

FAQS ABOUT AFFORDABLE CARE ACT IMPLEMENTATION PART 50, HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT AND CORONAVIRUS AID, RELIEF, AND ECONOMIC SECURITY ACT IMPLEMENTATION

October 4, 2021

Set out below are Frequently Asked Questions (FAQs) regarding implementation of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Affordable Care Act. These FAQs have been prepared jointly by the Departments of Labor, Health and Human Services (HHS), and the Treasury (collectively, the Departments). Like previously issued FAQs (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/ccio/resources/fact-sheets-and-faqs#Affordable_Care_Act), these FAQs answer questions from stakeholders to help people understand the law and benefit from it, as intended.

Rapid Coverage of Preventive Services for Coronavirus

Section 3203 of the CARES Act and its implementing regulations¹ require 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 Public Health Service Act (PHS Act) and its implementing regulations (or any successor regulations). The term “qualifying coronavirus preventive service” means an item, service, or immunization that is intended to prevent or mitigate coronavirus disease 2019 (COVID-19) and that is, with respect to the individual involved—

- An evidence-based item or service that has in effect a rating of “A” or “B” in the current recommendations of the United States Preventive Services Task Force (USPSTF); or
- An immunization that has in effect a recommendation from the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) (regardless of whether the immunization is recommended for routine use).

¹ Pub. L. No. 116-136 (2020); 26 CFR 54.9815-2713T(a)(1)(v), 29 CFR 2590.715-2713(a)(1)(v), and 45 CFR 147.130(a)(1)(v).

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law.

Plans and issuers must cover qualifying coronavirus preventive services without cost sharing starting no later than 15 business days (not including weekends or holidays) after the date the USPSTF or ACIP makes an applicable recommendation regarding a qualifying coronavirus preventive service. A recommendation from ACIP is considered in effect after it has been adopted by the Director of the CDC.

The Departments are issuing the following FAQs in response to the December 12, 2020 adoption by the Director of the CDC of the ACIP recommendation for vaccination with COVID-19 vaccines within the scope of the Emergency Use Authorization (EUA) or Biologics License Application (BLA) for the particular vaccine.

Q1: How does the December 12, 2020 ACIP recommendation impact when plans and issuers must provide coverage without cost sharing for COVID-19 vaccines under section 3203 of the CARES Act and its implementing regulations?

Plans and issuers must now cover COVID-19 vaccines and their administration, without cost sharing, immediately once the particular vaccine becomes authorized under an EUA or approved under a BLA, and according to the scope of the applicable EUA or BLA.

In a December 12, 2020 meeting, ACIP recommended: “For purposes of ACIP’s role under the Affordable Care Act, ACIP recommends use of COVID-19 vaccines within the scope of the Emergency Use Authorization or Biologics License Application for the particular vaccine.”² On the same day, the Director of the CDC adopted this ACIP recommendation. Although ACIP has made additional recommendations regarding COVID-19 vaccines since December 12, 2020, none of those recommendations affect plan and issuer coverage obligations regarding COVID-19 vaccines under the preventive services regulations, and therefore the December 12, 2020 recommendation remains in effect for this purpose.

The requirement under section 3203 of the CARES Act for plans and issuers to cover COVID-19 vaccines consistent with this ACIP recommendation became effective 15 business days after the December 12, 2020 adoption by the CDC. Therefore, effective January 5, 2021, plans and issuers must cover, without cost sharing, any COVID-19 vaccine authorized under an EUA or approved under a BLA by the FDA immediately upon the vaccine becoming authorized or approved. This coverage must be provided consistent with the scope of the EUA or BLA for the particular vaccine, including any EUA or BLA amendment, such as to allow for the administration of an additional dose to certain individuals, administration of booster doses, or the expansion of the age demographic for whom the vaccine is authorized or approved.

² See <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/slides-12-12/COVID-04-VOTE-508.pdf>. See also CDC Adult and Child and Adolescent Immunization Schedules, incorporating the December 12, 2020 ACIP recommendation, respectively, at <https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf> and <https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf>.

The Departments' prior guidance, FAQs about Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 44 (FAQs Part 44),³ issued on February 26, 2021, did not explicitly address the general ACIP recommendation for COVID-19 vaccines. In addition, the Departments understand that plans and issuers may be aware of subsequent ACIP recommendations and that it may be unclear which particular ACIP recommendations are relevant for purposes of triggering a coverage obligation under section 3203 of the CARES Act. This FAQ is intended to notify plans and issuers that the December 12, 2020 ACIP recommendation is the applicable recommendation for purposes of the definition of qualifying coronavirus preventive services under section 3203 of the CARES Act and its implementing regulations. Because plans and issuers may reasonably not have understood when coverage without cost sharing was required to begin under section 3203 of the CARES Act for COVID-19 vaccines authorized or approved (or for which the EUA or BLA was amended) since the December 12, 2020 recommendation was adopted, the Departments will only enforce the timing requirement to cover, without cost sharing, any COVID-19 vaccine authorized under an EUA or approved under a BLA by the FDA immediately upon the vaccine becoming authorized or approved (or the EUA or BLA being amended) prospectively, consistent with the scope of the particular EUA or BLA, to the extent additional coverage beyond what was articulated in previous guidance is required.⁴

Q2: Does FAQs Part 44, Q8, continue to apply?

