FEHB Program Carrier Letter

All FEHB Carriers

U.S. Office of Personnel Management Healthcare and Insurance

Letter No. 2020-08 Date: April 23, 2020

Fee-for-service [7] Experience-rated HMO [7] Community-rated HMO [7]

SUBJECT: Coverage of Diagnostic Testing, Preventive Services, and Telehealth for COVID-19

The purpose of this Carrier Letter is to provide information about coverage of testing, preventive services, and telehealth for COVID-19; it complements <u>Carrier Letter 2020-02</u>. Specifically, this Carrier Letter sets forth responsibilities pursuant to the Families First Coronavirus Response Act (FFCRA)² and the Coronavirus Aid, Relief, and Economic Security Act (CARES Act).

Diagnostic Tests

All FEHB Carriers must provide coverage, waive cost-sharing (including deductibles, copayments, and coinsurance), and waive prior authorization or other medical management requirements for:

- (1) An *in vitro* diagnostic test, as defined at 21 CFR 809.3⁴ (or its successor regulations), for the detection of SARS-CoV-2 or the diagnosis of COVID-19. The *in vitro* diagnostic test must be one:
 - A. That is approved, cleared, or authorized under section 510(k), 513, 515, or 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 360c, 360e, 360bbb-3);
 - B. The developer has requested, or intends to request, Emergency Use Authorization (EUA) under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3), unless and until the emergency use authorization request under such section 564 has been denied or the developer of such test does not submit a request under such section within a reasonable timeframe;

¹ Available at https://www.opm.gov/healthcare-insurance/healthcare/carriers/2020/2020-02.pdf

² Available at https://www.congress.gov/116/bills/hr6201/BILLS-116hr6201enr.pdf. The provisions applicable to the FEHB Program are sections 6001 and 6006(c) of the FFCRA.

³ Available at https://www.congress.gov/116/bills/hr748/BILLS-116hr748enr.pdf. The provisions applicable to the FEHB Program include sections 3201-3203 and 3701 of the CARES Act.

⁴ Under 21 CFR 809.3(a), "in vitro diagnostic products" are defined as reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. These products are devices as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)), and may also be biological products subject to section 351 of the Public Health Service Act (42 U.S.C. 262).

- C. That is developed in and authorized by a State that has notified the Secretary of Health and Human Services (Secretary of HHS) of its intention to review tests intended to diagnose COVID–19; or
- D. Other tests that the Secretary of HHS determines appropriate in guidance.

Carriers should note that the term "in vitro diagnostic test" includes a serological test for the detection of antibodies against SARS-CoV-2. See answer to Question 4 in the Frequently Asked Questions (FAQs) guidance document jointly developed by the Departments of Labor, HHS, and the Treasury (collectively the Departments).⁵

(2) Items and services furnished to an individual during healthcare provider office visits (which includes in-person visits and telehealth visits), urgent care center visits, and emergency room visits that result in an order for or administration of an *in vitro* diagnostic product described in paragraph (1), but only to the extent the items and services relate to the furnishing or administration of the product or to the evaluation of the individual for purposes of determining the need of the individual for such product, as determined by the individual's attending healthcare provider. For more information on items and services that must be furnished during healthcare provider office visits, see answers to Questions 5 and 8 in the Departments' FAQs.

FEHB Carriers must take the above actions beginning on or after March 18, 2020 (FFCRA's enactment date) during any portion of a public health emergency period, based on an outbreak of SARS-CoV-2, under section 319 of the Public Health Service Act (42 U.S.C. 247d). The Secretary of HHS declared such a public health emergency on January 31, 2020.⁶

We commend Carriers for the flexibilities in cost-sharing and utilization management that many have already implemented in response to Carrier Letter 2020-02 and appreciate your continuing efforts to address the COVID-19 pandemic.

Provider Reimbursement

With respect to the diagnostic tests and visits noted above, Carriers must reimburse providers as follows:

(1) If a Carrier has a negotiated rate with the provider in effect before the public health emergency declared by the HHS Secretary, such negotiated rate shall apply throughout the period of the declaration.

⁵ Available at https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-42.pdf

⁶ See https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx

(2) If a Carrier does not have a negotiated rate with the provider, the Carrier must reimburse the provider in an amount that equals the cash price for such service as listed by the provider on a public internet website, 7 or the Carrier may negotiate a rate with such provider for less than such cash price.

Please note that the CARES Act also requires providers of diagnostic tests for COVID-19 to make public the cash price of a COVID-19 diagnostic test on the provider's public internet website, and grants the Secretary of HHS authority to impose civil monetary penalties on any provider that does not comply with this requirement and has not completed a corrective action plan, in an amount not to exceed \$300 per day that the violation is ongoing.

Rapid Coverage of Preventive Services and Vaccines for Novel Coronavirus

Currently, there are no evidence-based preventive services or vaccines for the novel coronavirus that causes COVID-19. But when such preventive services or vaccines do become available, Carriers must cover them, without any cost-sharing, as soon as possible after approval, clearance, or authorization under section 510(k), 513, 515, or 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 360c, 360e, 360bbb–3).8

OPM's policy supplements the rapid coverage requirements under CARES Act section 3203. That statute directs Carriers to provide coverage, without cost-sharing, no later than 15 business days after a preventive service or vaccine has been recommended with an "A" or "B" rating by the United States Preventive Services Task Force (USPSTF) or by the Advisory Committee on Immunization Practices (ACIP). The CARES Act provision accelerates the traditional timeline for providing coverage of preventive services and vaccines; see Carrier Letter 2019-019 explaining that timeline. But given the public health emergency related to the novel coronavirus, OPM is directing FEHB Carriers to make coverage available even sooner than CARES Act's already accelerated timeline.

Telehealth Services

All Carriers who have not already done so should strongly consider waiving cost-sharing (including deductibles, copayments, and coinsurance) for telehealth or other remote care services associated with treatment of COVID-19.

Carriers that offer a health savings account (HSA)-qualified high deductible health plan (HDHP) may offer telehealth and other remote care services in their HDHP without a deductible in view of the telehealth safe harbor under section 3701 of the CARES Act. This safe harbor is applicable up until the start of Contract Year 2022.

⁷ Section 3202(b) of the CARES Act also requires providers of diagnostic tests for COVID-19 to make public the cash price of a COVID-19 diagnostic test on the provider's public internet website. Section 3202(b) of the CARES Act also grants the Secretary of HHS authority to impose civil monetary penalties on any provider that does not comply with this requirement and has not completed a corrective action plan, in an amount not to exceed \$300 per day that the violation is ongoing.

⁸ For more information see https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19

⁹ Available at https://www.opm.gov/healthcare-insurance/healthcare/carriers/2019/2019-01.pdf

Impact on Rates

For experience-rated plans, reimbursement for COVID-19 related benefits discussed in this letter can be reflected in future rates. Carriers with community-rated plans can load their rates in accordance with their documented rating methodology. If a community-rated plan's rating methodology includes adding a load for the services described above in other groups' 2020 rates or is charging groups for this additional coverage, the Carrier is allowed to include these additional costs in the 2020 Reconciliation, which is due April 30, 2020. If a Carrier does not load the 2020 rate or charge groups in 2020 for these benefits, the Carrier cannot load the 2020 FEHB rate.

If you have any questions about the information provided in this letter, please contact your Health Insurance Specialist.

Sincerely,

Laurie Bodenheimer Acting Director Healthcare and Insurance