 CFR 147.131(b)) that has a religious objection to providing coverage for some or all of any contraceptive services that would otherwise be required to be covered. The EBSA Form 700 is available at: https://www.dol.gov/ebsa/pdf/preventiveserviceseligibleorganizationcertificationform.pdf.

¹⁰ A model notice to HHS that eligible organizations may use, but are not required to use, is available at: http://www.cms.gov/cciio/resources/Regulations-and-Guidance/index.html#Prevention.

¹¹ Zubik v. Burwell, Nos. 14-1418 et al., 2016 WL 1203818, at *2 (Mar. 29, 2016).

¹² *Id*.

The Supreme Court specified that, while the RFRA litigation remains pending, "the Government may not impose taxes or penalties on [the plaintiffs] for failure to provide the … notice" required under the existing accommodation regulations. *Zubik*, 136 S. Ct. at 1561. At the same time, the Court also emphasized that "[n]othing in [its] opinion, or in the opinions or orders of the courts below, is to affect the ability of the Government to ensure that women covered by [plaintiffs'] health plans 'obtain, without cost, the full range of FDA approved contraceptives." *Id.* at 1560-1561 (quoting *Wheaton College v. Burwell*, 134 S. Ct. 2806, 2807 (2014)).

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On July 22, 2016, the Departments published a request for information (RFI) (81 FR 47741) seeking input from interested parties to determine, as contemplated by the Supreme Court's opinion in *Zubik*, whether modifications to the existing accommodation procedure could resolve the objections asserted by the plaintiffs in the pending RFRA cases, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage.

The Departments explained that they were using the RFI procedure because the issues addressed in the supplemental briefing in *Zubik* affect a wide variety of stakeholders, including many who are not parties to the cases that were before the Supreme Court. Other employers also have brought RFRA challenges to the accommodation, and their views may differ from the views held by the employers in *Zubik* and the consolidated cases. In addition, any change to the accommodation could have implications for the rights and obligations of issuers, group health plans, third party administrators, and women enrolled in health plans established by objecting employers. The RFI was intended to assist the Departments in determining whether there are modifications to the accommodation that would be available under current law and that could resolve the pending RFRA claims brought by objecting organizations. The Departments sought feedback from all interested stakeholders, including objecting organizations, and specifically requested that such organizations address the particular issues outlined in the RFI.

In response to the RFI, the Departments received over 54,000 public comments by the comment closing date of September 20, 2016. Commenters included the plaintiffs in *Zubik* and other religiously affiliated organizations, consumer advocacy groups, women's organizations, health insurance issuers, third party administrators and pharmaceutical benefit managers, other industry representatives, employers, members of the public, and other interested stakeholders. The Departments are issuing this FAQ after consideration of comments submitted by a broad array of stakeholders, including the *Zubik* plaintiffs and similar religious organizations, issuers or third party administrators, and commenters representing women's and consumer advocacy organizations.

Q: ARE THE DEPARTMENTS MAKING CHANGES TO THE ACCOMMODATION AT THIS TIME?

No. As described in more detail below, the comments reviewed by the Departments in response to the RFI indicate that no feasible approach has been identified at this time that would resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage. The comments demonstrate that a process like the one described in the Court's supplemental briefing order would not be acceptable to those with religious objections to the contraceptive-coverage requirement. Further, a number of comments illustrate that the administrative and operational challenges to a process like the one described in the Court's order are more significant than the Departments had previously understood and would potentially undermine women's access to full and equal coverage. For these reasons, the Departments are not modifying the accommodation regulations at this time.

As the government explained in its briefs in *Zubik*, the Departments continue to believe that the existing accommodation regulations are consistent with RFRA for two independent reasons. First, as eight of the nine courts of appeals to consider the issue have held, by virtue of objecting employers'

¹⁴ The public comments are accessible at https://www.regulations.gov/docket?D=CMS-2016-0123.

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ability to avail themselves of the accommodation, the contraceptive-coverage requirement does not substantially burden their exercise of religion. Second, as some of those courts have also held, the accommodation is the least restrictive means of furthering the government's compelling interest in ensuring that women receive full and equal health coverage, including contraceptive coverage.

