FEHB Program Carrier Letter All FEHB Carriers

U.S. Office of Personnel Management Healthcare and Insurance

Letter No. 2020-01

Fee-for-service [1]

Experience-rated HMO [1]

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Community-rated HMO [1]

SUBMISSION OF PROPOSALS

This is our annual call for benefit and rate proposals from Federal Employees Health Benefits (FEHB) Program Carriers. This letter sets forth the policy goals and initiatives for the FEHB Program for 2021. You must submit your benefit and rate proposals for the contract term beginning January 1, 2021 on or before May 31, 2020. OPM expects to complete benefit negotiations by July 31 and rate negotiations by mid-August to ensure a timely Open Season. As a reminder, Call Letter responsiveness is evaluated by your Contracting Officer as an element of Plan Performance Assessment (PPA).

FEHB PROGRAM BENEFITS AND INITIATIVES

OPM remains focused on maintaining and improving quality and affordability in the FEHB Program during the 2021 plan year. We expect FEHB Carriers to continue to offer innovative proposals that focus on the strategic priorities described in this Call Letter. Our quality initiatives for the upcoming plan year relate to opioids, addressing low-value care, and tobacco cessation. To maintain the focus on value-based care, Carriers are also asked to review and enhance transparency and decision support tools, cost-sharing for observation care, coverage of genetic therapies, as well as strategies to encourage use of preventive services. We ask Carriers to consider benefit proposals to implement coinsurance maximums on prescription drugs for nonhigh deductible health plans (HDHPs) or consumer driven health plans (CDHPs). You will note throughout the document references to prior guidance. Guidance and policy from previous Carrier Letters remain in effect unless superseded, and OPM will assess Carriers' compliance through review of benefit and rate proposals as well as contract reporting, including Carriers' results on applicable PPA measures.

I. Quality

The 2019 PPA cycle saw an increased average score reported by Carriers on combined Clinical Quality, Customer Service, and Resource Use (QCR) measures. The QCR measure set supports improving clinical quality, population health, and the customer experience. We appreciate efforts Carriers are making on these important result-oriented metrics and encourage your continued focus on improvements aimed at greater quality and enhancing the health and well-being of individuals covered under the FEHB Program. Carriers are reminded that the Clinical Quality

measures *Comprehensive Diabetes Care HbA1C* <8%, *Controlling High Blood Pressure*, and *Prenatal Care (Timeliness)*, along with a Resource Use measure, *Use of Imaging Studies for Low Back Pain*, are the four high priority measures in the 2020 and 2021 PPA. Previous Carrier Letters such as 2018-01 and 2019-10 have emphasized ways to manage diabetes and high blood pressure through comprehensive disease and medication management programs. In addition, over the past two years the FEHB PPA Best Practices Workgroup, a voluntary learning collaborative by and for FEHB Carriers, has featured Carriers sharing their strategies on three of the high priority measures. To join the PPA Best Practices Workgroup, please see Carrier Letter 2017-10.

While not specifically mentioned in this letter, the 2019 Call Letter asked Carriers to address:

- Mental Health and Substance Use Disorder Services by focusing their efforts on ensuring access to care. Carriers were requested to address the integration of mental health and primary care, expansion of mental health provider networks, and utilization of reimbursement models that integrated health, mental health and substance use disorder care.
- Patient Safety, with a focus on Maternal Health. Carriers were asked to support various population health initiatives when designing networks and engaging in hospital contracting.

This guidance remains in force, and OPM will assess Carriers' compliance through review of benefit and rate proposals as well as contract reporting, including Carriers' results on applicable PPA measures. Please refer to the <u>2019 Call Letter</u> for more information.

Opioids

In 2017, the opioid prescribing rate in the United States fell to the lowest it has been in more than 10 years at 58.7 prescriptions per 100 persons.¹ Though the overall national opioid prescribing rate continues to decline, some U.S. counties have dispensing rates that are several times higher than average. For example, some counties had rates that were seven times higher than that and in 16% of U.S. counties, enough opioid prescriptions were dispensed for every person to have one. With remaining concerns about prescribing rates, opioid use across the country, and as an Administration priority, Carriers must continue to focus on this important issue for the FEHB Program. The 2019 Call Letter asked Carriers to continue to address the opioid epidemic by focusing their efforts on opioid use in pregnancy, ensuring access to programs to identify and refer members at risk, promote evidence-based pain management, assess telehealth services for opioid use disorder (OUD) and other substance use disorder treatments, improve access to treatment programs, review policies for addiction treatment, identify improvement for care management of pregnant women with OUD, and promote a comprehensive coordinated approach

¹ See <u>https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html</u>

that provides care coordination and recovery support to members with OUD. That guidance remains in force, and will be monitored through applicable PPA measures, the Automated Data Collection (ADC) and contract monitoring. Please refer to the <u>2019 Call Letter</u> for more information.

