FEHB Program Carrier Letter
All FEHB and PSHB Carriers
(PSHB: Except for Medicare Part D portion)

FEHB ☒ PSHB ☒

U.S. Office of Personnel Management
Healthcare and Insurance

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Fee-for-service [5] Experience-rated HMO [5] Community-rated HMO [3]

Subject: Consolidated Pharmacy Benefits Guidance for the FEHB Program

This reissued Carrier Letter updates the Consolidated Pharmacy Benefits Guidance for the FEHB Program, and supersedes Carrier Letter 2023-03. The Consolidated Pharmacy Benefits Carrier Letter is updated and reissued periodically, incorporating any changes in pharmacy benefits guidance. It also includes two new sections, 'Pharmacy Benefit Design' and 'Coordination of Benefits' to incorporate related guidance based on Carrier Letters 2023-04 and 2023-06. Additionally, this letter clarifies policies on formulary management, utilization management, pharmacy network management, medication management, opioids, member experience and transparency, data, Pharmacy Benefit Management (PBM) arrangements, and population health. Within population health, there are updated policies on preventive services, contraception and the coverage of contraceptives, tobacco cessation, fertility benefits, coronavirus disease 2019 (COVID-19), and anti-obesity medications.

In the event of a conflict between this letter and a prior FEHB Carrier Letter, this letter supersedes.

Policy issues that are time-sensitive or related to emerging trends in the industry may initially be addressed in separate letters or within the annual Call Letter.

Overview

OPM expects Carriers to demonstrate effective prescription drug management and to have programs in place to appropriately coordinate with other health plan operations such as disease management and other medical benefit management programs.

Designing pharmacy benefits that reflect the diverse needs of the federal workforce will allow OPM to meet its strategic objective of being a model employer. A component of this objective is the assurance that pharmacy costs are efficiently and effectively managed to improve healthcare quality and affordability in the FEHB Program.

This Carrier Letter discusses the following topics:

I. Formulary Management
II. Utilization Management
III. Pharmacy Network Management
IV. Specialty Drug Management
V. Medication Management
VI. Opioids
VII. Member Experience and Transparency
VIII. Cost Containment
IX. Pharmacy Benefit Design
X. Coordination of Benefits
XI. Data
XII. PBM Arrangements
XIII. Population Health
XIV. Clinical Trial Coverage
XV. Genetic Testing

XVI. Fraud, Waste, and Abuse

XVII. Quality Measures

Appendix 1 includes a table of prior Carrier Letters relevant to each topic. For topics that extend beyond the scope of the pharmacy benefit, this letter will refer to the appropriate Carrier Letter. New, updated or clarified sections are marked with 'New' or 'Updated' in parenthesis.

I. Formulary Management (Updated)

Carriers must have a safe and clinically effective formulary that includes a range of medications in a broad distribution of therapeutic drug classes to serve the healthcare needs of its enrolled FEHB population. Safe means that the drug's benefits outweigh the risks for the drug's intended use and intended population. Effective is the extent to which a drug achieves its intended effect in a clinical setting.

Formulary Decision-Making Process

Established formulary decision-making processes are expected as part of managing the pharmacy benefit. Formulary decisions must be made by an established pharmacy and therapeutics (P&T) or medical policy committee.

Requirements for the committee:

- Free from conflicts of interest;
- Meets at least quarterly;
- Has documented processes in place to ensure the management of clinically appropriate, safe, and cost-effective drugs; and
- Composed of a group of individuals, the majority of which are actively practicing physicians, pharmacists, and mid-level practitioners (e.g., advanced practice registered nurses) and come from clinical specialties that adequately represent the clinical needs of the covered population.

OPM recognizes that Carriers may subcontract their formulary management, P&T committee function, or both.

Requirement: In such cases, OPM (via the Contracting Officer and copy OPMPharmacy@opm.gov) must receive details of such arrangements, including the contract(s) between the Carrier and its contractor(s) for formulary management or P&T committee functions.

Formulary Exception Process

A formulary exception process sets out the requirements for seeking coverage of a drug that is not covered on, or is excluded from, the formulary.

Requirements: Carriers must have a documented formulary exception process that permits reimbursement and coverage of non-formulary or excluded drugs when justified by members' medical needs. Descriptions of these processes must include the following timelines for standard and expedited reviews:

- For expedited requests, the Carrier or its PBM must review and respond within 24 hours of receiving required information (i.e., a prescriber's supporting statement).
- For standard, non-expedited requests, the Carrier or its PBM must review and respond within 72 hours of receiving required information (i.e., a prescriber's supporting statement).
- If a member receives an unfavorable coverage determination, the decision will contain information needed to file a request for reconsideration.

Non-Discriminatory Formulary Design

Effective formulary design prevents selection bias or discrimination and facilitates appropriate access to affordable prescription drug choices. A non-discriminatory formulary design does not have cost or access barriers imposed by disease or condition.

Requirements:

- Carriers must ensure non-discriminatory access to safe and clinically appropriate drug therapy for members with chronic conditions.
- When several drugs are available in a class to treat a condition, Carriers must not designate specialty conditions or limit drugs for such conditions to higher cost tier(s) of the formulary.
- Formulary design should not result in adverse tiering, wherein higher cost enrollees are steered away in favor of healthier populations.

New-to-Market Drugs

Formulary management is a dynamic process. Some Carriers routinely block new-to-market drugs from the adjudication system until the P&T or medical committee has a chance to review the drug.

Requirements:

- Carriers must have processes in place to review and effectuate a decision on formulary placement for all new-to-market drugs within 120 days of the drug being available for dispensing.
- For new FDA-approved drugs with significant clinical impact, OPM expects this timeframe to be significantly accelerated. Significant clinical impact means one that may prevent loss of bodily functions or death if used as a treatment as soon as possible.
- While the new-to-market block is in effect, the Formulary Exception Process applies.

Biosimilars (Updated)

The approval of biosimilar products, including interchangeable biosimilars, can improve access to care for patients by increasing the number of medication options and potentially lowering costs. An interchangeable biosimilar may be substituted for the reference product at the pharmacy

without the intervention of the prescribing health care provider, subject to state pharmacy laws, similar to how generic drugs are substituted.

