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Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
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Via email: IRARebateandNegotiation@cms.hhs.gov

RE: Biktarvy MFP Implementation: Access and Monitoring Considerations for People Aging with HIV

Dear Administrator Oz:

We are writing to raise several access questions related to implementation of Biktarvy's Maximum Fair Price (MFP) under the Medicare Drug Price Negotiation Program (MDPNP) as that price takes effect in 2028.

For background, HealthHIV is a partner and national non-profit working with healthcare organizations, communities, and providers to advance effective HIV, Hepatitis C (HCV), and sexually transmitted infection (STI) care through education and training, technical assistance and capacity building, advocacy, communications and health services research and evaluation.

And we appreciate the opportunities CMS has offered over the years to provide input on the MDPNP and its process, based on what's shared by communities and colleagues we represent. Since the announcement of Biktarvy's selection under the IRA, that engagement has taken on even more relevance; and we've worked to ground our IPAY 2027 and 2028 comments with feedback from others—across patients, caregivers and other stakeholders.

In efforts to reach those ends, HealthHIV supports the Inflation Reduction Act's (IRA) intention to reduce overall costs. That includes provisions that cap Medicare beneficiaries' annual out-of-pocket costs and ones that allow patients to spread those payments throughout the year. In fact, capping out-of-pocket costs is a tremendous benefit for the growing population of Americans aging with HIV. That helps the growing majority of People with HIV (PWH) who are age 50 or older afford and maintain access to their HIV treatment, other medications, and the coverage they rely on.

Following our comments on the Initial Price Applicability Year (IPAY) 2027 and IPAY 2028 draft guidance, our focus turns to implementation. And whether, in insurance carrier

decisions and prescribing practice, the way Biktarvy's MFP is carried through the payer system supports the HIV care continuum we've built across ecosystems for People aging with HIV or creates friction. From our vantage, questions continue to hinge on the payer, pharmacy, and program interactions that, in turn, will shape post-implementation access to and retention in lifelong HIV care.

With this letter, what we are most interested in conveying to and understanding from CMS is how these questions will be followed and what continuous quality improvement (CQI) data will be monitored as the price-setting provisions of the IRA, and the MDPNP they established, are put into practice for the roughly 101,000 beneficiaries currently estimated to be using Biktarvy. That gives us a clearer way to *square* what CMS is watching with what we're hearing from those likely to be affected and their providers around access and those interactions.

Our own state-level experience with HIV ecosystem changes (however slight or well-intended) tells us to pay attention to what happens afterward. Without that attention, the MFP can become a payer anchor and create a kind of denominator drift: The price travels, while the population and outcomes being measured can change. State reviews may apply the MFP across commercial coverage and public programs such as Medicaid and state employee plans, with that transported price coming from Medicare.

We've seen how unevenly affordability policies account for the financing, pharmacy access and program interactions that support the HIV care continuum. A pricing or affordability decision can move through reimbursement, coverage, pharmacy participation and ultimately patient access. *Can, being the operative word*.

That uncertainty is, in a nutshell, the reason for this letter *and* the recommendations that follow. Our aim is to better inform how the law's written charge is carried through implementation, and how we measure and evaluate whether its intended affordability gains reach patients—without destabilizing the access systems around them or adding administrative burden within them.

But we also know that data move systems, and can help payers decide when and how to adjust course if policy overcorrects *or* underperforms.

To help put some of these questions into context, we'd like to draw on findings from our own primary research, the *Fifth Annual State of Aging with HIV National Survey*, fielded in February 2026 among People aging with HIV and HIV-aging service providers across 37 states and the District of Columbia. For background, the annual survey looks at what aging with HIV means, particularly as geriatric care becomes more immediately necessary for many and increasingly so for others, as comorbidities, behavioral health, access and payment, and the system's workforce capacity shape their care. Our data highlight those pressures and how they are showing up in an interconnected HIV care environment. And in 2026, we found that over 98% of the consumer cohort reported being virally

suppressed, and nearly 100% reported taking antiretroviral medicines—the highest rates since we began tracking these measures in 2020.

These findings give us a useful starting point for looking at four (4) things in practice: *Affordability, coverage, pharmacy access, and the measures CMS can follow over time as the MFP takes effect.*

Affordability was already a problem; now let's see whether the MFP policy improves it. Our 2026 survey data are useful because they establish a baseline before the MFP takes effect. In the 2026 survey, 24% of People aging with HIV said their out-of-pocket costs for HIV care were difficult to afford, and 20% had delayed or avoided care because of insurance or out-of-pocket concerns. Among those reporting cost difficulty, 48% had delayed or avoided care, compared with 12% of others. That's a strong cross-sectional association without implying cause. It gives CMS a baseline for assessing whether intended affordability gains are reflected in patient experience and care-seeking behavior as the MFP takes effect.