FAQs Part 44, Q8, which provided guidance from the Departments on when plans and issuers must begin providing coverage of COVID-19 vaccines, is superseded to the extent it provides that the coverage requirement effective date is related to the vaccine-specific recommendations of ACIP, and notations will be made on the HHS and Department of Labor websites to reflect this modification.

HIPAA Nondiscrimination and Wellness Programs

Under PHS Act section 2705,⁵ Employee Retirement Income Security Act (ERISA) section 702, Internal Revenue Code (Code) section 9802, and the Departments' implementing regulations, plans and issuers are generally prohibited from discriminating against participants, beneficiaries,

³ See FAQs about Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 44 (Feb. 26, 2021), available at <https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-44.pdf> and <https://www.cms.gov/files/document/faqs-part-44.pdf>.

⁴ The Departments note that all organizations and providers participating in the CDC COVID-19 Vaccination Program (which currently includes any provider administering COVID-19 vaccines) must administer COVID-19 vaccines at no out-of-pocket cost to the individual receiving the vaccine. For more information on the CDC COVID-19 Vaccination Program, see <https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html>.

⁵ Section 1201 of the Affordable Care Act amended and moved the nondiscrimination and wellness provisions of the PHS Act from section 2702 to section 2705, and extended the nondiscrimination provisions to issuers offering individual health insurance coverage. The Affordable Care Act also added section 715(a)(1) to ERISA and section 9815(a)(1) to the Code to incorporate the provisions of part A of title XXVII of the PHS Act, including PHS Act section 2705, into ERISA and the Code and make these provisions applicable to group health plans and group health insurance issuers.

and enrollees in eligibility, premiums, or contributions based on a health factor.⁶ With respect to group health plans, an exception to this general prohibition allows premium discounts, rebates, or modification of otherwise applicable cost-sharing requirements (including copayments, deductibles, and coinsurance) in return for adherence to certain programs of health promotion and disease prevention, commonly referred to as wellness programs.

On June 3, 2013, the Departments issued final wellness program regulations⁷ under PHS Act section 2705 and the parallel provisions of ERISA and the Code that address the requirements for wellness programs provided in connection with group health coverage. Among other things, the final wellness program regulations set the maximum permissible reward (or penalty) under a health-contingent wellness program that is part of a group health plan (and any related health insurance coverage) at 30 percent of the cost of coverage (or 50 percent for wellness programs designed to prevent or reduce tobacco use).⁸ The final wellness program regulations also address the reasonable design of health-contingent wellness programs, and, with respect to rewards offered under such programs, the reasonable alternatives that must be offered to avoid prohibited discrimination.

In addition, under section 4980H of the Code, employers may be liable for employer shared responsibility payments if they offer coverage that is not affordable. Under 26 CFR 1.36B-2(c)(3)(v)(A)(4), nondiscriminatory wellness program incentives offered by an employer-sponsored plan that affect premiums are treated as “not earned” for the purpose of assessing affordability, with the exception of incentives related exclusively to tobacco use. In other words, those wellness program incentives unrelated to tobacco use that provide discounts to employees are disregarded in assessing affordability, while those incentives unrelated to tobacco use that impose surcharges on employees are taken into account in assessing affordability.

Recently, stakeholders have asked whether group health plans and issuers can provide incentives to encourage individuals to receive COVID-19 vaccines. The Departments are issuing these FAQs to respond to stakeholder questions.

⁶ The statute and its implementing regulations set forth eight health status-related factors, which the 2006 regulations refer to as “health factors” for simplicity. Under the statute and the regulations, the eight health factors are health status, medical condition (including both physical and mental illnesses), claims experience, receipt of health care, medical history, genetic information, evidence of insurability (including conditions arising out of acts of domestic violence), and disability. 71 FR 75014 (Dec. 13, 2006) (the 2006 regulations). In the Departments’ view, “[t]hese terms are largely overlapping and, in combination, include any factor related to an individual’s health.” 66 FR 1379 (Jan. 8, 2001).

