Biden Administration Strengthens Patient Protections in Accessing Prescription Drugs

**Final HHS Rule Expands Scope of Discrimination in Healthcare**

Washington DC... The Biden administration has issued a final rule that strengthens the implementation of the Affordable Care Act’s nondiscrimination provisions, that when properly enforced, should increase patient access and affordability of prescription drugs.

In the final rule, the application of the law has been reinstated and even strengthened from the previous regulation to include health insurers and all HHS programs and activities, including Medicaid. For the first time, the regulation calls out PBMs, and states that their activities are subject to the rule as they relate to “their role of administering prescription drug benefits on behalf of payers, pharmacy benefit managers develop drug formularies and related policies, create pharmacy networks, reimburse pharmacies for patients’ prescriptions, negotiate rebates and fees with drug manufacturers, process enrollees’ claims and appeals, and review drug utilization, among other things.”

The final rule also stresses that insurance marketing practices and benefit design are subject to the rule and describes certain practices that can be potentially discriminatory, including coverage, exclusions, limitation of benefits, prescription drug formularies, cost-sharing (including copays, coinsurance and deductibles) utilization management techniques (step therapy and prior authorization). The final rule also affirms that automated decision tools are subject to the rule and must be implemented in a nondiscriminatory manner.

“We applaud the Biden administration’s strengthening of the nondiscrimination regulation in order to ensure that patients, particularly those who rely on prescription drugs, are better protected against the discriminatory practices of some insurers and PBMs,” commented Carl Schmid, executive director of the HIV+Hepatitis Policy Institute. “Patients are being faced with high cost-sharing, excessive utilization management techniques, such as prior authorization, drug exclusions, and now even AI tools that decide what drugs they can receive. We can now be assured that, thanks to the ACA, they must be implemented in a nondiscriminatory manner.”
Schmid continued, “However, enforcement must still be necessary and will only happen on a case-by-case basis, driven by complaints. This leaves the burden on patients and based on our experience the complaints we have filed regarding access and affordability of HIV drugs haven’t always yielded success, and allowed insures and PBMs to continue their harmful practices. Hopefully, this new regulation will change that.”

The HIV+Hepatitis Policy Institute also applauds the final rule for affirming that discrimination based on sex includes sexual orientation and gender identity. This will certainly help many people improve their access to healthcare who are impacted by HIV.

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The HIV+Hepatitis Policy Institute is a national, non-profit organization whose mission is to promote quality and affordable healthcare for people living with or at risk of HIV, hepatitis, and other serious and chronic health conditions.