Coverage is its own distinct issue. Eleven percent of respondents switched HIV medications because a plan wouldn't cover one or they couldn't obtain prior authorization, and 12% appealed an insurance decision about an HIV medication. Among those required to switch, 49% filed an appeal, compared with 7% of others. These findings predate Biktarvy's 2028 MFP and shouldn't be read as an effect of the Medicare Drug Price Negotiation Program. They show the kinds of coverage friction CMS should watch as implementation proceeds.

Pharmacy access adds another dimension. One-fourth of respondents had switched pharmacies because of plan or formulary changes, 35% used two or more pharmacies, and 13% reported pharmacy or mail-service delivery challenges in the prior year. Medicare enrollees were about twice as likely as other consumers to use two or more pharmacies. The survey doesn't prove that Medicare caused that pattern or that multiple-pharmacy use itself represents a barrier. But it does help establish why CMS should analyze whether patients can obtain treatment when needed, including whether pharmacy or mail-service changes create delays.

The survey also gives CMS additional clinical context: 81% of respondents were taking medication for at least one chronic condition other than HIV, and 22% had adjusted HIV treatment because of drug interactions. For People aging with HIV, CMS should be able to see whether affordability improves without new barriers to obtaining treatment, staying on therapy, or remaining virally suppressed.

Factored together, these findings help identify what CMS can follow over time as the MFP takes effect.

And, that patient-level picture is especially relevant in HIV, where Medicare already recognizes the importance of stable access to HIV antiretroviral (ARV) treatment through

the *Six Protected Classes policy*. But "protected" has limits. "All or substantially all" speaks first to formulary inclusion. CMS treats formulary inclusion and utilization-management protections as separate parts of the framework, and the policy itself was created in part to reduce the risks of interrupted therapy. So the gap between being "protected" and having fully usable access is precisely what leads into the clinical and personal question. The standard still creates a meaningful level of predictability and durability for patients, yet treatment access banks in large part on formulary tier placement and cost sharing, pharmacy network design, point-of-sale claim processing, inventory decisions, and a pharmacy's ability to sustainably obtain and dispense a medication. Each of these factors can shape whether a covered prescription can actually be filled when a patient needs it.

That's something we feel CMS should keep visible as the MFP takes effect. Coverage can be established through policy, and a negotiated price can change the economics around that coverage. Whether a treatment works for a person remains a clinical and personal question, a distinction reinforced by partners and community members throughout CMS's public engagement events.

Therapeutic alternatives are also a secondary clinical consequence. The Town Hall reinforced that therapeutic class alone doesn't tell us whether another regimen can work for a particular person. Dosing requirements, fixed-dose combination design, treatment history, HBV coinfection, resistance history and testing, drug-drug interactions, adherence, and the clinical circumstances of People aging with HIV all inform that decision.

Then, once the prescription reaches the pharmacy, the financial side becomes more complicated. Part D sponsors, often through pharmacy benefit managers, establish pharmacy reimbursement arrangements, and manufacturers must provide access to the MFP either prospectively or through a retrospective refund. Under the retrospective approach, a pharmacy may acquire the drug above the MFP and wait for a refund of the difference. When a retrospective refund is used, the pharmacy can carry that acquisition cost until the refund arrives. Acquisition-cost exposure, reimbursement and refund timing all are practical cash-flow concerns that can affect whether a pharmacy can keep dispensing. Those pressures warrant particular attention for independent pharmacies, particularly in rural and frontier communities where pharmacy options are already limited. MedPAC's April 2026 preliminary analysis of 2025 pharmacy ownership data found that rural ZIP codes were predominantly served by independent pharmacies and noted that pharmacy closures can create network gaps in areas with few pharmacies.

And the Medicare Transaction Facilitator (MTF) is central to that refund process. Where a manufacturer uses retrospective MFP refunds, the 14-day manufacturer payment period begins after the MTF Data Module transmits the claim-level data elements to the manufacturer; it does not begin when the prescription is dispensed. A manufacturer can satisfy the 14-day payment requirement even if the dispensing pharmacy has not yet received the refund. Measuring the full interval from dispensing through receipt of the MFP

refund would give CMS a clearer basis for assessing whether delays create material cash-flow pressure for dispensing entities and how best to address it.

The interaction with the 340B Drug Pricing Program adds its own layer. A manufacturer isn't required to provide both an MFP and a lower 340B ceiling price on the same unit, and CMS isn't currently assuming responsibility for determining non-duplication between those discounts. When information establishing 340B eligibility arrives after an MFP refund has been paid, credits or other retrospective reconciliation may be necessary. That depends on timely and accurate claims information and can leave uncertainty over which price applies and when the transaction is finally settled. CMS should keep improving the exchange of 340B information through the MTF and monitor claims that require retrospective reconciliation, including how often they occur and how long they take to resolve.

