ACA COMPLIANCE OVERVIEW

Preventive Care Coverage Guidelines

The Affordable Care Act (ACA) requires non-grandfathered health plans and health insurance issuers to cover certain preventive health services without imposing cost-sharing requirements when the services are provided by in-network providers. These preventive health services include, for example, many cancer screenings, blood pressure, diabetes and cholesterol tests, vaccinations against diseases, and counseling on topics such as quitting smoking and losing weight. This coverage mandate also includes preventive health services for women, such as well-woman visits, breastfeeding support, domestic violence screening and contraceptives.

Plans and issuers may impose cost-sharing requirements on preventive care services that individuals receive from out-of-network providers. Also, plans and issuers may use reasonable medical management techniques to determine the frequency, method, treatment or setting for preventive care services, as long as they are not specified in the coverage guideline.

This ACA Overview describes the preventive care coverage guidelines that apply under the ACA.

LINKS AND RESOURCES

- Interim final rules from July 2010, relating to the coverage of preventive health services under the ACA.
- HRSA guidelines regarding women's preventive health care services.
- A list of recommended preventive services is available at: www.healthcare.gov/what-are-my-preventive-care-benefits.

Preventive Care Coverage

Under the ACA, non-grandfathered group health plans and issuers:

- Must cover certain preventive care services;
- May not charge copayments, coinsurance or deductibles for those services when delivered by an in-network provider; and
- May use reasonable medical management techniques when they are consistent with the ACA's preventive care guidelines.

Guidelines for Women

Additional coverage guidelines apply for women's preventive care services, such as:

- Well-woman visits
- Breastfeeding support
- Domestic violence screening
- Contraceptives

Coverage of Preventive Care Services

For plan years beginning on or after Sept. 23, 2010, non-grandfathered group health plans and issuers must cover certain preventive care services and may not charge copayments, coinsurance or deductibles for these services when delivered by an in-network provider. The recommended preventive care services covered by these requirements are:

- Evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force (USPSTF);
- Immunizations for routine use in children, adolescents and adults that are currently recommended by the Centers for Disease Control and Prevention (CDC);
- For infants, children and adolescents, evidence-informed preventive care and screenings provided for in the Health Resources and Services Administration (HRSA) guidelines; and
- For women, evidence-informed preventive care and screening provided in guidelines supported by HRSA.

Plans and issuers may impose cost-sharing requirements on preventive care services that individuals receive from out-of-network providers. Also, plans and issuers may use reasonable medical management techniques to determine the frequency, method, treatment or setting for preventive care services, as long as they are not specified in the recommendation or guideline.

The ACA's preventive care guidelines are periodically updated based on new medical research and recommendations. Updated guidelines generally take effect for plan years beginning on or after one year from the date the updated guideline is issued. However, coverage for newly recommended COVID-19 preventive care must be provided under an accelerated timeline—within 15 business days after the CDC's or USPSTF's recommendation. More information on the preventive care services that health plans and issuers must cover without cost sharing is available through HealthCare.gov.

UPDATE: Ongoing Litigation Regarding Preventive Care Mandate

On March 30, 2023, the U.S. District Court for the Northern District of Texas struck down a key component of the ACA's preventive care coverage mandate. The District Court ruled that preventive care coverage requirements based on an A or B rating by the USPSTF on or after March 23, 2010, violate the U.S. Constitution. The District Court also ruled that the requirement to cover HIV Preexposure Prophylaxis (PrEP) for high-risk individuals violates the plaintiffs' rights under Religious Freedom Restoration Act. Accordingly, the District Court granted an injunction against the enforcement of those requirements and vacated all related agency actions.

The Biden administration appealed the District Court's decision to the 5th Circuit Court of Appeals. On May 15, 2023, the 5th Circuit put enforcement of the District Court's ruling on hold and the parties to the lawsuit subsequently agreed that the 5th Circuit's enforcement stay will remain in effect pending the case's appeal. The 5th Circuit is expected to issue a decision by the end of 2023. It is uncertain whether the District Court's ruling will be reversed or upheld by the 5th Circuit. For now, non-grandfathered health plans and issuers should continue to cover, without cost sharing, the full range of preventive care services required by the ACA, including items or services that have an A or B recommendation by the USPSTF.