NOTIFICATION TO ISSUERS WITHOUT SELF-CERTIFICATION

In its request for supplemental briefing in *Zubik*, the Supreme Court asked the parties to address "whether and how contraceptive coverage may be obtained by [objecting employers'] employees through [the employers'] insurance companies, but in a way that does not require any involvement of [the employers] beyond their own decision to provide health insurance without contraceptive coverage to their employees." Specifically, the Court described—

a situation in which [objecting employers] would contract to provide health insurance for their employees, and in the course of obtaining such insurance, inform their insurance company that they do not want their health plan to include contraceptive coverage of the type to which they object on religious grounds. [The employers] would have no legal obligation to provide such contraceptive coverage, would not pay for such coverage, and would not be required to submit any separate notice to their insurer, to the Federal government, or to their employees. At the same time, [the employers'] insurance compan[ies]—aware that [the employers] are not providing certain contraceptive coverage on religious grounds—would separately notify [the employers'] employees that the insurance company will provide cost-free contraceptive coverage, and that such coverage is not paid for by [the employers] and is not provided through [the employers'] health plan[s].¹⁶

The Departments sought comments on whether this alternative would be acceptable to objecting organizations, and if not, whether further procedures or systems could resolve their RFRA concerns. The Departments asked if organizations specifically object on RFRA grounds to informing their issuers that they object to contraceptive coverage "on religious grounds," or to a requirement that the request by an eligible organization to its issuer be made in writing or through use of a particular form. The Departments also sought comments on whether it would be feasible for issuers to implement the accommodation without the written notification requirement and what effect this alternative procedure would have on the access of women to seamless contraceptive coverage.

In light of the comments received, the Departments have determined not to amend the regulations at this time. On the one hand, comments from parties before the Supreme Court (and other objecting employers) do not suggest that the change identified by the Supreme Court would resolve their concerns. On the other hand, the Departments received comments stating that eliminating written notification would create significant administrative problems and potential legal liabilities for issuers, and would hinder women's access to care. As described in greater detail below, these comments

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¹⁵ Zubik, 2016 WL 1203818, at *2.

¹⁶ Id

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have shown that the elimination of the written notification requirement would raise complications that would undermine the statute's goal of ensuring full and equal health coverage for women, the extent of which were not known to the Departments at the time the government filed its supplemental briefs in *Zubik*.

First, comments on behalf of issuers stated that eliminating written notifications would impose administrative costs by forcing them to create new systems to distinguish and track different employers, employees, and the coverage to be provided.¹⁷ For example, commenters stated that issuers currently rely on the written notifications to track the differences between eligible organizations that are seeking an accommodation due to their religious objections -- organizations that the Supreme Court has said are "effectively exempt" from the contraceptive-coverage requirement -- and religious employers that are automatically exempt under the HRSA guidelines. These comments asserted that eliminating written notifications would burden issuers with creating new systems to distinguish and track these two categories of employers.

Given the different ways in which issuers must treat and respond to these two types of entities, the Departments understand that issuers must be able to easily and separately track the coverage issued to the plans sponsored by these different organizations. With respect to exempt organizations, issuers merely need to eliminate contraceptive benefits from the group health insurance policy. However, with respect to eligible organizations that avail themselves of the accommodation, issuers must take the additional step of making separate payments for contraceptive services, along with providing notice of the availability of such payments. Furthermore, some eligible organizations may object to covering all forms of contraceptive services in their group health coverage while others may object only to certain types of contraceptive services. The Departments conclude therefore that written notification from employers significantly improves issuers' ability to appropriately identify and administer coverage for each of these two categories of employers. The commenters also said that issuers might be subject to legal risks if written notification were eliminated, because they would have no written record to demonstrate compliance with applicable law and regulations to the extent they relied on an organization's oral representation of its eligibility for the accommodation that was later determined to be incorrect. Such legal risks would be magnified, according to the commenters, in circumstances in which issuers would have to rely on agents and brokers to verify eligibility.