We commend Carriers for implementing several processes and programs to address safe opioid utilization and ensure access to treatment for OUD. However, in order to further mitigate the effects of the opioid epidemic, Carriers must continue ongoing efforts to minimize the overutilization and misuse of opioids; ensure access to non-opioid, non-pharmacological pain treatments, as well as drugs for medication assisted treatment (MAT); and expand access to behavioral health services. Naloxone-based rescue agents are essential for the prevention of opioid overdose related deaths, and we remind Carriers that OPM recognizes these rescue agents as preventive care.²

For 2021, each Carrier must demonstrate a multi-pronged approach to addressing the opioid crisis including ensuring safe opioid utilization; providing access to non-opioid based pain treatments and treatments for opioid use disorder, including naloxone; and addressing the needs of members already on chronic opioid therapy.³

Addressing Low-Value Care such as Unnecessary Diagnostic Testing and Clinical Procedures

The National Academy of Medicine estimated in 2013 that 30 percent of U.S. healthcare spending is wasted.⁴ A recent JAMA article came to similar conclusions.⁵ Low-value care includes care with a high risk to cause harm versus its benefit, care provided in an inefficient manner, care that is clinically inappropriate, or care for which there are safer, more cost-effective alternatives.

OPM's goal is for its members to receive high-value care. Towards this goal, we are asking Carriers to identify specific examples of low-value care (including low-value pharmaceuticals) that will no longer be covered benefits (or will receive enhanced review) for FEHB members. Some potential resources are the Choosing Wisely initiative of the American Board of Internal Medicine Foundation, which has identified over 550 examples of low-value care⁶ vetted by medical professional societies, and recent statewide reports that have identified specific and

² See <u>https://www.opm.gov/healthcare-insurance/healthcare/carriers/2018/2018-05a.pdf</u>

³ See https://www.hhs.gov/opioids/sites/default/files/2019-10/8-

Page%20version_HHS%20Guidance%20for%20Dosage%20Reduction%20or%20Discontinuation%20of%20Opioids.pdf

⁴ Institute of Medicine 2013. Best Care at Lower Cost: The Path to Continuously Learning Health Care in America. Washington, DC: The National Academies Press. <u>https://doi.org/10.17226/13444</u> or <u>https://www.ncbi.nlm.nih.gov/pubmed/24901184</u>

⁵ Shrank WH, Rogstad TL, Parekh N. Waste in the US Health Care System: Estimated Costs and Potential for Savings. *JAMA*. 2019;322(15):1501–1509. <u>https://doi.org/10.1001/jama.2019.13978</u>

⁶ See https://www.choosingwisely.org/

actionable examples of low-value care.^{7, 8} We would also like Carriers to identify internal procedures for continuing review of covered benefits to identify and avoid payment and provision of low-value care.

Tobacco Cessation

The <u>2019 Call Letter</u> asked Carriers to re-invigorate messaging about the tobacco cessation benefit by clarifying that e-cigarettes are tobacco products under the benefit, ensuring there are no Carrier-imposed barriers when accessing the benefit, focusing on the use of e-cigarettes among youth and how parents can access education materials, and emphasizing providers' role in screening all patients for tobacco product use and encouraging all tobacco users to quit. The <u>2019 Technical Guidance</u> provides additional information on how to achieve these objectives.

The 2019 ADC results revealed opportunities for Carriers to improve how they address tobacco product cessation, particularly with respect to increasing communication between Carriers and providers about the FEHB tobacco cessation benefit as well as actively promoting the cessation benefit to members who use tobacco products. While conventional cigarettes and other combustible tobacco products still pose the greatest health risks, e-cigarettes are not harmless. E-cigarettes typically contain nicotine - which is highly addictive and can harm the developing brain - in addition to other harmful substances, including ultrafine particles, heavy metals, volatile organic compounds, and cancer-causing chemicals. E-cigarettes and other vaping products can also be used to deliver other substances, including tetrahydrocannabinol (THC), the primary psychoactive substance in marijuana. Nicotine addiction is a recognized substance use disorder and the concurrent use of THC and other cannabinoids and/or opioids in the e-cigarette pods may require residential treatment.