Biosimilars are expected to foster competition and deliver increased member and Carrier savings from negotiated discounts. Carriers need to review benefits as biosimilar products, including interchangeable biosimilars, enter the market.

Requirements:

- Carriers must have a strategy in place to promote the use of biosimilars, including interchangeable biosimilars, under the pharmacy and the medical benefits. Carriers should focus on differentiating preferred and non-preferred specialty products in both the pharmacy and the medical benefits as more biosimilars come to market.
- Carriers are expected to align reimbursement and formularies to encourage biosimilar, including interchangeable biosimilar, adoption, reduce member and Carrier costs, and educate providers and members about biosimilars, including interchangeable biosimilars.
- Carriers must remain vigilant to avoid potential adverse consequences of formulary management strategies with respect to all products, as discussed under "Non-Discriminatory Formulary Design" above.

Exclusions and Off-Label Use (Updated)

Under the Federal Food, Drug and Cosmetic Act, a drug is considered investigational until the Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) or Center for Biologics Evaluation and Research (CBER) evaluates the new drug application (NDA) or Biologics License Application (BLA), respectively, and finds that the sponsor has provided "substantial evidence" that the drug was proven safe and effective for its intended use. Once such a finding is made, the FDA approves the drug for marketing and no longer considers it investigational.

Requirements:

- Carriers must accept FDA approval of a drug or biological product through a designated FDA pathway and not deny benefits based upon a separate determination for their plan that the drug is experimental or investigational.
- As with all other covered benefits, prescribed drugs, devices, or biological products must be medically necessary and appropriate for the member's condition for the member to receive coverage.

Carriers are not required to cover "experimental or investigational procedures, treatments, drugs or devices." However, the FDA recognizes that there may be circumstances under which "good medical practice and the best interests of the patient" prompt prescribers to prescribe a product for "an indication not in the approved labeling."

Requirement in such cases: Carriers must cover drugs prescribed for off-label use if the medication can be legally prescribed, its use is supported by clinical evidence from established compendia or peer-reviewed literature and is consistent with generally accepted medical practice.

Coverage of FDA-approved drugs, devices, and biological products goes beyond the scope of the pharmacy benefit. For the full guidance on when to defer to FDA determinations, Carriers should refer to Carrier Letter 2018-10.

Formulary Review

Carriers must regularly review formularies for tier placement of new drugs and ensure that drugs placed in higher (less preferable or more costly) tiers have therapeutically similar drugs in lower (more preferable or less costly) tiers of the formulary, when such drugs are available. Carriers must also adhere to the requirements of a non-discriminatory formulary design, as outlined above.

Plans proposing to change formularies or make extensive changes to their existing formularies for the next plan year must provide the following

information to their Health Insurance Specialist as part of the annual proposal.

Requirements:

- A formulary comparison showing proposed changes
- A formulary justification for the changes being proposed
- A member disruption analysis showing the member impact based on prior utilization
- A cost savings analysis (if applicable); and
- A transition plan including a communication plan for providers, pharmacies, and members.

Carriers must have a documented process in place to notify utilizing members of upcoming changes to the formulary.

Mid-Year Formulary Changes (Updated)

Mid-year changes can enhance formularies by adding drugs or removing or relaxing utilization management (UM) requirements for drugs. On the other hand, some mid-year changes can restrict formularies by removing drugs, moving drugs to higher tiers, or tightening UM requirements for drugs, which, in turn, may result in disruption of benefits to members.

Requirements:

Changes to formularies may not become effective until an itemized list is provided to your Contracting Officer.

- Carriers must notify their Contracting Officer at least 70 days prior to making any restrictive formulary change during the plan year that has member impact. A member is impacted if they are on a prescription at the time of the formulary change.
- Carriers must provide written notice to members affected by a mid-year restrictive formulary change at least 60 days prior to the date

the formulary change becomes effective. The written notice must include the following:

  - Name of the affected drug
  - Whether the drug is being removed from the formulary or changing its preferred or tiered cost-sharing status
  - Alternative drugs in the same therapeutic class or cost-sharing tier and expected cost-sharing for those drugs; and
  - How members may obtain a coverage determination

- Carriers have the option to grandfather members impacted by a restrictive formulary change for coverage and cost-sharing for the remainder of the plan year. In such cases, member notification is not required. However, Carriers must notify OPMPharmacy@OPM.gov and their Contracting Officer at least 10 days prior to making any restrictive mid-year formulary change that has no member impact.
- Carriers may immediately remove from their formulary drugs deemed unsafe based on new information from the FDA on a drug's safety or efficacy or removed from the market by their manufacturer without meeting the advance notice requirement specified above. In such cases, Carriers must provide retrospective notice of any such formulary changes to affected enrollees and OPM as soon as possible.

For the full guidance on when mid-year formulary changes may occur, Carriers should refer to Carrier Letter 2020-18.

II. Utilization Management (Updated)

Trends in prescription drug spending have demonstrated the importance of utilization management both within the FEHB Program and industrywide.

Greater utilization of existing drugs and the high cost of new medications contribute significantly to overall FEHB Program costs.

Evidence-based and well-designed utilization management tools ensure that members receive the most appropriate medications while minimizing errors, adverse effects, and unnecessary prescription drug use and cost.