Based on these concerns, comments indicated that, even without a legal requirement to use a required form, issuers would likely seek written documentation, such as an attestation, from objecting employers to confirm the employer's eligibility as a condition of administering the accommodation. For example, an issuer might demand written documentation as a pre-condition for entering into a contract with an organization seeking the accommodation. The commenters indicated that if the written notification requirement were eliminated, employers might object to providing this type of verification, which is currently commonplace for certain purposes, such as communicating grandfathered status. The Departments note that, under the current accommodation,

Related to these comments with respect to the administrative costs of distinguishing and tracking different coverage to be provided, the Departments note that an eligible organization may seek an accommodation so that it need not contract, arrange, pay, or provide a referral for *all* otherwise required contraceptive services, or any subset of such services. Thus, there could be many different combinations of contraceptive services that an issuer must cover, and within each such combination, some such benefits must be provided by the group health insurance policy, and others for which the issuer must make separate payments.

once an issuer has been provided the documentation specified in the accommodation regulations, it may not require any further documentation from an eligible organization regarding its status as such.¹⁸

Second, several commenters suggested that the lack of written notice would create confusion and miscommunication, which in turn would lead to disputes between the parties, billing problems, and reduced access to care for women. For example, comments from women's advocacy organizations stated that lack of written notice could have repercussions for processing payments to a provider. This could disrupt continuity of care and burden women seeking to resolve any miscommunication between the objecting entity and the issuer. Further, according to these commenters, it could also impose the additional burden of affected women having to affirmatively assert their eligibility in situations where an employer has not timely provided its oral objection.

One commenter stated that, without a written notification, an eligible employer's representative may misstate an employer's wishes or incorrectly assert eligibility for the accommodation, resulting in a dispute that delays the process of arranging contraceptive coverage for women.

Several commenters representing women's and consumer advocacy organizations stressed the importance of written documentation for verifying compliance and ensuring that women are able to obtain direct, continuous access to the full range of contraceptive methods without cost. These commenters also suggested that eliminating written documentation could hamper the Departments' oversight and enforcement efforts.

Third, as noted above, the Departments have not identified any comments from objecting employers, including any of the *Zubik* plaintiffs, stating that eliminating the written notification requirement would be sufficient to satisfy their RFRA concerns. For example, one comment indicate that employers would object to "any requirement . . . that has the purpose or effect of providing access to or increasing the use of contraceptive services."

The Departments agree that written documentation establishing that a given employer requested the accommodation, and that it satisfies the definition of an eligible organization, is of value to document the legal responsibilities and rights of employees, issuers, and beneficiaries, as well as to minimize the number of disputes between employers and issuers regarding the accommodation. In turn, the Departments conclude that, by minimizing such disputes and providing certainty regarding which organizations have and have not requested the accommodation, the written notice requirement minimizes the potential number of employers that will be in violation of the contraceptive-coverage requirement. By helping to define which organizations have and have not availed themselves of the accommodation, written documentation also ensures that women receive timely access to contraceptive coverage, as it will help issuers to quickly and effectively determine the appropriate source of payment for such services, i.e., payment through the group health insurance policy, or separate payment for contraceptive services. And as the government explained in its Supreme Court briefs, the regulatory requirement for eligible organizations to provide written notification of their objection is consistent with RFRA.

¹⁸ 26 CFR 54.8815-2713A(c)(1)(i), 29 CFR 2590.715-2713A(c)(1)(i), 45 CFR 147.131(c)(1)(i).

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OTHER APPROACHES WITH RESPECT TO INSURED PLANS DESCRIBED IN THE SUPPLEMENTAL BRIEFING

The *Zubik* plaintiffs proposed that when an eligible employer with an insured plan requests insurance coverage that excludes contraceptive coverage to which it objects on religious grounds, the employer's issuer should be required to provide the required coverage through separate insurance policies that cover only contraceptives and in which women should have to affirmatively enroll. Pet. Supp. Br. 3-12.¹⁹ The Departments sought comments on whether this alternative procedure would resolve the RFRA claims of objecting organizations; whether it would be feasible for health insurance issuers and consistent with State insurance laws; what effect this approach would have on the ability of women enrolled in group health plans established by objecting employers to obtain seamless coverage for contraceptive services; and whether there might be alternatives other than contraceptive-only policies or affirmative enrollment requirements that would resolve the RFRA objections of objecting organizations.