The 340B interaction also extends beyond claim-level reconciliation into the statutory pricing system. Under the Inflation Reduction Act, an MFP is included in Medicaid Best Price (MBP) and excluded from Average Manufacturer Price (AMP). Depending on how the MFP interacts with other statutory pricing calculations, this can affect Medicaid rebate calculations and the 340B ceiling price over subsequent reporting periods. The timing of those changes may extend across reporting periods, giving CMS another pathway to monitor.

Additional downstream responses are (much) less predictable. Manufacturers may reconsider voluntary ADAP rebates, supplemental discounts, list prices, or other commercial arrangements as negotiated prices are implemented. Those responses aren't required by the MDPNP and shouldn't be presumed, but they are another area worth watching. In short, identify the mechanism, don't presume the outcome and watch the operational data as it comes in.

The pharmacy reimbursement side of the equation deserves its own agenda and attention. CMS says the negotiated price used in payment by a Part D sponsor can't exceed the MFP plus any dispensing fees, and plans can negotiate below the MFP. Dispensing fees remain separately negotiated, but CMS hasn't—to our knowledge—established requirements for those fees.

Dispensing selected drugs involves inventory costs, claims processing, MTF reconciliation, patient counseling, adherence support and other services that can be particularly significant in HIV care. We're encouraged that CMS has called for sustainable and fair reimbursement practices, as well as adequate and fair compensation for pharmacies dispensing selected drugs. But given the access implications, we think that warrants both advance consideration of clearer guardrails before 2028, without prescribing a national fee methodology, and ongoing evaluation—a CQI lens—of whether reimbursement supports those services across different pharmacy types and ownership structures.

That inquiry should include the effects of vertical integration. Colleagues have pointed out that a pharmacy affiliated with a Part D sponsor or pharmacy benefit manager may be better positioned within plan networks. Or that they might have broader geographic reach or serve a larger share of prescriptions—giving the enterprise greater capacity to manage payment timing, reimbursement and financial flows across related entities.

Independent and community-based HIV specialty pharmacies may rely more directly on their own working capital to finance acquisition costs and extended receivables.

Amid the administration's broader policy attention to CMS's Rural Health Transformation Program, PBM reform and 340B reform, many of the same questions are being raised around vertically integrated hospital and pharmacy systems. That perspective is useful as CMS examines whether reimbursement, dispensing fees, MFP refund timing, stocking patterns and network participation differ across affiliated and non-affiliated pharmacies. And where those differences affect their ability to dispense an MFP-selected drug, that can impact adherence, health outcomes and avoidable downstream costs.

We've also been asked to pay closer attention to the difference between pharmacy presence and *usable* pharmacy access. A pharmacy appearing in licensing or network data doesn't inevitably mean a beneficiary can obtain a prescription there; that's particularly true in rural and frontier communities where dispensing locations and service areas may look very different on the ground.

These reimbursement and ownership questions are unfolding within a Part D market with fewer standalone plan options. In early 2026, 44% of Part D enrollees were in stand-alone prescription drug plans (PDPs); that enrollment number includes employer-group PDPs and territories. Separately, 360 PDP offerings are available across the 34 Part D regions. Part D enrollment is also concentrated among a small number of large plan sponsors, many operating across insurance, pharmacy benefit management, and pharmacy functions. For People aging with HIV, that market structure can shape pharmacy contracting, reimbursement, network participation, and the capacity of dispensing entities to manage the timing of MFP payments and refunds.

Those same interactions take on added significance as MFPs are used as reference points in state affordability policy, where the Medicare price is no longer operating only inside Medicare. State discussions are also making clear that payer-level savings, patient affordability, and pharmacy access are distinct outcomes and should not be assumed to move together. CMS should account for those downstream uses when evaluating and communicating the effects of negotiated prices.

In closing, Biktarvy gives CMS a distinct opportunity. It's the first HIV treatment selected for Medicare negotiation, and it arrives as more People with HIV age into Medicare and trust the program to sustain lifelong treatment. That trust carries both a relationship and an expectation that access will remain dependable as policy changes are put into practice.

This is an important early test of how negotiated prices work in HIV care—past 2028's point-of-price-setting and into real-world effects on coverage, pharmacies and the programs that sustain access. How CMS follows that experience can help inform future implementation as Medicare's role in HIV care continues to grow.

We hope CMS's monitoring will include the full timeline for MFP effectuation and refunds; MFP and 340B reconciliation; reimbursement across pharmacy ownership models; pharmacy stocking and network participation; and downstream effects across programs serving PWH. Those measures should also be considered alongside the patient-level outcomes described above, including affordability, staying on treatment, pharmacy access and sustained viral suppression.

HealthHIV appreciates CMS's consideration of our recommendations. And we are committed to working with CMS as this moves forward and to sharing what we're learning from People aging with HIV, providers, pharmacies and programs supporting the HIV care continuum.

Appreciatively,

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REFERENCES

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