⁷ See 78 FR 33158 (Jun. 3, 2013). These final wellness program regulations update earlier regulations implementing the nondiscrimination and wellness program provisions established under the 2006 regulations. 71 FR 75014 (Dec. 13, 2006). The Affordable Care Act amended the statutory nondiscrimination and wellness provisions to in large part reflect the 2006 regulations regarding wellness programs.

⁸ The cost of coverage is determined based on the total amount of employer and employee contributions towards the cost of coverage for the benefit package under which the employee is (or the employee and any dependents are) receiving coverage. 26 CFR 54.9802-1(f)(3)(ii) and (f)(4)(ii), 29 CFR 2590.702-1(f)(3)(ii) and (f)(4)(ii), and 45 CFR 146.121(f)(3)(ii) and (f)(4)(ii).

Q3: May a group health plan (or health insurance issuer offering coverage in connection with a group health plan) offer participants in the plan a premium discount for receiving a COVID-19 vaccination?

Yes, if the premium discount complies with the final wellness program regulations.^{9,10} A premium discount that requires an individual to perform or complete an activity related to a health factor, in this case obtaining a COVID-19 vaccination, to obtain a reward would be considered a wellness program that must comply with the five criteria for activity-only wellness programs described in paragraph (f)(3) of the final wellness program regulations.¹¹

To satisfy these criteria, a wellness program that provides a premium discount to individuals who obtain a COVID-19 vaccination must be reasonably designed to promote health or prevent disease and must provide a reasonable alternative standard to qualify for the discount. For example, the wellness program may offer a waiver or the right to attest to following other COVID-19-related guidelines to individuals for whom it is unreasonably difficult due to a medical condition or medically inadvisable to obtain the COVID-19 vaccination in order to qualify for the full reward. The plan must also provide notice of the availability of the reasonable alternative standard under the wellness program. Further, the reward the plan provides in connection with the vaccine incentive program must not exceed 30 percent of the total cost of employee-only coverage and must give individuals eligible for the program the opportunity to qualify for the reward under the program at least once per year.

⁹ Compliance with the final wellness program regulations is not determinative of compliance with any other provision of the PHS Act, ERISA, the Code, or any other State or Federal law, including the Americans with Disabilities Act (ADA) and the Genetic Information Nondiscrimination Act (GINA). See 26 CFR 54.9802-1(h), 29 CFR 2590.702(h), 45 CFR 146.121(h), 29 CFR 1630, and 29 CFR 1635. Furthermore, these FAQs address wellness program incentives provided by group health plans and health insurance issuers and do not address incentives offered by employers as part of workplace policies and unrelated to their group health plan. Employers considering the adoption of COVID-19 vaccination programs that provide incentives should consult Section K of the Equal Employment Opportunity Commission's [What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws](#). Questions K.16. through K.21 restate the current guidance under Title I of the ADA and Title II of GINA.

¹⁰ See 78 FR 33158 (Jun. 3, 2013).

¹¹ The final wellness program regulations provide that a health-contingent wellness program that is an activity-only wellness program does not violate the wellness program provisions only if all of the following requirements are satisfied: (1) the program must give individuals eligible for the program the opportunity to qualify for the reward under the program at least once per year; (2) the reward for the activity-only wellness program, together with the reward for other health-contingent wellness programs with respect to the plan, must not exceed the applicable percentage (defined as 30 percent (or 50 percent for wellness programs designed to prevent or reduce tobacco use) of the total cost of employee-only coverage under the plan); (3) the program must be reasonably designed to promote health or prevent disease; (4) the full reward under the activity-only wellness program must be available to all similarly situated individuals (which includes allowing a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual for whom, for that period, it is unreasonably difficult due to a medical condition or medically inadvisable to satisfy the otherwise applicable standard); and (5) the plan or issuer must disclose in all plan materials describing the terms of an activity-only wellness program the availability of a reasonable alternative standard to qualify for the reward (and, if applicable, the possibility of waiver of the otherwise applicable standard), including contact information for obtaining a reasonable alternative standard and a statement that recommendations of an individual's personal physician will be accommodated. See 26 CFR 54.9802-1(f)(3), 29 CFR 2590.702(f)(3), and 45 CFR 146.121(f)(3).

Example: A group health plan offers a 25 percent premium discount of the cost of employee-only coverage to all participants who receive a COVID-19 vaccination in accordance with the recommendations of ACIP (and does not offer any other reward under other health-contingent wellness programs with respect to the plan). To help facilitate participants receiving the vaccination, the plan also maintains a toll-free hotline to answer questions about COVID-19 vaccination and offer assistance to schedule appointments to receive a COVID-19 vaccination. The plan provides the same premium discount to individuals for whom it is unreasonably difficult due to a medical condition or medically inadvisable to obtain a COVID-19 vaccination if the individual attests to complying with the CDC's mask guidelines for unvaccinated individuals. The plan also provides notice of the availability of this alternative to all participants. Participants may qualify annually for this premium discount.

