FAQS ABOUT AFFORDABLE CARE ACT AND CORONAVIRUS AID, RELIEF, AND ECONOMIC SECURITY ACT IMPLEMENTATION PART 59

April 13, 2023

Set out below are Frequently Asked Questions (FAQs) regarding implementation of the Affordable Care Act and the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), in light of the recent court decision in *Braidwood Management Inc. v. Becerra.*[1] These FAQs have been prepared jointly by the Departments of Labor, Health and Human Services (HHS), and the Treasury (collectively, the Departments), along with the Office of Personnel Management. These FAQs answer questions from stakeholders to help people understand the law and promote compliance. Previously issued FAQs are available at https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/aca-implementation-faqs and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs#Affordable_Care_Act.

COVERAGE OF PREVENTIVE SERVICES

Public Health Service (PHS) Act section 2713 and its implementing regulations relating to coverage of preventive services[2] require non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage to cover, without the imposition of any cost-sharing requirements, the following items or services:

- 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) with respect to the individual involved, except for the recommendations of the USPSTF regarding breast cancer screening, mammography, and prevention issued in or around November 2009;[3]
- Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) with respect to the individual involved;
- With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration (HRSA); and

[1] Civil Action No. 4:20-cv-00283-O (N.D. Tex. Mar. 30, 2023).

[2] *See* 26 CFR 54.9815-2713; 29 CFR 2590.715-2713; and 45 CFR 147.130.

[3] The USPSTF published updated breast cancer screening recommendations in January 2016. However, section 223 of title II of Division H of the Consolidated Appropriations Act, 2023 (Pub. L. 117-328) requires that for purposes of PHS Act section 2713, USPSTF recommendations relating to breast cancer screening, mammography, and prevention issued before 2009 remain in effect until January 1, 2025.

- With respect to women, such additional preventive care and screenings not described in PHS Act section 2713(a)(1) as provided for in comprehensive guidelines supported by HRSA.[4]

If a recommendation or guideline does not specify the frequency, method, treatment, or setting for the provision of a recommended preventive service, then the plan or issuer may use reasonable medical management techniques to determine any such coverage limitations. To the extent not specified in a recommendation or guideline, a plan or issuer may rely on the relevant clinical evidence base and established reasonable medical management techniques to determine the frequency, method, treatment, or setting for coverage of a recommended preventive item or service.[5] Additionally, plans and issuers subject to PHS Act section 2713 must cover, without cost sharing, items and services that are integral to the furnishing of a recommended preventive service, regardless of whether the item or service is billed separately.[6]

The District Court's Decision in *Braidwood*

On March 30, 2023, the United States District Court for the Northern District of Texas issued a final judgment in the case *Braidwood Management Inc. v. Becerra*[7] (*Braidwood* decision). The court held that the USPSTF's recommendations operating in conjunction with PHS Act section 2713(a)(1) violate the Appointments Clause of Article II of the United States Constitution and are therefore unlawful. The court vacated any and all actions taken by the Departments to implement or enforce PHS Act section 2713(a)(1)'s preventive service coverage requirements in response to an "A" or "B" recommendation by the USPSTF on or after March 23, 2010, and enjoined the Departments from implementing or enforcing PHS Act section 2713(a)(1)'s preventive service coverage requirements in response to an "A" or "B" rating from the USPSTF in the future.[8] The Departments disagree with the District Court's ruling and are considering all available options in consultation with the Department of Justice; the Department of Justice filed a notice of appeal on March 31, 2023, and a motion for a stay on April 12, 2023.

The Departments are issuing these FAQs to provide initial guidance on how the *Braidwood* decision affects the requirement to cover preventive services without cost sharing under PHS Act section 2713. The Departments anticipate issuing additional guidance in the future to further address plans' and issuers' obligations under PHS Act section 2713(a)(1) in light of the *Braidwood* decision.

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[4] For exemptions and accommodations with respect to contraceptive coverage, *see* 26 CFR 54.9815-2713A; 29 CFR 2590.715-2713A; and 45 CFR 147.131 through 147.133.

[5] *See* 26 CFR 54.9815-2713(a)(4); 29 CFR 2590.715-2713(a)(4); and 45 CFR 147.130(a)(4).

[6] *See* 85 FR 71142, 71174 (Nov. 6, 2020).

[7] Civil Action No. 4:20-cv-00283-O (N.D. Tex. Mar. 30, 2023).