In response to the RFI, objecting employers argued that to be truly independent, contraceptive coverage must be provided to women enrolled in health plans of objecting employers through separate insurance policies. The Departments identified no comments indicating that eliminating written notification by itself would be sufficient. In fact, several commenters stated that, even if the government were to eliminate the written notice requirement, the accommodation would have to be modified in other ways to satisfy their concerns. One commenter, quoting from the petitioners' brief in *Zubik*, stated that there must be an enrollment process that is distinct from (and not an automatic consequence of) enrolling in the employer's plan. Another commenter stated that the issuer or third party administrator should be required to provide eligible participants and beneficiaries with a separate enrollment card for contraceptive coverage that would require activation by each participant or beneficiary. The commenter stated that this should replace the current requirement that participants automatically receive coverage for contraceptive services. (For further discussion of this issue, see section below titled "Separate Enrollment Cards and Activation.")

A number of commenters emphasized the significant problems posed by requiring separate contraceptive-only coverage. Commenters identified several obstacles under State contract and insurance law. Comments submitted on behalf of issuers asserted that some State insurance regulators do not have authority under State law to approve single-benefit policies (other than dental or vision). The commenters also explained that cost-free contraception policies would not satisfy laws conditioning policy approval on a "reasonable premium" or constitute valid contracts because the prospective policyholder would not provide consideration. In addition, they commented that under State licensure laws, issuers that sell group coverage could not offer contraceptive-only policies to individual women because they are not licensed to offer coverage in the individual market and that State laws would prevent issuers licensed to issue group coverage in one State from issuing individual policies to employees of an eligible organization residing in other States.

¹⁹ As of the date of publication of this FAQ, petitioners' supplemental brief is available at http://www.scotusblog.com/wp-content/uploads/2016/04/Non-profits-response-to-Zubik-order-4-12-16.pdf. Petitioners' supplemental reply brief is available at http://www.scotusblog.com/wp-content/uploads/2016/04/Zubik-order-non-profits-reply-brief-4-20-161.pdf.

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In addition, several commenters stated that separate contraceptive coverage policies may have a different provider network from that of the group health plan that provides the women's other health benefits, which would mean that the separate contraceptive policies would not necessarily include women's regular doctors. One commenter stated that it would be costly and administratively burdensome for issuers to develop and implement new eligibility, enrollment, and claims-adjudication systems for contraception-only coverage, as they would differ from their existing systems. Several commenters also maintained that requiring women to seek out separate contraceptive coverage would create the same barriers in access that the Affordable Care Act's preventive services provision was designed to eliminate. The Departments agree these approaches would potentially undermine women's access to full and equal coverage, contrary to the statutory objective of reducing barriers to the use of important preventive services.

SELF-INSURED PLANS

The Supreme Court's supplemental briefing order in *Zubik* addressed only employers with "insured plans." In its supplemental brief, the government described the operation of the accommodation for self-insured plans and explained that an alternative process like the one the Court posited for insured plans could not work for the many employers with self-insured plans:

If an employer has a self-insured plan, the statutory obligation to provide contraceptive coverage falls only on the plan—there is no insurer with a preexisting duty to provide coverage. Accordingly, to relieve self-insured employers of any obligation to provide contraceptive coverage while still ensuring that the affected women receive coverage without the employer's involvement, the accommodation establishes a mechanism for the government to designate the employer's TPA [third party administrator] as a 'plan administrator' responsible for separately providing the required coverage under [ERISA]. That designation is made by the government, not the employer, and the employer does not fund, control, or have any other involvement with the separate portion of the ERISA plan administered by the TPA.