Conclusion: The vaccine incentive program meets the criteria to be an activity-only health-contingent wellness program. The reward the plan provides in connection with the vaccine incentive program does not exceed 30 percent of the total cost of employee-only coverage and the opportunity to qualify is offered annually. The plan provides a reasonable alternative standard to qualify for the reward, in this case the opportunity to attest to complying with the CDC's mask guidelines, to individuals for whom it is unreasonably difficult due to a medical condition or medically inadvisable to obtain a COVID-19 vaccination, and the plan provides notice of the availability of the reasonable alternative standard. This program is also reasonably designed to promote health and prevent disease (and is not a subterfuge for discriminating based on a health factor), as the program rewards individuals who obtain a COVID-19 vaccination, while the reasonable alternative standard is not overly burdensome, and is also designed to prevent infection with SARS-CoV-2, the virus that causes COVID-19. Further, the plan's maintenance of a toll-free hotline to provide information about the COVID-19 vaccine and assistance with meeting the underlying standard (in this case, receiving a COVID-19 vaccination or fulfilling the reasonable alternative) are additional facts and circumstances demonstrating that the program is reasonably designed to promote health or prevent disease because they help ensure that the program is not overly burdensome.

Q4: May a group health plan or health insurance issuer condition eligibility for benefits or coverage for otherwise covered items or services to treat COVID-19 on participants, beneficiaries, or enrollees being vaccinated?

No. PHS Act section 2705, ERISA section 702, Code section 9802, and the Departments' implementing regulations generally prohibit plans and issuers from discriminating against participants, beneficiaries, and enrollees in eligibility, premiums, or contributions based on a health factor.¹² The Departments' implementing regulations state that rules for eligibility include, among other things, rules related to benefits (including rules related to covered benefits

¹² As amended by the Affordable Care Act, the nondiscrimination provisions under PHS Act section 2705 apply to health insurance issuers offering group or individual health insurance coverage. *See supra* note 5.

and benefit restrictions).¹³ Benefits under the plan must be uniformly available to all similarly situated individuals and any restriction on benefits must apply uniformly to all similarly situated individuals and must not be directed at individuals based on a health factor.¹⁴ Accordingly, plans and issuers may not discriminate in eligibility for benefits or coverage based on whether or not an individual obtains a COVID-19 vaccination. Furthermore, while there is an exception to the general prohibition on discrimination based on a health factor for wellness programs that meet federal standards, this exception is available only for premium discounts or rebates, or modifications of otherwise applicable cost-sharing mechanisms, and not for denying eligibility for benefits or coverage based on a health factor.¹⁵

Q5: How are premium discounts and surcharges for receiving or not receiving the COVID-19 vaccination, respectively, treated for purposes of determining affordability of coverage with respect to the employer shared responsibility payment under section 4980H(b) of the Code?

Wellness incentives that relate to the receipt of COVID-19 vaccinations are treated as not earned for purposes of determining whether employer-sponsored health coverage is affordable. Although premium incentives are permissible as part of a nondiscriminatory wellness program, premium incentives other than incentives relating exclusively to tobacco use, including wellness programs encouraging vaccinations for COVID-19, are treated as not earned when determining the employee's required contribution for an offer of health coverage under 26 CFR 1.36B-2(c)(3)(v)(A)(4). Thus, for example, if the individual premium contribution under a COVID-19 vaccination wellness program was reduced by 25 percent, this reduction is disregarded for purposes of determining whether the offer of that coverage is affordable for purposes of assessing liability for the employer shared responsibility payment. Conversely, if an individual's premium contribution for health coverage under a COVID-19 vaccination wellness program is increased by a 25 percent surcharge for a non-vaccinated individual, that surcharge would not be disregarded in assessing affordability.

¹³ See 26 CFR 54.9802-1(b)(1)(ii)(F), 29 CFR 2590.702(b)(1)(ii)(F); 45 CFR 146.121(b)(1)(ii)(F) and 147.110.

¹⁴ See 26 CFR 54.9802-1(b)(2)(i)(B), 29 CFR 2590.702(b)(2)(i)(B); 45 CFR 146.121(b)(2)(i)(B) and 147.110.

¹⁵ The general prohibition against discrimination in premiums and contributions under PHS Act section 2705(b), ERISA section 702(b), and Code section 9802(b) provides the general prohibition shall not be construed to prevent a group health plan, or a health insurance issuer offering group health insurance coverage, from establishing premium discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence to programs of health promotion and disease prevention. The general prohibition against discrimination in rules for eligibility under PHS Act section 2705(a), ERISA section 702(a), and Code section 9802(a) contains no such exception.