Carriers are asked to review the <u>2019 Call Letter</u> and <u>2019 Technical Guidance</u> on this topic with special attention to increasing provider awareness, promotion, and use of the FEHB tobacco cessation benefit. This will help more adults and youth quit the use of all tobacco products, prevent youth use of all tobacco products, and educate members about the risks associated with all tobacco product use.

II. Affordability

Transparency

OPM's continuing efforts to increase transparency reflect the Administration's strategic vision for reforming the American healthcare system through choice and competition, as articulated in Executive Order (E.O.) 13877, "Improving Price and Quality Transparency in American Healthcare to Put Patients First" (June 27, 2019). As E.O. 13877 states, "It is the policy of the

⁷ Washington Health Alliance. 2018. First, Do No Harm – Calculating Health Care Waste in Washington State. Seattle, WA. https://wahealthalliance.org/alliance-reports-websites/alliance-reports/first-do-no-harm/

⁸ Mafi JN, Russell K, Bortz BA, et. al. Low-Cost, High-Volume Health Services Contribute the Most to Unnecessary Health Spending. Health Aff. 2017; 36(10): 1701-1704. <u>https://doi.org/10.1377/hlthaff.2017.0385</u>

Federal Government to ensure that patients are engaged with their healthcare decisions and have the information requisite for choosing the healthcare they want and need."

The <u>2019 Call Letter</u> highlighted OPM's long-standing interest in the availability of clear cost information as important for consumers who want to make more informed decisions concerning their health care. Both drug transparency tools and medical services transparency tools allow individuals to take a more active role in their healthcare selections.

OPM applauds Carriers who have already designed price and quality transparency tools that allow enrollees to make informed healthcare decisions. Ensuring enrollee access to meaningful transparency tools helps OPM achieve its Strategic Objective 1.4, to improve healthcare quality and affordability in the FEHB Program. As a reminder, by 2021, all Carriers must provide robust search tools that meet the transparency objectives set forth in the 2019 Call Letter.

Provider Contracting Status and Surprise Billing

A lack of transparency regarding a provider's contracting status with an FEHB Carrier (innetwork, out-of-network, etc.) can often lead to unexpected costs for enrollees. To minimize the likelihood of this, OPM has required Carriers to develop and implement online provider search tools. To further these efforts, no later than plan year 2022, Carriers should ensure that listings for in-network hospitals in their provider search tools include information on the availability of in-network providers at that hospital or treating facility for certain categories of physicians and services. This information may take the form of a hyperlink to a webpage providing additional information, but the presentation of the information should make it easy for a member to identify in-network and out-of-network services at any given hospital or treating facility contracting with the member's plan.

In addition, surprise billing has garnered a great deal of attention from Federal and state policymakers as well as print and social media because of the significant and unexpected financial burden it can present. Surprise billing commonly occurs in emergent and urgent clinical settings when members don't have the opportunity to search for and select their provider. It can also occur when members are unaware of ancillary providers involved in their care (e.g., radiologists, anesthesiologists, pathologists, assistant surgeons), or are unaware that these providers are not in their plan's network when seeking care at an in-network treating facility. This information is generally not shown in association with the treating hospital or facility in online provider directories, which is usually the primary place where members seek this type of care information. We are continuing to look for ways to address surprise billing for FEHB enrollees in the future.

Patient Responsibility for Observation Care

Hospitals sometimes provide observation care for patients without admitting the patient to the hospital for inpatient care. The observation hospitalization can include short-term treatment and

tests to help doctors decide whether the patient meets the medical criteria for admission and can continue from one hour to multiple days.

In most situations, without directly asking, a member has no way of knowing whether he or she is receiving observation care overnight or is receiving care under an inpatient admission. Currently, some Carriers apply outpatient cost-sharing to observation care that exceeds 24 hours, which is often more costly to the member than inpatient cost-sharing. Due to this lack of transparency, members cannot determine their liability for potentially higher-cost care.

Accordingly, Carriers should review plan benefits, and where necessary, mitigate any inequity in member cost-sharing based on hospital observation care that exceeds 24 hours. For example, if an enrollee is responsible for a copayment of \$150 for an inpatient hospitalization, an enrollee would be responsible for a \$150 copayment for hospital observation care that has exceeded 24 hours. Proposals to equalize member cost-sharing between hospital observation care that exceeds 24 hours and inpatient hospital care should be cost neutral.