Requirements:

- Carriers must implement, operate, and reinforce drug utilization management strategies that are based on current clinical guidelines and have been shown to be effective in assuring high quality care and clinically appropriate cost savings.
- Carriers must promptly review and respond to requests for prior authorization (PA) and any other utilization management edits following receipt of all required information. For expedited requests, the Carrier must review and respond within 24 hours. For other, non-expedited requests, the Carrier must review and respond within 72 hours. In situations where the Carrier does not have sufficient information to make a determination, there should be at least one outreach attempt to the member and the provider for additional information within a reasonable timeframe.
- If a member receives an unfavorable coverage determination, the decision will contain information needed to file a request for reconsideration.
- Carriers must have in place a process to review all expiring PAs and must notify members a minimum of 45 days before the expiration of a PA for a maintenance medication.[1] Carriers are encouraged to consider putting in place an automatic renewal for PAs if the member has a chronic condition, has been filling the medication regularly and the PA is not in place for safety reasons. Carriers should refer to Carrier Letter 2021-03.
- In emergency situations, such as natural disasters and other public health emergencies, Carriers must remain abreast of the situation. On a case-by-case basis, in consultation with the relevant public health authority and OPM, Carriers must be prepared to relax referral or pre-authorization requirements. These situations can extend beyond the scope of the pharmacy benefit. Carriers should refer to

[1] Maintenance medications are medications commonly used to treat conditions that are considered chronic or long-term and usually require regular use of medicines.

resources in Carrier Letter 2014-26 and subsequent guidance, including the section "Emergency Use" in Carrier Letter 2018-10.

III. Pharmacy Network management (Updated)

Well-designed pharmacy networks can encourage members to use the most appropriate, clinically advantageous and cost-effective pharmacy channels.

Equitable member access, availability, quality, and safety issues across all pharmacy channels within a pharmacy network must be evaluated and addressed on an ongoing basis. Equitable access means that the Carrier must provide pharmacy access to serve the needs of the entire enrolled population.

Requirement: Plans must optimize the use of high-value medication distribution channels[2] by aligning member incentives with the plan's most cost-effective options. In doing so, Carriers must ensure members have equitable access to in-network retail pharmacy options and do not incur additional out-of-pocket costs.

IV. Specialty Drug Management

Specialty drugs can be used to treat chronic, complex, or life-threatening conditions and usually are manufactured through biologic processes. While offering major medical breakthroughs, specialty drugs are also often costly and may require specific clinical monitoring and special handling by the dispensing pharmacy. Decisions on when and whether to cover these new specialty medications can be complex and involve the pharmacy or medical benefit or both depending on the drug indication, the route of administration, associated diagnostic testing, and the condition being treated.

[2] Carrier Letter 2014-03 states "We strongly encourage plans to optimize the use of high value medication distribution channels by aligning member incentives with the plan's most cost effective options. This may include mail order or retail programs that offer 90 day supplies of maintenance medications."

Requirements:

- Carriers must have in place a robust specialty drug management program that manages drugs under both medical and pharmacy benefits. A robust specialty drug management program ensures appropriate medication use, provides proactive clinical support, and promotes member safety.
- OPM expects Carriers to have a site-of-care program to manage specialty drugs under the medical benefit.
- Specialty management programs, such as utilization and trend management programs, must be applied to drugs managed either under pharmacy or medical benefits.

V. Medication Management

Chronic physical and mental health conditions continue to be a primary concern in the healthcare market. Carriers cite heart disease, diabetes, breast cancer, cerebrovascular disease, inflammatory conditions, and respiratory conditions as both the most prevalent and costly chronic conditions. Medication management programs work collaboratively with members who have chronic conditions and multiple drug regimens to assess their medication needs, help improve adherence, manage medication costs, and avoid adverse safety events to improve health outcomes. Effective medication management programs are critical to achieving optimal member outcomes and keep premiums affordable.

Value-Based Insurance Design (VBID) can also improve the quality of care and reduce the cost of care for members with chronic diseases. VBID refers to structuring member cost sharing and health plan design elements to encourage the use of high-value clinical services that have the greatest potential to positively impact member health.

Requirements (Updated): Carriers should have medication management programs to optimize the medication needs of their enrolled FEHB population. The programs, at minimum, must address transitions of care, polypharmacy, and complex medication management, including medication

appropriateness, effectiveness, and safety. Where possible, the program should use VBID as described in Carrier Letter 2017-01 and Carrier Letter 2021-05.

VI. Opioids (Updated)

Reducing and preventing opioid misuse is a critical Administration priority.

Requirements (Updated):

- Carriers must promote evidence-based pain management through coverage of and access to non-pharmacological therapies and non-opioid medications or devices used to treat pain.
- Carriers must ensure access to programs which identify members at risk for opioid use disorder (OUD) using tools such as point-of-sale edits, retrospective data review, and outreach referral programs.
- Carriers must have provider outreach and education (including network dental providers, as applicable) regarding opioid risks, screening of patients for opioid use history, pathways for referral to OUD treatment, as well as recommendations for Prescription Drug Monitoring System use.
- Carriers must provide enrollee outreach and education regarding opioid risks and the availability of other modalities for the treatment of pain.
- Carriers should, when supported by clinical evidence and safety standards, have quantity and prior approval limits on opioid medications, along with safety edits for initial opioid prescription fills and high morphine milligram equivalent doses. Pain management strategies must be individualized to each patient's unique situation using shared decision-making between the prescriber and patient.
- Carriers must have ongoing efforts in place to promote safe disposal of prescription medications.
- Carriers must, when supported by clinical evidence and safety standards, improve access to Medication Assisted Treatment (MAT),

such as removing prior approval requirements and adjusting formulary placement.

- Carriers must make naloxone-based agents or other non-naloxone-based products indicated for the emergency treatment of opioid overdose and education related to opioid overdose readily accessible with at least one opioid rescue agent available without cost-share.
- Carriers must have processes in place to detect and remedy concerns about overuse, misuse, or fraud related to opioid prescribing.

OPM recognizes opioid overdose rescue agents as preventive care. This allows a corresponding cost-share waiver and removal of any financial barriers that would prevent members from obtaining opioid reversal agents. This also allows high deductible health plans (HDHPs) to provide some opioid overdose rescue agents without applying a deductible under the preventive care safe harbor of Section 223(c)(2)(C) of the Internal Revenue Code.

In March 2023, the FDA approved the first over-the-counter (OTC) naloxone product for reversal of opioid overdose. Recognizing the availability of new OTC naloxone opioid rescue agents, Carriers must continue to make at least one opioid overdose agent readily accessible without cost-share.

Addressing the opioid epidemic is not limited to strategies implemented within the pharmacy benefit and should be a multi-pronged approach as described in Carrier Letter 2021-03, Carrier Letter 2020-01, and related guidance.

