HIV+HEP
POLICY INSTITUTE

January 16, 2025

Mr. Michael Conway
Commissioner, Colorado Division of Insurance
1560 Broadway, Suite 850
Denver CO 80202

RE: Comments on Draft Amended Regulation 4-2-73 and Bulletin No. B-4.112

Submitted via E-mail to DORA_INS_RulesandRecords@state.co.us

Dear Commissioner Conway:

The **HIV+Hepatitis Policy Institute**, a leading national HIV and hepatitis policy organization promoting quality and affordable healthcare for people living with or at risk of HIV, hepatitis, and other serious and chronic health conditions, appreciates the opportunity to offer comments on draft proposed amended regulation 4-2-73 and amended bulletin No. B-4.112 relating to coverage of HIV pre-exposure prophylaxis (PrEP) by state-regulated plans.

We commend the Division of Insurance for taking the initiative to update state guidance on PrEP coverage. We support a finalized regulation and bulletin that clarifies that all PrEP medications and services must be covered without prior authorization or cost-sharing.

We urge you to clarify that all FDA-approved PrEP medications must be covered without prior authorization or cost-sharing.

Now that federal insurance regulators have issued updated guidance that recognizes that all FDA-approved PrEP medications are incorporated in the USPSTF recommendation and must be covered without prior authorization or cost-sharing, we commend you for issuing guidance that echoes that requirement for insurers.

We believe that paragraphs D, E, and F of Section 5 do not make it clear enough that utilization management including prior authorization or step therapy is not allowed for PrEP, including to "direct individuals prescribed PrEP to use one formulation over another."[1] We believe Paragraph D, which prohibits prior authorization or step therapy only for pharmacist-prescribed PrEP, should instead prohibit prior authorization or step therapy for any formulation of PrEP prescribed by any clinical provider. We are concerned that Paragraph E, which requires carriers to expedite requests for PrEP by deeming them equivalent to urgent prior authorization

[1] https://www.cms.gov/files/document/faqs-implementation-part-68.pdf (page 4)

requests as defined in C.R.S 10-16-124.5(8)(b), is in conflict with the prohibition on prior authorization for PrEP. We hope that Colorado can implement its expectation that carriers respond quickly to provider requests for PrEP (which we support) without reference to prior authorization processes. With these changes to Paragraphs D and E, we would support Paragraph F, which forbids the imposition of additional utilization management procedures or requirements.

We urge you to clarify that the guidance encompasses any FDA-approved form of PrEP.

The USPSTF recommends the prescription of PrEP using "effective antiretroviral therapy" to individuals at increased risk of acquiring HIV. This recommendation is not specific to particular PrEP medications. Given that many long-acting formulations, both injectable and oral, are in development, with approval of a novel biannual injectable form of PrEP expected as soon as this year, we believe states must require zero-cost access to all FDA-approved medications for the prevention of HIV, rather than limiting coverage to the three medications that are currently available. This will prevent the need for a new round of guidance each time a new PrEP drug becomes available and ensure access to all forms of effective HIV prevention for many who choose long-acting drugs that increase adherence, such as those who are unable to adhere to a regimen of daily pills, including the insecurely housed, or those who have confidentiality concerns about the storage of oral medication, or others.

Since cost-sharing is prohibited for PrEP in all non-grandfathered plans, there is no need for an explicit prohibition of adverse tiering.

Section 5.C. of draft amended regulation 4-2-73 specifies (for individual and small group plans only) that no more than 50% of drugs used for HIV prevention may be placed on a plan's highest-cost formulary tier. Though the Division is to be commended on focusing on adverse tiering of PrEP formulations, since grandfathered plans (which do not need to comply with the ACA preventive coverage mandate) are excluded from the scope of this amended guidance, we are concerned that this section leaves the impression that charging cost-sharing for some PrEP medications is permissible.

We thank you for clarifying that all services integral to PrEP, such as laboratory testing or clinical visits, must be covered without prior authorization or cost-sharing. Insurers should be required to simplify coding requirements for PrEP services.

We support your reaffirmation in this proposed amended guidance that all required clinical and laboratory services for PrEP must be covered without cost-sharing, and for echoing federal regulators' attention to how insurers must not allow complex coding requirements to prevent zero-cost access to PrEP. The new CDC ICD-10 code for PrEP, combined with Modifier 33 to flag $0-cost-sharing ACA preventive services, mean that PrEP services can be unambiguously flagged. Insurers should no longer be able to use complex coding requirements that vary from

issuer to issuer to excuse wholesale non-compliance with the law.[2]

The updated USPSTF PrEP recommendation and federal guidance mean that it is a timely juncture for states who wish to improve access to HIV prevention to update state guidance. But updated state guidance is not enough – we urge Colorado to vigorously enforce these state requirements.

The expansion of access to PrEP is one of the goals of the Colorado HIV/AIDS Strategy (COHAS) 2022-2026. The importance of PrEP access is also reflected in the creation by the Colorado Department of Public Health and the Environment of the Public Health Intervention Program (PHIP) which helps Colorado residents pay for PrEP care and medications. Though Colorado's PrEP uptake exceeds the national average, uptake among Blacks, Hispanics, and women lags significantly, underscoring the necessity for state governments to bolster access using all tools available.[3]

We continue to hear from PrEP users who are being charged cost-sharing for PrEP drugs and services despite federal and state requirements. Recent studies have shown that about a third of commercial insurance claims for PrEP (medications, including the generic, required laboratory testing, and provider visits) are associated with cost-sharing, demonstrating the urgent need for enforcement actions from federal and state insurance regulators.[4] New Mexico's Superintendent of Insurance, for example, has required issuers in that state to audit PrEP claims, identify cost-sharing charged in violation of federal and state requirements, and reimburse people who were erroneously charged.

We applaud the Colorado Division of Insurance for proposing the draft regulation and bulletin, and we thank you for engaging stakeholders in a public comment process.

Should you have any questions or comments, please feel free to contact Carl Schmid by phone at (202) 462-3042 or by email at cschmid@hivhep.org, or Kevin Herwig by phone at (617) 666-6634 or by email at kherwig@hivhep.org. Thank you very much.

Sincerely,

Carl E. Schmid II
Executive Director

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[2] https://nastad.org/sites/default/files/2023-10/PDF-HIV-Prevention-BillingAndCoding-101223.pdf
[3] https://map.aidsvu.org/profiles/state/colorado/prevention-and-testing#1-1-PrEP
[4] See https://www.croiconference.org/wp-content/uploads/sites/2/posters/2024/1117.pdf for ancillary services; for drug cost-sharing, see Slide 11, https://hivhep.org/wp-content/uploads/2024/05/Key-PrEP-Policy-Issues-Impacting-Access-for-InsuredPopulations-5.29.24.pdf. From Zachry et al, Impact of the United States Preventive Task Force Guidelines on PreExposure Prophylaxis (PrEP) Claims and HIV-1 Infection Incidence: An Interrupted Time Series with Segmented Regression Analysis. AMCP-Nexus 2023, Orlando FL