Pharmacy Benefit Transparency Tools

Real time benefit-check tools (RTBT) inform prescribers of a drug's formulary status, utilization management edits if applicable, and lower cost alternative drug therapies, if available. This can improve medication adherence, reduce member out-of-pocket costs, and lower prescription drug costs. Carriers must adopt one or more RTBT that can integrate with at least one prescriber's e-prescribing system or electronic health record, no later than plan year 2021.

Drugs and Biologics

The <u>2019 Call Letter</u> asked Carriers to address the rising cost of prescription drugs with specialty drug management, medication management programs, point-of-sale rebates, and incentivizing generic drugs. That guidance remains in force, and OPM will assess Carriers' compliance through review of benefit and rate proposals as well as contract reporting, including Carriers' results on applicable PPA measures.

Genetic Therapies

Therapies that use genetically modified cells to treat disease (e.g. CAR-T cells) or viral vectors to genetically modify host cells to repair genetic defects (e.g., Luxturna, Zolgensma) are a new and rapidly developing area of medicine. In some cases, these therapies may replace other less effective therapies and could decrease the total cost of care over the long term. Gene therapy for Hemophilia A (Factor 8 deficiency) is such an example, since the gene therapy that treats this disease will replace a lifetime of expensive factor replacement therapy.

OPM is interested in Carriers' strategies to cover these therapies, consistent with the policy set forth in Carrier Letter <u>2018-10</u>, while managing the associated costs, which currently range from \$400,000 to \$2.1 million per patient. In your benefit proposal, please include your process for approving treatment. Approval can be either by presence on a formulary, or through an

exception process. These new gene therapies are approved by the FDA through a process similar to biologics and should therefore be treated as biologics for the purpose of the policy.

Biosimilars

The Administration's Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs,⁹ issued May 11, 2018, directed the FDA to issue new policies to improve the availability, competitiveness, and adoption of biosimilars. As a result of the Administration's directive, the FDA released a Biosimilar Action Plan¹⁰ which outlines how the FDA is going to encourage innovation and competition among biologics and bring more biosimilars to market. The FDA has since issued interchangeability guidance¹¹ for biosimilars. These are indicators of the Federal government's commitment to the biosimilar market. The approval of biosimilar products can improve access to care for patients by increasing the number of medication options and potentially lower costs.¹² It is anticipated that biosimilars will foster competition and deliver increased savings from negotiated discounts.

The Congressional Budget Office has estimated that biosimilars may initially be priced 25 percent below their brand-name counterparts and after several years of competition may be priced as much as 40 percent below the reference product.¹³

Achieving the projected cost savings from the adoption of biosimilars will require additional action from payers. For 2021, each FEHB Carrier is required to have a strategy in place to promote the use of biosimilars under the pharmacy and the medical benefit. FEHB Carriers are expected to align reimbursement and formularies to encourage appropriate biosimilar adoption and educate providers and members about biosimilars.

Coinsurance Maximum for Prescription Drugs

Over the years, several Carriers have moved away from drug copayments to coinsurance, in which the member pays a percentage of the negotiated cost of the drug. As the cost of prescription drugs continues to rise, there is concern that some FEHB members may not be able to afford their medication costs and that the amount of their cost share is less transparent. This is especially true for FEHB members in plans that do not have a maximum limit on coinsurance for prescription drugs. Research has indicated that as member out-of-pocket costs grow, the rate of

demonstratinginterchangeability-reference-product-guidance-industry ¹² Biosimilar product information. FDA website. <u>https://www.fda.gov/drugs/biosimilars/biosimilar-product-information</u>

⁹ See <u>https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf</u>

¹⁰ FDA guidance document. Biosimilar Action Plan: <u>https://www.fda.gov/media/114574/download</u>

¹¹ FDA guidance document. Considerations in demonstrating interchangeability with a reference product guidance for industry. Food & Drug Administration website. <u>https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-</u>

¹³ US Congressional Budget Office. S. 1695 Biologics Price Competition and Innovation Act of 2007. US Congressional Budget Office website. http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/94xx/doc9496/s1695.pdf

prescription abandonment or delays in filling prescriptions increases, which in turn has implications for downstream health care costs.^{14, 15, 16}

OPM encourages Carriers to place a maximum dollar limit on the cost of drugs that are subject to coinsurance (e.g., 20% up to a maximum of \$150) for non-HDHP or CDHP plans to reduce the financial burden on members while keeping premiums neutral.