VII. Member Experience and Transparency (Updated)

Member Transparency Tools

Transparent benefit information assists members in understanding their benefits and costs. Beginning in 2006, OPM focused on fostering pharmacy price transparency. OPM remains strongly committed to transparency and the provision of cost-effective care to our members. Current and prospective enrollees have convenient access to information about the formulary tier,

member cost-share and utilization management requirements for covered prescription drugs.

Carriers have made significant strides in improving transparency tools, from formulary lists to drug cost calculators.

General requirements:

- Current formulary lists must be available online and easily accessible to members.
- Carriers must continue to seek improvements to the member experience by applying innovative solutions, new technologies, and enhanced transparency to ensure members understand their benefits structure and cost sharing requirements.
- Carriers must continue to improve the interactive functionality of existing transparency tools, including drug cost calculators, and add enhancements that will further increase transparency and foster member engagement.
- During Open Season, member transparency tools must accurately reflect the current and upcoming contract year formularies and benefits.

Requirements for drug cost calculators: Drug cost calculators must be accurate, intuitive, easy to navigate, understandable, and member-friendly. Carriers' drug cost calculators must offer, at a minimum, the following features:

- Ease of navigation that provides the ability to move within screens without being redirected back to the beginning of the menu
- User-friendly capabilities and explanations of basic pharmacy benefit concepts in an easy-to-understand manner
- Pricing information, including information about any utilization management edits applied and any accumulators, such as deductibles and out-of-pocket maximums
- Pricing for brand and generic alternatives

- Explanations of benefit plan factors that impact drug pricing such as day supply limits
- A list of formulary alternative medications including biosimilars; and
- Pricing across a variety of pharmacy networks

Provider Transparency Tools

Technology continues to improve the efficiency of provider and pharmacy electronic workflows. Enhanced provider tools such as electronic prior authorizations allow the provider to exchange clinical information in real time, which results in quicker coverage determination turnaround times, reduced prescription abandonment rates, and increased member satisfaction. Additionally, prescription transparency tools can allow the provider to view the member's drug cost information, including out-of-pocket costs specific to the member's Carrier and offer appropriate lower-cost therapeutic equivalent treatments, if applicable. These technologies can help the provider offer more member-centric and cost-effective care with each clinical encounter.

Requirements:

- Carriers should adopt technologies that streamline the pharmaceutical coverage determination process and enhance member experience.
- Carriers should promote the use of provider tools, when available, such as electronic prior authorization and benefit check tools that display drug formulary and pricing information at the time of prescribing.
- Carriers must adopt one or more real-time benefit-check tools (RTBT) that can integrate with at least one electronic-prescribing system or health record.

VIII. Cost Containment

The prescription drug benefit is a significant portion of overall FEHB Program costs. Most Carriers also report an increase in per member per year drug costs.

Requirements:

- Carriers must continuously review plan design, network, and benefit management initiatives to address the rising cost of health care.
- Carriers must also review healthcare expenditures to ensure correlation with high quality and efficiency in the delivery of services to members.
- Carriers must ensure that members are charged the lesser of the prescription price or applicable cost-share amount for prescription medications. OPM considers the prescription price to be the drug's negotiated price plus dispensing fee or the cash price at the point of sale.
- Carriers must ensure that pharmacies with which they contract directly or through a PBM are not restricted from disclosing prescription prices. This is consistent with the Patient Right to Know Drug Prices Act signed into law in 2018.

Generic Drugs

The availability of generic drugs in the United States has significantly lowered the cost of prescription drugs. Pharmaceutical manufacturer copayment coupons or copay cards have been offered to reduce member out-of-pocket expenses on brand drugs. Copay cards have been linked to an increase in brand drug sales. Though this reduces out-of-pocket costs for members, it can bypass plan design and lower the Generic Dispensing Rate (GDR).

Requirement: Carriers must have policies and programs in place to encourage the use of generic drugs.

Coinsurance

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. Some Carriers have moved away from drug copayments to coinsurance.

Requirement: Carriers must make every effort 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.

IX. Pharmacy Benefit Design (New Section)

Copay maximizer, copay optimizer, and other similar programs, collectively known as copay adjustment programs, require a deviation in the prescription drug benefit design to capture savings from manufacturer non-needs-based assistance. Programs that eliminate or bypass the copay/coinsurance maximums negotiated as protections in the benefit design are not in the best interest of the enrollee or the Federal government. OPM prohibits Carriers from utilizing any programs that manipulate the prescription drug benefit design, or other similar programs.

Manufacturer non-needs-based assistance programs are available to FEHB enrollees without third party intervention, so FEHB enrollees will still have access to these programs.

Requirements:

- Transparency is a requirement of the FEHB contract.
- All contracts, agreements, documentation, or other evidence related to the pharmacy benefit design and costs must be available without redaction to Healthcare and Insurance staff for oversight purposes and are subject to audits by the Office of the Inspector General. A lack of access to the underlying contracts or other arrangements with third-party vendors does not satisfy the FEHB pass-through

transparency requirements outlined in the contracts between the Carrier and OPM.

X. Coordination of Benefits (New Section)

Postal Service Health Benefits Plan and Medicare Part D Prescription Drug Coordination

The Postal Service Health Benefits ("PSHB") Program is a new program beginning January 2025 within the Federal Employees Health Benefits ("FEHB") Program, established by the Postal Service Reform Act of 2022 ("PSRA"), and codified at 5 U.S.C. 8903c. The PSRA requires plans in the PSHB Program to provide prescription drug benefits through Medicare Part D to Part D-eligible Postal Service annuitants and their Part D-eligible family members.[3] Specifically, PSHB Carriers are required to provide prescription drug benefits through prescription drug plan (PDP) EGWPs to these individuals through either a PDP or a contract with a PDP sponsor. A Carrier may also provide prescription drug coverage through an MA-PD EGWP, as approved by OPM.