The government's designation of the TPA must be reflected in a written plan instrument. To satisfy that requirement, the accommodation relies on either (1) a written designation sent by the government to the TPA, which requires the government to know the TPA's identity, or (2) the self-certification form, which the regulations treat as a plan instrument in which the government designates the TPA as a plan administrator. There is no mechanism for requiring TPAs to provide separate contraceptive coverage without a plan instrument; self-insured employers could not opt out of the contraceptive-coverage requirement by simply informing their TPAs that they do not want to provide coverage for contraceptives. Gov't Supp. Br. 16-17 (citations omitted).

²⁰ Zubik, 2016 WL 1203818, at *2.

The *Zubik* plaintiffs also stated that an arrangement like the one posited in the Supreme Court's briefing order for insured plans could not work for self-insured plans. See Pet. Supp. Br. 16-17.

The RFI sought comment on any possible modifications to the current accommodation for self-insured plans, including self-insured church plans, which would resolve objecting organizations' RFRA objections while still providing women full and equal access to coverage. Specifically, the RFI asked whether there are any reasonable alternative means available under existing law by which the Departments could ensure that women enrolled in self-insured plans maintained by objecting employers receive separate contraceptive coverage that is not contracted, arranged, paid, or referred for by the objecting organization but that is provided through the same third party administrators that administer the rest of their health benefits.

The Departments did not identify any comments in response to the RFI that described a feasible pathway for oral notification to third party administrators with respect to self-insured plans to allow full and equal provision of contraceptive services to the women enrolled in those plans.

Some commenters noted that third party administrators often do not require separate notification, written or oral, that a self-insured plan will not be providing contraceptive coverage because other documentation, such as summary plan descriptions or provider contracts, will indicate that such coverage is not provided under the plan. However, without a written plan instrument, which is provided for in the current accommodation, there is no mechanism to designate a third party administrator as the ERISA plan administrator for purposes of arranging or providing separate payments for contraceptive services.

Many commenters suggested that cost-free contraception should be provided by the federal government through mechanisms that differ substantially from the procedure for insured plans described in the Supreme Court's supplemental briefing order. For example, some commenters suggested that for those self-insured plans that have third party administrators that are not able to provide separate cost-free contraceptive coverage to covered employees, the objecting employer could simply inform such third party administrators of the employer's objection and the government would "exempt" such self-insured plans and third party administrators from the requirement to provide separate cost-free contraceptive coverage. In those cases, commenters proposed that the government could provide coverage by having the employer notify HHS that the employer will not provide coverage and HHS would then coordinate with IRS to determine the identity of that employer's employees through W-2 or other tax information otherwise supplied by the objecting employer. These commenters suggest that such a program could be paid for by using credits against Federally-facilitated Exchange (FFE) user fees (which are already being used for the existing accommodation).

One commenter asserted that the federal government could directly subsidize the cost of purchasing contraceptive items and services for those employees who participate in an eligible organization's group health plan. However, as the Departments have previously indicated in rulemaking in response to comments suggesting that the government reimburse plan participants for the costs of contraceptive services,²¹ and in its briefs to the Supreme Court, this approach raises legal and

²¹ 80 FR 41317, 41328 (July 14, 2015).

practical obstacles to access to seamless coverage. Consistent with the statutory objective of promoting access to preventive services, such as contraceptive coverage, without cost-sharing, plan participants and beneficiaries should not be required to incur additional costs or burdens to receive access. Therefore, they should not be required to enroll in new programs or to surmount other hurdles to receive access to coverage.

SEPARATE ENROLLMENT CARDS AND ACTIVATION

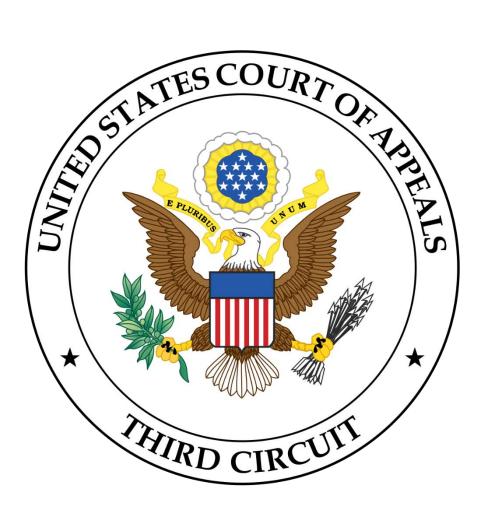
As stated above, several objecting organizations have suggested that some of their objections to the accommodation could be alleviated by providing a separate enrollment card for contraceptive coverage. Under this approach, women would not enroll in a separate insurance policy for contraceptive coverage, but would receive a separate enrollment card that would be automatically activated only when a woman who is enrolled in the group health plan attempts to obtain contraceptive benefits.

