



RAAP APPLAUDS US DISTRICT COURT DECISION TO STRIKE DOWN HHS RULE TO ALLOW INSURERS TO NOT COUNT COPAY ASSISTANCE

Washington, D.C. (10-2-2023) – Patients who depend on prescription drugs won a major victory in U.S. District Court as the Court struck down a federal rule that had allowed health insurers to not count drug manufacturer copay assistance towards a beneficiary’s out of pocket costs.

The plaintiffs, three individuals and three patient advocacy groups, including HIV+Hepatitis Policy Institute, Diabetes Leadership Council, and the Diabetes Patient Advocacy Coalition, sued the Centers for Medicare & Medicaid Services (“CMS”) over its rule that allows for but does not require accumulator programs.

Plaintiffs alleged that the rule conflicts with the Affordable Care Act’s statutory definition of “cost sharing,” conflicts with the agencies’ preexisting regulatory definition of “cost sharing,” and is arbitrary and capricious.

The Court ruled that CMS’ rule must be set aside based on its contradictory reading of the same statutory and regulatory language and the fact that the agencies have yet to offer a definitive interpretation of this language that would support the rule.

“RAAP applauds the ruling by the US District Court”, said Michael Eging, Executive Director of the Rare Access Action Project (RAAP).

“This ruling will significantly help patients who have been forced to pay unnecessary and extremely costly over charges on critical prescription drugs.

“As the Court agreed in its decision, a regulation simply cannot have two different meanings to the same regulated entity. This US District Court decision is a major win for patients who are already suffering and should not have ever been charged upwards of thousands of dollars more for their needed medications”, concluded Eging.

Through this decision, the Court will set aside the 2021 NBPP based on both its contradictory reading of the same statutory and regulatory language and the fact that the agencies have yet to offer a definitive interpretation of this language that would support their authorization of copay accumulators. Copay accumulators will now only be permissible for branded drugs that have a generic version.

For more information, e-mail: evan@rareaccessactionproject.com, or contact Evan Kozlow at 202-731-1275.

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RAAP, the Rare Access Action Project, is a coalition of life sciences and patient stakeholders that explore creative policy solutions to address structural issues in access and coverage. Our priority is to help ensure rare disease patients have access to the care and treatments they need. RAAP is a registered 501 (c)4 non-profit organization.