The PSHB Program has specific and separate Medicare requirements for plans and individuals that will be addressed separately from those that apply to FEHB plans, as indicated in this section. For instance, in the initial contract year (2025), PSHB Carriers must offer PSHB plans that have coverage with equivalent benefits and cost-sharing to the 2025 FEHB plans offered by that carrier, except to the extent needed to integrate Medicare Part D prescription drug benefits.[4]

FEHB plan [non-PSHB plan] and Medicare Part D Prescription Drug Coordination

Carriers are encouraged to offer Medicare Part D prescription drug products as FEHB Program enrollees and family members are able to benefit from Part D coverage. Carriers may offer a CMS-approved Medicare Part D Employer

[3] 5 U.S.C. 8903c(h).
[4] 5 U.S.C. 8903c(c)(2).

Group Waiver Plan (EGWP) through a Prescription Drug Plan (PDP), a contract with a PDP sponsor, or through a Medicare Advantage Prescription Drug Plan (MA-PD). Carriers should refer to Carrier Letter 2023-02 and related guidance.

Individuals covered under an FEHB plan are not required to enroll in Medicare. Individuals will have the option to enroll in an FEHB Carrier's MA-PD EGWP, if applicable, to receive additional, enhanced coverage. OPM has allowed FEHB Carriers to automatically group enroll individuals into their PDP EGWPs.

Automatic Group Enrollment

According to Carrier Letters 2023-04 and 2023-06, FEHB Carriers are allowed to automatically group enroll Medicare Part D eligible FEHB plan enrollees and covered family members into a PDP EGWP as long as the Carrier follows CMS guidelines and meets the following OPM requirements.

Requirements:

- FEHB Carriers must implement a seamless, customer-friendly approach to allowing affected enrollees or family members to opt-out of Medicare PDP EGWP group enrollment, if they so choose.
- FEHB Carriers must implement a PDP EGWP group enrollment opt-out process that is simple, transparent, and easy to understand (e.g., it cannot require wet signature, mailing via USPS, etc.).
- FEHB Carriers that utilize automatic group enrollment must comply with all requirements for group enrollment contained in CMS guidance,[5] including those requirements contained in the PDP Enrollment and Disenrollment Guidance.
- FEHB Carriers offering Medicare Part D EGWPs are required to include specific language with respect to group enrollment in Section 9 of the FEHB brochures.

[5] U.S. Centers for Medicare & Medicaid Services. *Medicare Prescription Drug Eligibility and Enrollment* (October 25, 2023).

- FEHB Carriers are required to educate current and prospective FEHB plan enrollees or family members about the potential impact of an additional premium, known as an Income Related Monthly Adjustment Amount (IRMAA), required for certain individuals with high income.
- FEHB Carriers must maintain a strategy for educating enrollees or family members, processing EGWP enrollments, and providing customer service before, during, and after enrollment.
- FEHB Carriers may not reduce FEHB plan benefits for individuals who are enrolled in Medicare, or any other primary coverage, because of the added coverage.
- FEHB Carriers must provide individuals for whom Medicare is primary with FEHB coverage that is equal to or greater than the FEHB coverage they would have received without Medicare in all instances.
- FEHB Carriers must ensure that annuitants enrolled in an EGWP have access, through the Medicare EGWP formulary, to all drugs covered under the corresponding FEHB formulary at the same or lower cost-share than they would have otherwise been responsible for if they enrolled solely in the FEHB plan.

Medicare Part B and FEHB/PSHB Drug Coordination

FEHB plans and, effective January 1, 2025, PSHB plans, must coordinate benefits with Medicare. Medicare Part B covers outpatient provider services as well as drugs that are typically administered in an office setting. Medicare Part B may also cover some drugs available in the outpatient pharmacy setting such as immunosuppressants, some anti-cancer, anti-emetic, and dialysis drugs. In such instances, existing technology allows a Carrier to electronically coordinate benefits in real time and determine which insurer is the primary payer. Carriers must coordinate drug coverage for FEHB and PSHB enrollees and family members with Medicare Part B.

XI. Data (Updated)

OPM is required by statute to study the operation and administration of the FEHB Program. As such, Carriers are required to furnish reasonable reports

that OPM determines to be necessary to carry out its functions. This includes, but is not limited to, reports on prescription drug and health care spending pursuant to an interim final rule published on November 23, 2021, and as outlined in Carrier Letter 2022-12.

Requirements (Updated):

- Carriers must use internal data to determine their strategies, programs, and innovations. For example, pharmacy claims data can help identify non-adherent patients and the Carrier can intervene to ensure high-value medication use.
- Carriers must submit aggregate pharmacy claims and utilization data to OPM on an annual basis. Carriers should refer to the additional guidance, submission instructions, and format in Carrier Letter 2021-09 and Carrier Letter 2023-05.
- Carriers must submit prescription drug and health care spending data to the U.S. Department of Health and Human Services (HHS) in accordance with the FEHB-specific instructions in the Prescription Drug Data Collection (RxDC) Reporting Instructions from CMS. Carriers must annually submit the data subject to any flexibilities authorized by OPM.

XII. PBM Arrangements (Updated)

Standards for PBM arrangements are set out in the FEHB contracts. OPM has identified the following transparency principles:

- Pass-through transparent pricing is an arrangement based on the PBM's costs in which the Carrier receives the value of the PBM's negotiated discounts, rebates, or other credits.
- The PBM's profit under the contract comes from clearly identifiable sources.
- The PBM's administrative fees, such as dispensing fees, are clearly identified to retail claims, mail claims, and clinical programs, if applicable.

- All contracts and other documentation that support amounts charged to the Carrier contract are fully disclosed to and auditable by the Carrier, or its agent, and the OPM OIG.

OPM further clarified its contractual PBM standards in Carrier Letter 2022-20, by replacing "drugs" with "drugs, products, and supplies" for experience-rated HMOs and fee-for-service plans. Carriers should refer to Carrier Letter 2010-04, Carrier Letter 2022-20, Carrier Letter 2024-02, and their contracts for the current requirements for PBM arrangements.