If objecting employers prefer the use of a separate enrollment card for contraceptive coverage, the Departments note that under the current accommodation regulations, issuers or third party administrators could provide a separate enrollment card for contraceptive coverage. The current regulations do not specify the manner in which an issuer or third party administrator provides "enrollment cards" or other means of providing similar, relevant information to enrollees, as long as the manner in which the card or other information is provided does not unduly inhibit or hamper access to the benefit. See 29 CFR 2560.503-1, which is applicable to ERISA plans and incorporated in 26 CFR 54.9815-2719(b)(2)(i), 29 CFR 2590.715-2719(b)(2)(i), and 45 CFR 147.136(b)(2)(i), which are applicable to non-grandfathered health plans and coverage. As stated above, under current rules, the issuer or third party administrator could provide a separate enrollment card for contraceptive coverage.²² The card could bear a different design to distinguish it from enrollment cards used to access services covered by the employer's group health plan, and could omit the name of the employer and/or the plan as well. The card could use the same identification number as is used on the enrollment card for services covered by the group health plan, or could have a different number provided there is a mechanism in place (such as by linking the two numbers in the issuer's or third party administrator's processing systems) that enables the issuer or third party administrator to easily identify enrollees. The foregoing arrangements are permissible if they are not used as an impediment to obtaining benefits and do not unduly inhibit or hamper a plan participant or beneficiary from accessing benefits provided pursuant to the accommodation (e.g., a plan procedure providing for the denial of benefits based on failure to present or "activate" the enrollment card or "opt in," even when the provider has otherwise verified participant status).

²² Id.

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Funding History | HHS.gov Case: 17-3752 Document: 003113290759 Page: 1 Date Filed: 07/12/2019 U.S. Department of Health & Human Services Office of Population Affairs **HHS A-Z Index Pregnancy** Reproductive Health Guidelines Title X **Prevention Performance About OPA** Grants & Funding Measures HHS Home > OPA > Title X Family Planning > About Title X Grants > Funding History Text Resize A A A **Title X Family Planning** Print **[27**] Share **About Title X Grants Funding History** Statutes and Regulations

The Title X Family Planning program ["Population Research and Voluntary Family Planning Programs" (Public Law 91-572)], was enacted in 1970 as Title X of the Public Health Service Act. Title X is the only federal grant program dedicated solely to providing individuals with comprehensive family planning and related preventive health services. The Title X program is designed to provide access to contraceptive services, supplies, and information to all who want and need them. By law, priority is given to persons from low-income families.

The Title X Family Planning program is administered within the Office of the Assistant Secretary for Health by the Office of Population Affairs (OPA).

For additional HHS budget information, please visit the HHS Office of Budget.

Funding History

Fiscal Year	Title X Appropriated Funds
2019	\$286,479,000
2018	\$286,479,000
2017	\$286,479,000
2016	\$286,479,000
2015	\$286,479,000
2014	\$286,400,000
2013	\$278,349,286 (Revised FY 13 Annualized CR level)
2012	\$297,400,000*

https://www.hhs.gov/opa/title-x-family-planning/about-title-x-grants/funding-history/index.html[7/15/2019 9:10:10 AM]