Specific Coverage Requirements

Office Visits

Interim final rules issued by the Departments clarify the cost-sharing requirements when a recommended preventive care service is provided during an office visit. Whether cost-sharing requirements may be imposed depends on whether the preventive care service is billed or tracked separately, and whether the preventive care service is the primary purpose of the office visit. Cost-sharing is permitted only if:

- The recommended preventive care service is billed separately (or is tracked as individual encounter data separately) from an office visit; or
- The recommended preventive care service is not billed separately from the office visit and the primary purpose of the office visit is not to obtain the recommended preventive care service.

Cost-sharing requirements are not allowed in cases where the recommended preventive care service is not billed separately, but it is the primary purpose of the office visit.

Examples

Example 1—An individual covered by a group health plan visits an in-network health care provider. While visiting the provider, the individual is given a cholesterol screening (a recommended preventive care service). The provider bills the plan for an office visit and for the laboratory work of the cholesterol screening test. The plan may not impose any cost-sharing requirements with respect to the laboratory work. Because the office visit is billed separately from the cholesterol test, the plan may impose cost-sharing requirements for the office visit.

Example 2—An individual covered by a group health plan visits an in-network health care provider to discuss recurring abdominal pain. During the visit, the individual has a blood pressure screening (a recommended preventive care service). The provider bills the plan for an office visit. The blood pressure screening was not the primary purpose of the visit. Therefore, the plan may impose a cost-sharing requirement for the office visit charge.

Example 3—A child covered by a group health plan visits an in-network pediatrician to receive an annual physical exam (a recommended preventive care service). During the office visit, the child receives additional items and services that are not recommended preventive services. The provider bills the plan for an office visit. The recommended preventive care service was not billed as a separate charge and was the primary purpose of the visit. Therefore, the plan may not impose a cost-sharing requirement for the office visit.

Tobacco Cessation Interventions

The USPSTF recommends that clinicians ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products. An FAQ issued in May 2014, clarifies what plans and issuers are expected to provide as preventive coverage for tobacco cessation interventions. The Departments will consider a group health plan or health insurance issuer to be in compliance with the requirement to cover tobacco use counseling and interventions, if, for example, the plan or issuer covers, without cost-sharing:

- Screening for tobacco use; and
- For those who use tobacco products, at least two tobacco cessation attempts per year. For this purpose, covering a cessation attempt includes coverage for:

- Four tobacco cessation counseling sessions of at least 10 minutes each (including telephone counseling, group counseling and individual counseling) without prior authorization; and
- All Food and Drug Administration (FDA)-approved tobacco cessation medications (including both prescription and over-the-counter medications) for a 90-day treatment regimen, when prescribed by a health care provider, without prior authorization.

The USPSTF updated its tobacco cessation guidance in 2021 to incorporate newer information, including evidence on the harms of e-cigarettes or vaping. The USPSTF continues to recommend that clinicians ask all adults about tobacco use, advise them to stop using tobacco, and provide behavioral interventions and FDA-approved pharmacotherapy for cessation to nonpregnant adults who use tobacco.

Coverage of Colonoscopies

FAQs issued by the Departments in May 2015, October 2015 and April 2016 clarified that, if a colonoscopy is scheduled and performed as a preventive screening procedure for colorectal cancer pursuant to the USPSTF recommendation, the plan or issuer is required to cover all of the following without cost sharing:

- Anesthesia services performed in connection with the preventive colonoscopy, if the attending provider determines that anesthesia would be medically appropriate for the individual;
- The required specialist consultation prior to the screening procedure if the attending provider determines that the pre-procedure consultation would be medically appropriate for the individual;
- Polyp removal performed during the screening procedure;
- Any pathology exam on a polyp biopsy performed in connection with the colonoscopy; and
- Bowel preparation medications prescribed for the colonoscopy by the provider.

In addition, FAQs from January 2022 provide that plans and issuers must cover, without cost sharing, a colonoscopy conducted after a positive non-invasive stool-based screening test or direct visualization screening test for colorectal cancer.

Coverage of Weight Management Services for Adult Obesity

According to an FAQ issued in October 2015, non-grandfathered plans and issuers must cover screening for obesity in adults without cost sharing. In addition, the USPSTF currently recommends intensive, multicomponent behavioral interventions for weight management for adult patients with a body mass index (BMI) of 30 kg/m2 or higher. The recommendation specifies that intensive, multicomponent behavioral interventions include, for example, the following:

- Group and individual sessions of high intensity (12 to 26 sessions in a year);
- Behavioral management activities, such as weight-loss goals;
- Improving diet or nutrition and increasing physical activity;
- Addressing barriers to change;
- Self-monitoring; and

- Strategizing how to maintain lifestyle changes.