[8] The *Braidwood* court also concluded that the requirement under PHS Act section 2713(a)(1) to cover PrEP with effective antiretroviral therapy for persons who are at high risk of HIV acquisition, consistent with a June 11, 2019 USPSTF recommendation, violated the rights of some of the plaintiffs before the court under the Religious Freedom Restoration Act. The court enjoined the Departments from implementing or enforcing the PrEP coverage requirement as against these plaintiffs.

Q1: Which USPSTF-recommended items and services are affected by the *Braidwood* decision?

The *Braidwood* decision applies to items and services required to be covered by plans and issuers without cost sharing "in response to an 'A' or 'B' recommendation by the [US]PSTF on or after March 23, 2010."[9]

This means that plans and issuers must continue to cover, without cost sharing, items and services recommended with an "A" or "B" rating by the USPSTF before March 23, 2010. The Departments recognize that the USPSTF has updated a significant number of the recommendations since March 23, 2010, such as by changing their rating from an "A" or "B," changing the recommendation so that it applies to different populations, changing the recommendation to refer to a different subset of items or services, or rescinding the recommendation. The Departments anticipate providing additional guidance with respect to the pre-March 23, 2010 recommendations.

Q2: Following the *Braidwood* decision, are plans and issuers required under PHS Act section 2713 to continue to provide coverage, without cost sharing, for items and services recommended with an "A" or "B" rating by the USPSTF on or after March 23, 2010?

The *Braidwood* decision prevents the Departments from implementing and enforcing PHS Act section 2713(a)(1)'s coverage requirements for items and services recommended with an "A" or "B" rating by the USPSTF on or after March 23, 2010. However, the Departments strongly encourage plans and issuers to continue to cover such items and services without cost sharing.[10] Preventive services help people avoid acute illness, identify and treat chronic conditions, reduce the risk of cancer or facilitate early detection, and improve health. Coverage for USPSTF-recommended preventive services has reduced disparities in, and improved, disease and condition screening rates.[11] Analysis suggests that 60% of participants, beneficiaries, and enrollees use a preventive service each year[12] and have come to rely on receiving coverage without cost sharing for preventive items and services. The *Braidwood* decision does not preclude plans and issuers from continuing to provide the full extent of such coverage.

Q3: Does the *Braidwood* decision affect the requirements under PHS Act section 2713(a)(2)-(4) to provide coverage without cost sharing for immunizations recommended by ACIP or preventive care and screenings for infants, children, and adolescents, as well as for women as provided for in comprehensive guidelines supported by HRSA?

No. The *Braidwood* court did not enjoin enforcement of PHS Act section 2713 or vacate its implementing regulations and guidance related to immunizations recommended by ACIP and preventive care and screenings provided for in comprehensive guidance supported by HRSA

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[9] *Braidwood Management Inc. v. Becerra,* Civil Action No. 4:20-cv-00283-O (N.D. Tex. Mar. 30, 2023).

[10] *See also* Q7.

[11] *See* HHS Assistant Secretary for Planning and Evaluation, Access to Preventive Services without Cost-Sharing: Evidence from the Affordable Care Act (Issue Brief No. HP-202201) (Jan. 11, 2022), available at https://aspe.hhs.gov/sites/default/files/documents/786fa55a84e7e3833961933124d70dd2/preventive-services-ib-2022.pdf.

[12] Amin, K., et. al., Preventive Services Use Among People with Private Insurance Coverage. Peterson-KFF Health System Tracker (Mar. 20, 2023), available at https://www.healthsystemtracker.org/brief/preventive-services-use-among-people-with-private-insurance-coverage/.

(including, but not limited to, contraceptive coverage), so those requirements are not impacted by the *Braidwood* decision. Plans and issuers must continue to cover such items and services—which include, but are not limited to, immunizations recommended by ACIP, as well as contraceptive services, breastfeeding services and supplies, cervical cancer screening, and pediatric preventive care recommended by HRSA—without cost sharing, consistent with all applicable regulations and guidance.

Some of these recommendations and guidelines overlap with items and services recommended with an "A" or "B" rating by the USPSTF on or after March 23, 2010. To the extent a recommendation is made by ACIP or provided for in comprehensive guidelines supported by HRSA, plans and issuers are required to provide coverage, without cost sharing, for these items and services, even if they also are items and services recommended with an "A" or "B" rating by the USPSTF on or after March 23, 2010.[13]

Q4: Does the *Braidwood* decision prevent states from enacting or enforcing state laws that require health insurance issuers offering group or individual health insurance coverage to provide coverage, without cost sharing, for items and services recommended with an "A" or "B" rating by the USPSTF on or after March 23, 2010?