XIII. Population Health (Updated)

Mental Health and Substance Use Disorder Benefits

OPM requires Carriers to comply with the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA). The Consolidated Appropriations Act, 2021 (CAA) amended MHPAEA to provide important new protections related to non-quantitative treatment limitations (NQTLs) on mental health or substance use disorder (MH/SUD) benefits. The Departments of Labor, Health and Human Services, and the Treasury (collectively, "the Departments") prepared Frequently Asked Questions (FAQs) which can be used as a compliance resource. Carriers that impose NQTLs on MH/SUD benefits must perform and document their comparative analyses of the design and application of NQTLs. Carriers must make their comparative analyses available upon OPM's direction. MH/SUD services go beyond the scope of the pharmacy benefit. Carriers should refer to Carrier Letter 2021-16.

Tobacco Cessation

The FEHB Program is a long-time leader in ensuring coverage for tobacco cessation benefits in the FEHB population. Carrier Letter 2001-09 and Carrier Letter 2010-06 communicated the ongoing requirement for all plans to provide comprehensive smoking cessation benefits. This includes coverage for prescription and over-the-counter drugs approved by the FDA to treat tobacco dependence, without copayments and not subject to annual deductibles or annual or lifetime dollar limits. Tobacco cessation goes

beyond the scope of the pharmacy benefit. Carriers should refer to Carrier Letter 2019-01 and related guidance.

Gender Affirming Care and Services

Carriers participating in the FEHB Program may not have a general exclusion of services, drugs or supplies related to gender dysphoria. In accordance with Executive Orders 13988 and 14035, Carriers must continue to improve access to gender affirming care and services (GACS) for transgender and gender diverse individuals. Carriers should ensure formularies include equitable access to medications, including medically necessary hormonal therapies. Clinical criteria should be evidence-based, transparent, easy-to-access, and not impose unnecessary barriers to medically necessary care. GACS goes beyond the scope of the pharmacy benefit. Carriers should refer to Carrier Letter 2023-12, Carrier Letter 2022-03, Carrier Letter 2015-12, and related guidance.

Preventive Services

Carriers are responsible for covering preventive services recommended with an "A" or "B" rating by the United States Preventive Services Task Force (USPSTF), as well as immunizations recommended by the Advisory Committee on Immunization Practices (ACIP), and women's health services specified in guidelines issued by the Health Resources and Services Administration (HRSA). All updates to preventive services guidelines and recommendations must be applied as they occur throughout the year by all Carriers.

USPSTF recommendations with a "D" rating indicate that the USPSTF recommends against the service because there is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits and should not be covered as a preventive service. Carriers should refer to guidance in Carrier Letter 2021-03.

Preventive care goes beyond the scope of the pharmacy benefit. Carriers should refer to the guidance in Carrier Letter 2022-03, Carrier Letter 2022-07, Carrier Letter 2019-01, and Carrier Letter 2015-14.

Contraception and Coverage for Contraceptive Care (Updated)

Access to affordable contraception is a Biden-Harris Administration priority, and Carriers should continue their focus on this important initiative. As noted in previous guidance, including Carrier Letter 2022-17, FEHB plans must have a safe and clinically effective formulary that includes a range of medications in a broad distribution of therapeutic drug classes, including contraceptive drugs, to serve the healthcare needs of the FEHB population. This includes covering at least one contraceptive with no cost sharing from each of the categories in the Women's Preventive Service Guidelines Supported by the Health Resources and Services Administration (HRSA-supported guidelines) on their formulary, as well as covering surgical sterilization for women. Any new classes that become approved, granted, or cleared by the FDA would also be subject to this requirement.

In addition, FEHB plans must cover, without cost sharing, any contraceptive services and FDA-approved, -cleared, or -granted products that a member and their attending provider have determined to be medically appropriate for the member, whether or not those services or products are specifically identified in the categories listed in the HRSA-supported Guidelines.

Carrier Letter 2022-17 allows FEHB plans to use reasonable medical management techniques, consistent with the Departments' prior FAQs Part 54 (Question 8).

Carriers must make available an easily accessible, transparent, and sufficiently expeditious exceptions process that is not unduly burdensome so the member or their provider (or other individual acting as the member's authorized representative) can obtain coverage for the medically necessary service or product without cost sharing. OPM expects Carriers to respond to contraception exception requests within 24 hours of receipt of sufficient information to make a coverage determination.

OPM will determine whether an FEHB plan's exceptions process is easily accessible, transparent, sufficiently expeditious, and not unduly burdensome based on all relevant facts and circumstances, including whether and how

the FEHB plan notifies providers or covered individuals of the exceptions process, and the steps the individual or their provider (or other individual acting as a patient's authorized representative) must take to utilize the exceptions process.

OPM will consider an exceptions process to be easily accessible if an FEHB plan's documentation includes relevant information regarding the exceptions process under the plan, including how to access the exceptions process without initiating an appeal pursuant to the disputed claims process, the types of information the FEHB plan requires as part of a request for an exception, and contact information for a representative of the plan who can answer questions related to the exceptions process.

OPM will consider an exceptions process to be transparent if, at a minimum, the information relevant to the exceptions process (including, if used, a standard exception form with instructions) is included and prominently displayed in plan documents, and in any other plan materials that describe the terms of the plan's coverage of contraceptive items and services (such as a prescription drug formulary). OPM expects FEHB plans to make this information available in a format and manner that is readily accessible, such as electronically (on a website, for example) and on paper.

As noted in Carrier Letter 2024-03, on January 22, 2024, the Departments issued Frequently Asked Questions (FAQs) about Affordable Care Act Implementation Part 64.The Departments noted that barriers to accessing contraceptive coverage persist despite previous guidance and the mandate of covering contraceptives. As such, as explained in Carrier Letter, 2024-03, OPM strongly encourages FEHB plans to adopt the therapeutic equivalence approach specified in the Departments' FAQs Part 64 in addition to adhering to existing guidelines.

- FEHB plans must continue to cover the full-range of FDA-approved, -cleared, and -granted contraceptives without cost sharing. An FEHB plan may continue to follow the guidance set forth in Carrier Letter 2022-17 and explained above. Further, consistent with Question 1 of FAQs Part 64, FEHB plans are **strongly encouraged** to follow the

therapeutic equivalence approach defined in the FAQs with respect to FDA-approved contraceptive drugs and drug-led devices.