While plans and issuers may use reasonable medical management techniques to determine the frequency, method, treatment or setting for a recommended preventive service (to the extent not specified in the recommendation or guideline regarding that preventive service) plans are not permitted to impose general exclusions that would encompass recommended preventive services.

HIV PrEP

On June 11, 2019, the USPSTF released a recommendation for HIV Preexposure Prophylaxis (PrEP) for high-risk individuals**,** which requires plans and issuers to cover HIV PrEP without cost sharing for plan years beginning on or after June 30, 2020. The Departments issued FAQs in July 2021 that provide the following guidance regarding this coverage:

- Plans and issuers are required to provide coverage without cost sharing for items or services that the USPSTF recommends should be received by a participant, beneficiary or enrollee **prior to being prescribed anti-retroviral medication** as part of the determination of whether that medication is appropriate for the individual and for ongoing follow-up and monitoring. This includes baseline and monitoring services such as HIV testing, Hepatitis B and C testing, creatinine testing, pregnancy testing, sexually transmitted infection (STI) screening and counseling, and adherence counseling.

- The USPSTF PrEP recommendation specifies the frequency of certain services for individuals specified in the recommendation. Plans and issuers may use reasonable medical management techniques to determine the frequency, method, treatment or setting for the provision of a recommended preventive service only to the extent not specified in the applicable recommendation.

Women's Preventive Care Services

In addition to the USPSTF's recommendations for preventive care services, health plans and issuers must cover preventive care services for women outlined in HRSA-supported guidelines. According to HHS, these guidelines help ensure that women receive a comprehensive set of preventive health services without having to pay a copayment, a deductible or coinsurance.

Contraceptive Coverage Mandate – Available Exemptions

The HRSA-supported guidelines recommend that adolescent and adult women have access to the full range of contraceptives and contraceptive care. According to the Departments, health plans and issuers must cover without cost sharing:

- At least one form of contraception in each of the categories listed in HRSA's guidelines (e.g., intrauterine devices with progestin, injectable contraceptives, oral contraceptives-combined pill, emergency contraception-levonorgestrel and sterilization surgery for women); and

- Any contraceptive services and FDA-approved, -cleared or -granted products that an individual's health care provider determines to be medically appropriate (including newer contraceptive products, regardless of whether they are included in HRSA's guidelines).

Exemptions to the ACA's contraceptive coverage requirement are available to religious employers and eligible employers who object to providing this coverage based on their sincerely held religious beliefs or moral convictions. An optional

accommodation approach is also available for employers who object to this coverage. The accommodation process allows an employer to avoid providing coverage for contraceptives under its health plan while requiring the employer's issuer or TPA, as applicable, to separately provide or arrange for this coverage.

Exemption for Churches

Group health plans of certain nonprofit religious employers (such as churches and other houses of worship) are exempt from the ACA's contraceptive coverage requirement. Under this exemption, eligible employers offering health coverage may decide whether or not to cover contraceptive services, consistent with their beliefs. A "religious employer" is defined as a nonprofit entity that is referred to in Internal Revenue Code (Code) Section 6033(a)(3)(A)(i) or (iii). This definition primarily includes churches, other houses of worship and their affiliated organizations.

Exemptions for Other Employers

On Nov. 7, 2018, the Departments issued the following two final rules to expand the number of employers who are eligible for an exemption from the ACA's contraceptive coverage mandate:

- **Objection based on religious beliefs**: The first final rule provides a broad exemption for employers who object to providing contraceptive coverage based on their sincerely held religious beliefs.
- **Objection based on moral convictions:** The second final rule provides an exemption for certain employers who object to providing contraceptive coverage based on their sincerely held moral convictions (but not religious beliefs).

In addition, the final rules changed the accommodation approach for employers who are eligible for an exemption so that it is a voluntary option instead of a mandatory process. Under the accommodation process, employers can exclude contraceptive coverage from their health plans, while participants and beneficiaries receive contraceptive coverage or payments arranged by their issuers or TPAs.

New Proposed Rule: On Jan. 20, 2023, the Departments released a proposed rule to expand access to contraceptive coverage without cost sharing. The proposed rule would **rescind the moral exemption** to covering contraceptives but retain the existing religious exemption. The proposed rule would also **establish a new way for individuals to access contraceptives at no cost** when they are enrolled in plans that qualify for an exemption and do not use the optional accommodations process. Under the proposed rule, individuals would be able to obtain contraceptive services at no cost directly from a willing health care provider. At this time, the rules are only in the proposed form and have not been finalized.