No. The *Braidwood* decision generally does not affect the application of state laws that require health insurance issuers offering group or individual health insurance coverage to provide coverage without cost sharing of items and services recommended with an "A" or "B" rating by the USPSTF on or after March 23, 2010, and issuers generally must continue to comply with any such applicable state laws.[14]

Q5: To the extent a plan or issuer is permitted and elects to make changes to its coverage, may it make those changes in the middle of the plan or policy year?

As stated in Q2, although the *Braidwood* decision prevents the Departments from implementing and enforcing PHS Act section 2713(a)(1)'s coverage requirements for items and services recommended with an "A" or "B" rating by the USPSTF on or after March 23, 2010, plans and issuers are not required to make any changes to coverage or cost sharing as a result of the *Braidwood* decision, and the Departments strongly encourage plans and issuers to continue to cover, without cost sharing, items and services affected by the court's decision.

Plans and issuers should consider other provisions of applicable federal and state law when determining whether changes to the terms of the plan or coverage may be made during a plan or policy year. Further, plans and issuers, including self-insured plans, may still be required to cover the full scope of recommended preventive services under other legal and contractual requirements. This includes any applicable state law requirements, as well as the terms of any contracts, including

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[13] The ACIP immunization recommendations are available at https://www.cdc.gov/vaccines/acip/recommendations.html. The women's preventive service guidelines supported by HRSA are available at https://www.hrsa.gov/womens-guidelines. The preventive service guidelines for infants, children, and adolescents supported by HRSA are available at https://downloads.aap.org/AAP/PDF/periodicity_schedule.pdf.

[14] In addition, issuers generally must continue to comply with applicable state laws that prohibit issuers from modifying coverage other than at the time of coverage renewal. *See* Q5.

collective bargaining agreements or other requirements, that may prevent changes during a plan or policy year.

Q6: Must plans and issuers notify participants, beneficiaries, and enrollees if they change the terms of their coverage with respect to USPSTF-recommended items and services that were affected by the *Braidwood* decision?

To the extent a plan or issuer is permitted and elects to make changes to coverage, the plan or issuer must comply with applicable notice requirements when making any changes to the terms of coverage with respect to items and services recommended by the USPSTF. This includes complying with the requirements under PHS Act section 2715(d)(4) and final rules issued by the Departments regarding the Summary of Benefits and Coverage (SBC), which provide that if a group health plan or health insurance issuer offering group or individual health insurance coverage makes a material modification (as defined under Employee Retirement Income Security Act (ERISA) section 102) to any of the terms of the plan or coverage that would affect the content of the SBC, that is not reflected in the most recently provided SBC, and that occurs other than in connection with a renewal or reissuance of coverage, the plan or issuer must provide notice of the modification to enrollees not later than 60 days prior to the date on which the modification will become effective.[15]

Plans and issuers also must comply with any additional applicable notice requirements, including requirements that apply in the event of a reduction in covered benefits or services or other modification of plan terms. This includes the requirement that a plan subject to ERISA generally must provide a summary of material reduction in covered services or benefits within 60 days of adoption of a material reduction[16] in group health plan services or benefits.[17]

HIGH DEDUCTIBLE HEALTH PLANS AND SAFE HARBOR FOR PREVENTIVE CARE

Generally, a health plan will fail to be treated as a high deductible health plan (HDHP) if it provides benefits for any year before the applicable minimum deductible for that year is satisfied. However, Code section 223(c)(2)(C) provides a safe harbor for the absence of a preventive care deductible. That section states, "[a] plan shall not fail to be treated as a high deductible health plan by reason of failing to have a deductible for preventive care (within the meaning of Social Security Act section 1871, except as otherwise provided by the Secretary)." Thus, an HDHP may provide preventive care benefits without a deductible or with a deductible below the minimum annual deductible under Code section 223(c)(2)(C).

Notice 2004-23[18] describes preventive care services that may be provided by an HDHP before the satisfaction of the minimum annual deductible under the statutory safe harbor, including an appendix of preventive care screening services. The list of preventive care services that may be

[15] PHS Act section 2715(d)(4); 26 CFR 54.9815-2715(b); 29 CFR 2590.715-2715(b); and 45 CFR147.200(b). PHS Act section 2715 is incorporated into ERISA section 715 and Internal Revenue Code (Code) section 9815. The notice of modification must be provided in a form that is consistent with the rules of 26 CFR 54.9815-2715(a)(4), 29 CFR 2590.715-2715(a)(4), and 45 CFR 147.200(a)(4).
[16] The term "material reduction" is defined in 29 CFR 2520.104b-3(d)(3).
[17] *See* 29 CFR 2520.104b-3(d)(2) regarding the 90-day alternative rule for furnishing the required information.
[18] 2004-15 IRB 725.

provided by an HDHP under the safe harbor has been expanded in several subsequent notices.[19] Notice 2013-57[20] clarifies that preventive care for purposes of Code section 223(c)(2)(C) also includes preventive services required to be covered by a plan or issuer without the imposition of cost-sharing requirements under PHS Act section 2713.