- Consistent with Question 2 of FAQs Part 64, OPM will consider a drug or drug-led device to be therapeutically equivalent to another drug or drug-led device if the drug products or drug-led devices are identified as therapeutic equivalents (that is, designated with a code with the first letter "A") in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book).
- Carriers are also strongly encouraged to recognize the 'Dispense as Written' (DAW) function that is currently available on a prescription as the prescriber's expression of medical necessity for contraceptive drugs and drug-led devices.
- Through member and provider education initiatives, FEHB plans must amplify the availability of contraceptive care and provide information about how to access contraceptive coverage.

Carriers should inform covered individuals to contact OPM at contraception@opm.gov if they have difficulty accessing contraceptive coverage or have concerns about a plan's compliance with OPM's requirements.

Coverage for contraceptive care goes beyond the scope of the pharmacy benefit. Carriers should refer to the guidance in Carrier Letter 2024-03, Carrier Letter 2022-17, Carrier Letter 2022-05, and Carrier Letter 2022-03.

Fertility Benefits (New Section)

OPM strongly supports the provision of benefits that will help enrollees and covered family members, including those experiencing iatrogenic infertility, build their families and recognizes the valuable role of artificial insemination (AI) and assisted reproductive technologies (ART).

Requirements:

- Carriers must cover drugs associated with artificial insemination when deemed medically necessary.

- Carriers must cover the cost of IVF-related drugs for three cycles annually to defray the overall cost of IVF cycles for FEHB enrollees.

Fertility benefits coverage goes beyond the scope of the pharmacy benefit. Carriers should refer to Carrier Letter 2023-04, Carrier Letter 2023-06, and related guidance.

Coverage Related to COVID-19 (Updated)

Carriers must continue to cover, without cost-sharing, COVID-19 vaccines (including their administration), and any other qualifying coronavirus preventive services intended to prevent or mitigate COVID-19 on an in-network basis.

Consistent with the requirement for administering COVID-19 vaccines under section 3203 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Carriers must 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 USPSTF or by the ACIP.

Under the FDA's Emergency Use Authorization (EUA) for Paxlovid, state-licensed pharmacists are permitted to prescribe Paxlovid to eligible patients when the EUA's requirements for prescribing are met. Accordingly, carriers must reimburse state-licensed pharmacists for their assessment and prescribing of Paxlovid to eligible patients when the terms of the revised EUA have been followed. Carriers must stay informed and in compliance with any changes to the FDA's revised EUA for Paxlovid.

Coverage related to COVID-19 goes beyond the scope of the pharmacy benefit. Carriers should refer to the guidance in Carrier Letter 2020-02, Carrier Letter 2020-08, Carrier Letter 2020-19, Carrier Letter 2022-01, Carrier Letter 2022-08, Carrier Letter 2022-21, and Carrier Letter 2023-08 including related guidance on testing and therapeutics.

Anti-Obesity Medications

Carriers are not allowed to exclude anti-obesity medications from coverage based on a benefit exclusion or a carve out. Carriers must have adequate

coverage of FDA approved anti-obesity medications on their formulary to meet patient needs and must make available their exception process to members. Carriers must cover at least one anti-obesity drug from the glucagon-like peptide-1 (GLP-1) class for weight loss and cover at least 2 additional oral anti-obesity drug options. As new anti-obesity drugs are approved by the FDA, OPM expects Carriers to evaluate and update their coverage of anti-obesity drugs. This includes drug therapies indicated for adolescents ages 12 years and older. In cases where utilization management edits are applied, the process and evidence-based criteria for coverage must be transparent, readily accessible, and follow OPM required turnaround timelines. Weight loss coverage goes beyond the scope of the pharmacy benefit. Carriers should refer to Carrier Letter 2023-01, Carrier Letter 2022-03, and related guidance.

Benefits for Certain Medical Foods

A medical food as defined in the Orphan Drug Act (21 USC § 360ee (b)(3)), is "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." These diseases are typically classified as Inborn Errors of Metabolism (IEM), and medical foods help maintain neurological and physical function throughout the lifespan. They may also prevent birth defects in the unaffected children of pregnant mothers affected by phenylketonuria (PKU). OPM requires Carriers to offer coverage for medical foods formulated and prescribed to treat IEM regardless of age, mode of administration, disease, or whether it is the sole source of nutrition. Carriers should refer to guidance in Carrier Letter 2022-03 and Carrier Letter 2021-03, and related guidance.

XIV. Clinical trial Coverage

Section 2709 of the Public Health Service Act, as amended by the Affordable Care Act, requires group health plans to provide coverage for approved clinical trials. FEHB plans are expected to comply with these coverage

requirements for clinical trials, regardless of grandfathered status. Carriers are encouraged to cover monoclonal antibodies directed against amyloid for the treatment of Alzheimer's Disease in CMS-approved randomized controlled trials and in clinical trials approved by NIH using CMS CED criteria. This is consistent with HHS' policy of encouraging coverage in limited circumstances. Coverage of clinical trials goes beyond the scope of the pharmacy benefit. Carriers should refer to Carrier Letter 2022-11, Carrier Letter 2012-09, and subsequent guidance.

XV. Genetic Testing

Genetic tests are increasingly available to refine the clinical management of many conditions. Applications of these tests range from pre-conception counseling for prospective parents, to evaluation of metabolic disorders, to precision cancer diagnosis and treatment. Defining covered benefits in this area is challenging, but OPM recognizes that effective genetic benefits management can speed time to diagnosis, optimize treatment, improve health outcomes, and avoid costs associated with adverse drug effects.

Defining a genetic testing benefit goes beyond the scope of the pharmacy benefit. Carriers should refer to Carrier Letter 2018-01.

XVI. Fraud, Waste, and Abuse

Carriers must, at minimum, perform activities to prevent, detect, investigate, and report fraud, waste, and abuse.