Preventive Services

The 2019 Call Letter asked Carriers to ensure enrollee access to recommended preventive services, compliance with cost-sharing requirements, and population health. That guidance remains in force, and OPM will assess Carriers' compliance through review of benefit and rate proposals as well as the ADC, contract reporting, including Carriers' results on applicable PPA measures.

HDHPs and Preventive Care Benefits

High Deductible Health Plans (HDHPs) require that the combined medical and pharmacy deductible be met before traditional coverage begins, with the exception of certain preventive care benefits. Per IRS Notice 2019-45,¹⁷ coverage of additional preventive care benefits for certain chronic conditions is permitted before the deductible is met or at a lower deductible than the HDHP statutory minimum. We encourage Carriers to review the applicable Notice and adjust benefits accordingly.

Wellness Incentives

FEHB Carriers have requested clarification from OPM regarding prior guidance on incentives provided to members to participate in wellness activities, as well as disease management activities and programs. OPM continues to encourage appropriate use of these incentives, if they do not create a tax liability for members. Consequently, incentive proposals must limit cash or cash equivalent wellness incentive benefits to medical care that falls within the exclusion in Section 213 of the Internal Revenue Code¹⁸ or that is not considered income under IRS rules and guidance.19

¹⁴ Chernew ME, Shah MR, Wegh A, et al. Impact of decreasing copayments on medication adherence within a disease management environment. Health Aff (Millwood). 2008;27(1):103-12.

¹⁵ Colombi AM, Yu-Isenberg K, Priest J. The effects of health plan copayments on adherence to oral diabetes medication and health resource utilization. J Occup Environ Med. 2008;50(5):535-41.

¹⁶ Zullig Ll, Bosworth H, Engaging Patients to optimize Medication Adherence. NEJM Catalyst. May 14, 2017 https://catalyst.nejm.org/optimizepatients-medication-adherence/ ¹⁷ Additional Preventive Care Benefits Permitted to be Provided by a High Deductible Health Plan Under § 223 <u>https://www.irs.gov/pub/irs-</u>

drop/n-19-45.pdf

¹⁸ See 26 U.S.C.§213(d)

¹⁹ See https://www.irs.gov/pub/irs-wd/201622031.pdf

OPM has eliminated the specific dollar limits set forth in Carrier Letter 2014-03 on non-taxable wellness incentives. OPM encourages Carriers to offer wellness incentives as a tool to holistic approaches to health. As stated in Carrier Letter 2016-04, OPM maintains that well-crafted incentives can promote participation in screening activities and reinforce the adoption of healthy behaviors. There are no dollar limits as to the value Plans may offer in terms of wellness incentives; however, any value provided to enrollees must be limited to qualified medical expenses or *de minimis* incentives.²⁰ Examples of permissible wellness incentives for non-HDHPs include debit cards limited to purchases for qualified medical expenses²¹ and reduced copayments for covered benefits.

Fraud, Waste, and Abuse

The <u>2019 Call Letter</u> asked Carriers to address Controlling Fraud, Waste, and Abuse by adjusting benefit designs to better control fraudulent payments. That guidance remains in force, and OPM will assess Carriers' compliance through review of benefit and rate proposals as well as contract reporting, including Carriers' results on applicable PPA measures.

III. Technical Guidance

We will provide guidance on applicable initiatives, submission of benefit and rate proposals, and preparation of brochures in the Technical Guidance.

CONCLUSION

OPM's goal for the FEHB Program is to provide quality, affordable health benefits for Federal employees, annuitants, and their families. Continuous open and effective communication between OPM contracting staff and Carriers should occur to ensure a seamless negotiation cycle. Please discuss all proposed benefit changes with your Health Insurance Specialist.

We look forward to the negotiations for the upcoming contract year. Thank you for your commitment to the FEHB Program.

Sincerely,

Laurie Bodenheimer Acting Director Healthcare and Insurance

²⁰ See <u>https://www.irs.gov/government-entities/federal-state-local-governments/de-minimis-fringe-benefits</u>

²¹ See IRS Publication 502 for a description of qualified medical expenses <u>https://www.irs.gov/pub/irs-pdf/p502.pdf</u>