Legislative Mandates

Past Program Priorities

Service Delivery Improvement

Family Planning Annual Report

Program Policy Notices

Program Priorities

Funding History

Title X Grantees

Preventive Services

Training & Resources

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	2011	\$299,400,000
	2010	\$317,491,000
	2009	\$307,491,000
	2008	\$299,981,000
	2007	\$283,146,000
	2006	\$283,103,000
	2005	\$285,977,000
	2004	\$278,348,000
	2003	\$273,350,000
	2002	\$265,000,000
	2001	\$253,932,000
	2000	\$238,885,000
	1999	\$215,000,000
	1998	\$203,452,000
	1997	\$198,452,000
	1996	\$192,592,000
	1995	\$193,349,000
	1994	\$180,918,000
	1993	\$173,418,000
	1992	\$149,585,000
ine	1991	\$144,311,000
	1990	\$139,135,000
70,	1989	\$138,320,000
*60°	1988	\$139,663,000
	1987	\$142,500,000
	1986	\$136,372,000
Caldinieglonine	1985	\$142,500,000
	1984	\$140,000,000
	1983	\$124,088,000
	1982	\$124,176,000

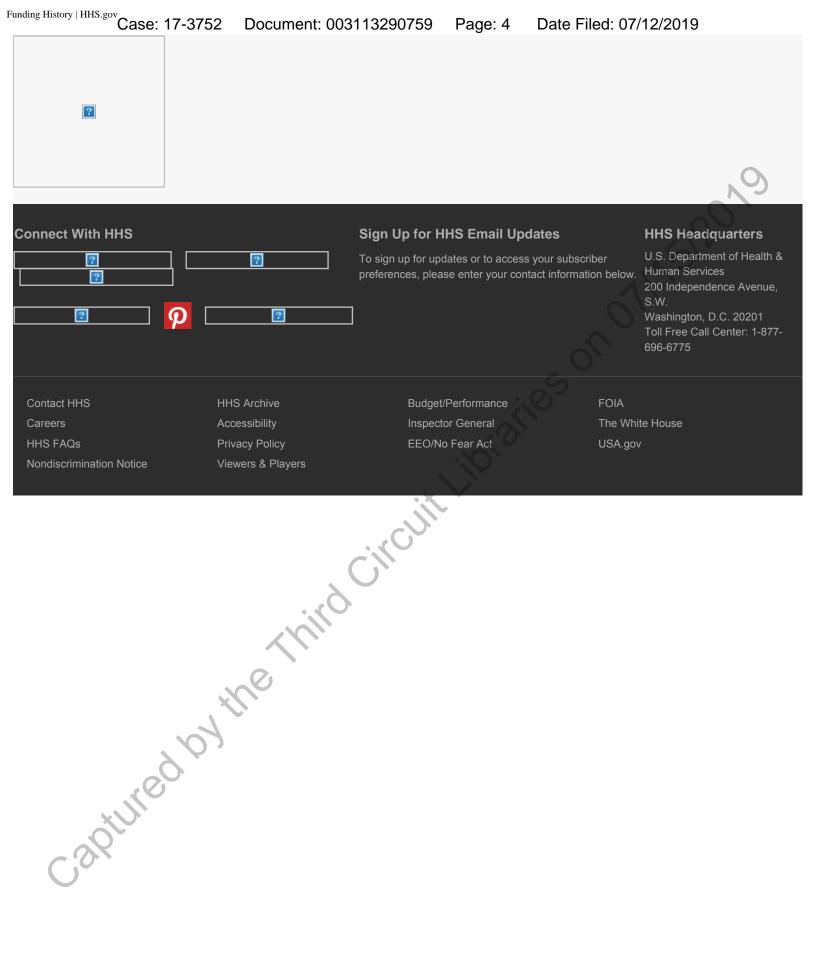
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1981	\$161,671,000
1980	\$162,000,000
1979	\$135,000,000
1978	\$135,000,000
1977	\$113,000,000
1976	\$100,615,000
1975	\$100,615,000
1974	\$100,615,000
1973	\$100,615,000
1972	\$61,815,000
1971	\$6,000,000

^{*}Congress imposed a 0.19% rescission, resulting in a net appropriation of \$296,838,000.

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Preventive care benefits for children | HealthCare.gov Case: 17-3752 Document: 003113290760 Page: 1 Date Filed: 07/12/2019



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Preventive care benefits for children

Most health plans must cover a set of preventive health services for children at no cost. This includes Marketplace and Medicaid coverage.