Requirements:

- Carriers must implement processes that monitor pharmacy claims to identify outliers that may be evidence of fraud, waste, and abuse.
- The PBM must establish fraud, waste and abuse detection processes and procedures.
- Other entities that provide services or supplies to the PBM related to the administration of payments or benefits must certify to the PBM

the establishment of fraud, waste and abuse detection processes and procedures.

Fraud, waste, and abuse goes beyond the scope of the pharmacy benefit. Carriers should refer to Carrier Letter 2017-13, Carrier Letter 2019-01, and their contracts for guidance on fraud, waste, and abuse generally and with respect to pharmacy claims.

XVII. Quality Measures (Updated)

Plan Performance Assessment evaluates Carrier performance and provides more transparency for enrollees. Some measures used in Plan Performance Assessment will cover pharmacy topics, but this goes beyond the scope of the pharmacy benefit. Carriers should refer to the annually published Plan Performance Assessment Manual, most recently Carrier Letter 2023-11, and other related guidance.

For questions about this Carrier Letter or other aspects of pharmacy operations for the FEHB Program, please write to OPMPharmacy@opm.gov and copy your Health Insurance Specialist.

Sincerely,

Laurie Bodenheimer
Associate Director
Healthcare and Insurance

Appendix 1: Table of Carrier Letters

Topic	Carrier Letters
Formulary Management	Carrier Letter 2020-01, Carrier Letter 2020-06, Carrier Letter 2020-18, Carrier Letter 2019-01, Carrier Letter 2018-01, Carrier Letter 2018-05, Carrier Letter 2018-10, Carrier Letter 2017-01, Carrier Letter 2017-04, Carrier Letter 2016-03, Carrier Letter 2016-04, Carrier Letter 2016-07, Carrier Letter 2014-03, Carrier Letter 2012-09
Utilization Management	Carrier Letter 2021-03, Carrier Letter 2020-08, Carrier Letter 2019-01, Carrier Letter 2018-01, Carrier Letter 2018-05, Carrier Letter 2016-03, Carrier Letter 2016-04, Carrier Letter 2016-07, Carrier Letter 2014-26, Carrier Letter 2014-03, Carrier Letter 2012-09
Pharmacy Network Management	Carrier Letter 2018-05, Carrier Letter 2014-03
Specialty Drug Management	Carrier Letter 2019-01, Carrier Letter 2017-01, Carrier Letter 2017-04, Carrier Letter 2014-03, Carrier Letter 2012-09
Medication Management	Carrier Letter 2021-05, Carrier Letter 2019-01, Carrier Letter 2018-01, Carrier Letter 2018-05, Carrier Letter 2017-01, Carrier Letter 2016-04, Carrier Letter 2016-07
Opioids	Carrier Letter 2021-03, Carrier Letter 2020-01, Carrier Letter 2019-01, Carrier Letter 2019-05, Carrier Letter 2018-01, Carrier Letter 2018-05, Carrier Letter 2017-01, Carrier Letter 2016-03
Member Experience and Transparency	Carrier Letter 2019-01, Carrier Letter 2017-01, Carrier Letter 2017-04, Carrier Letter 2016-03, Carrier Letter 2016-07
Cost Containment	Carrier Letter 2019-01, Carrier Letter 2018-01, Carrier Letter 2016-03, Carrier Letter 2016-07, Carrier Letter 2014-12, Carrier Letter 2012-09, Carrier Letter 2011-05, Carrier Letter 2011-10, Carrier Letter 2006-09, Carrier Letter 2003-15, Carrier Letter 2002-14
Pharmacy Benefit Design	Carrier Letter 2023-04
Coordination of Benefits	Carrier Letter 2023-02, Carrier Letter 2023-04, Carrier Letter 2023-06

Topic	Carrier Letters
Data	Carrier Letter 2023-05, Carrier Letter 2022-12, Carrier Letter 2021-09, Carrier Letter 2020-17, Carrier Letter 2019-01, Carrier Letter 2016-03, Carrier Letter 2016-07
PBM Arrangements	Carrier Letter 2024-02, Carrier Letter 2022-20, Carrier Letter 2010-04, Carrier Letter 2009-15, Carrier Letter 2006-09, Carrier Letter 2004-04
Population Health	Carrier Letter 2024-03, Carrier Letter 2023-12, Carrier Letter 2023-08, Carrier Letter 2023-01, Carrier Letter 2022-21, Carrier Letter 2022-17, Carrier Letter 2022-08, Carrier Letter 2022-07, Carrier Letter 2022-05, Carrier Letter 2022-03, Carrier Letter 2022-01, Carrier Letter 2021-16, Carrier Letter 2021-03, Carrier Letter 2020-02, Carrier Letter 2020-08, Carrier Letter 2020-19, Carrier Letter 2019-01, Carrier Letter 2018-01, Carrier Letter 2017-04a, Carrier Letter 2015-12, Carrier Letter 2015-14, Carrier Letter 2014-04, Carrier Letter 2010-06, Carrier Letter 2008-17, Carrier Letter 2001-09
Clinical Trial Coverage	Carrier Letter 2022-11, Carrier Letter 2018-01, Carrier Letter 2018-10
Genetic Testing	Carrier Letter 2019-01, Carrier Letter 2018-01, Carrier Letter 2018-10
Fraud, Waste, and Abuse	Carrier Letter 2019-01, Carrier Letter 2017-13, Carrier Letter 2014-29, Carrier Letter 2011-13, Carrier Letter 2007-12, Carrier Letter 2003-02, Carrier Letter 2003-23, Carrier Letter 2003-25, Carrier Letter 2002-01
Quality Measures	Carrier Letter 2022-19, Carrier Letter 2021-19, Carrier Letter 2020-20, Carrier Letter 2018-15, Carrier Letter 2017-02, Carrier Letter 2017-12, Carrier Letter 2017-15, Carrier Letter 2016-02, Carrier Letter 2016-11, Carrier Letter 2016-14, Carrier Letter 2015-10, Carrier Letter 2015-15, Carrier Letter 2015-19, Carrier Letter 2014-19, Carrier Letter 2014-28