Q7: Following the *Braidwood* decision, may an HDHP continue to provide benefits for items and services recommended with an "A" or "B" rating by the USPSTF on or after March 23, 2010 before the minimum annual deductible under Code section 223 has been met?

Yes. Until further guidance is issued, items and services recommended with an "A" or "B" rating by the USPSTF on or after March 23, 2010, will be treated as preventive care for purposes of Code section 223(c)(2)(C), regardless of whether these items and services must be covered, without cost sharing, under PHS Act section 2713.

RAPID COVERAGE OF PREVENTIVE SERVICES AND VACCINES FOR CORONAVIRUS

Section 3203 of the CARES Act[21] requires non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage to cover, without cost-sharing requirements, any qualifying coronavirus preventive service pursuant to section 2713(a) of the PHS Act and its implementing regulations (or any successor regulations). Under the statute, the term "qualifying coronavirus preventive service" means an item, service, or immunization that is intended to prevent or mitigate COVID-19 and that is:

- An evidence-based item or service that has in effect a rating of "A" or "B" in the current recommendations of the USPSTF; or
- An immunization that has in effect a recommendation from ACIP with respect to the individual involved.

Coverage of a qualifying coronavirus preventive service must begin 15 business days after the date on which an applicable recommendation is made by USPSTF or ACIP.

Q8: How does the *Braidwood* decision affect the requirement under CARES Act section 3203 to cover qualifying coronavirus preventive services?

As stated in Q3, the *Braidwood* decision does not change the requirement to cover without cost sharing immunizations recommended by ACIP. Therefore, plans and issuers must continue to provide coverage, without cost sharing, for any qualifying coronavirus preventive service that is an immunization that has in effect a recommendation from ACIP with respect to the individual involved, including COVID-19 vaccines and their administration.[22] As of the date of these FAQs,

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[19] *See* Notice 2004-50, Q&As 26-27 (2005-33 IRB. 196); *see also* Notice 2019-45 (2019-32 IRB 593).
[20] 2013-40 IRB 293.
[21] Pub. L. 116-136 (2020).
[22] This includes COVID-19 vaccines furnished after the end of the COVID-19 public health emergency. *See* FAQs about Families First Coronavirus Response Act, Coronavirus Aid, Relief, and Economic Security Act, and Health Insurance Portability and Accountability Act Implementation Part 58 (Mar. 29, 2023), Q4, available at https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-58.pdf and https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/downloads/faqs-part-58.pdf.

the USPSTF has not recommended any qualifying coronavirus preventive services with an "A" or "B" rating, so there is no impact to plans' and issuers' coverage of these services.

FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM

The Federal Employees Health Benefits statute, at 5 U.S.C § 8902, provides the Office of Personnel Management (OPM) with broad authority to negotiate for benefit plans for Federal employees. In particular, the statute provides that OPM "may contract with qualified carriers" and that "each contract … shall contain a detailed statement of benefits offered … *as [OPM] considers necessary or desirable*." 5 U.S.C § 8902(a), (d) (emphasis added). OPM has required inclusion of preventive services based on quality industry standards prior to the Affordable Care Act, as described in FEHB Carrier Letters pre-dating the Affordable Care Act.

Q9: Are carriers offering plans in the Federal Employees Health Benefits Program required to continue to cover items and services recommended with an "A" or "B" rating by the USPSTF on or after March 23, 2010?

Yes. The FEHB statute, 5 U.S.C § 8902, provides OPM with broad authority to negotiate for benefit plans for Federal employees. Accordingly, as set forth in Carrier Letter 2019-01, OPM will continue to require coverage, without cost sharing, of all evidence-based items and services that have in effect a rating of "A" or "B" in the current recommendations of the USPSTF, including those recommended on or after March 23, 2010.[23]

[23] U.S. Office of Personnel Management, FEHB Program Carrier Letter, Letter No. 2019-01 (Mar. 14, 2019), available at https://www.opm.gov/healthcare-insurance/healthcare/carriers/2019/2019-01.pdf.