IMPORTANT

These services are free only when delivered by a doctor or other provider in your plan's network.

Coverage for children's preventive health services

All Marketplace health plans and many other plans must cover the following list of preventive services for children without charging you a copayment or coinsurance. This is true even if you haven't met your yearly deductible.

- 1. Alcohol, tobacco, and drug use assessments for adolescents
- 2. Autism screening for children at 18 and 24 months
- 3. Behavioral assessments for children ages: <u>0 to 11 months</u>, <u>1 to 4 years</u>, <u>5 to 10 years</u>, <u>11 to 14 years</u>, <u>15 to 17 years</u>
- 4. <u>Bilirubin concentration screening</u> for newborns
- 5. Blood pressure screening for children ages: <u>0 to 11 months</u>, <u>1</u> to 4 years , <u>5 to 10 years</u>, <u>11 to 14 years</u>, <u>15 to 17 years</u>
- 6. Blood screening for newborns

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- 7. Cervical dysplasia screening for sexually active females
- 8. Depression screening for adolescents beginning routinely at age 12
- 9. Developmental screening for children under age 3
- are 10. Dyslipidemia screening for all children once between 9 and 11 years and once between 17 and 21 years, and for children at higher risk of lipid disorders ages: 1 to 4 years, 5 to 10 years, 11 to 14 years, 15 to 17 years
- 11. Fluoride chemoprevention supplements for children without fluoride in their water source
- 12. Fluoride varnish for all infants and children as soon as teeth are present
- 13. Gonorrhea preventive medication for the eyes of all newborns
- 14. Hearing screening for all newborns; and for children once between 11 and 14 years, once between 15 and 17 years, and once between 18 and 21 years
- 15. Height, weight and body mass index (BMI) measurements for children ages: 0 to 11 months, 1 to 4 years, 5 to 10 years, 11 to 14 years, 15 to 17 years
- 16. Hematocrit or hemoglobin screening for all children
- 17. Hemoglobinopathies or sickle cell screening for newborns
- 18. Hepatitis B screening of for adolescents at high risk, including adolescents from countries with 2% or more Hepatitis B prevalence, and U.S.-born adolescents not vaccinated as infants and with at least one parent born in a region with 8% or more Hepatitis B prevalence: 11–17 years
- 19. HIV screening for adolescents at higher risk
- 20. Hypothyroidism screening for newborns
- 21. Immunization vaccines for children from birth to age 18 doses, recommended ages, and recommended populations vary:

- Diphtheria, Tetanus, Pertussis (Whooping Cough)
- Haemophilus influenza type b
- Hepatitis A
- Hepatitis B
- Human Papillomavirus (HPV)
- Inactivated Poliovirus
- Influenza (flu shot)
- Measles
- Meningococcal
- Pneumococcal
- Rotavirus
- Varicella (Chickenpox)
- Ratiles of other for 22. Iron supplements for children ages 6 to 12 months at risk for anemia
- 23. Lead screening for children at risk of exposure
- 24. Maternal depression screening for mothers of infants at 1, 2, 4, and 6-month visits
- 25. Medical history for all children throughout development ages: 0 to 11 months, 1 to 4 years, 5 to 10 years, 11 to 14 years, 15 to 17 years
- 26. Obesity screening and counseling
- 27. Oral health risk assessment for young children ages: 0 to 11 months, 1 to 4 years, 5 to 10 years
- 28. Phenylketonuria (PKU) screening for newborns
- 29. Sexually transmitted infection (STI) prevention counseling and screening for adolescents at higher risk
- 30. Tuberculin testing for children at higher risk of tuberculosis ages: 0 to 11 months, 1 to 4 years, 5 to 10 years, 11 to 14 years, 15 to 17 years

More information about preventive services iprailes on others. for children

- Preventive services for children age 0 to 11 months
- Preventive services for children age 1 to 4 years
- Preventive services for children age 5 to 10 years
- Preventive services for children age 11 to 14 years
- Preventive services for children age 15 to 17 years

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- Learn more about preventive care from the CDC
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