Challenges for Health Plans – Gene Therapy Exclusions and Impending Rash of Special Enrollments

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We want to alert plan sponsors to two developments that may impact health plans: (1) continued U.S. Food and Drug Administration (FDA) approval of gene therapy treatments, and (2) the end of a rule banning the state Medicaid and CHIP systems from enforcing eligibility standards to drop enrolled individuals from coverage during the COVID-19 pandemic.

Gene Therapy

Historically, gene therapy has been considered an experimental treatment and, thus, often excluded from health plan coverage. With FDA approval of a number of gene therapy treatments, and more in the pipeline, plans can no longer rely on the experimental nature of these expensive treatments to exclude them from coverage. While many insurers and stop-loss carriers generally cover FDA-approved treatments, they are often carving out coverage for certain specialty drugs and FDA-approved treatments with a cost in excess of a specified threshold (typically $500,000). Stop-loss carriers are also "lasering out" certain participants (specifically providing that the stop-loss carrier will exclude claims from the designated individuals when calculating the amounts payable under the policy) so that the carriers can avoid the high cost of these treatments.

Plan sponsors should look carefully at renewals to ensure that they understand what costs will be covered and whether plan design changes are needed. There are a number of thorny issues to navigate and consideration of your plan's specific demographics may impact the analysis. For help navigating these issues, contact your Vorys counsel.

Medicaid Eligibility Audits are Resuming

During the COVID-19 pandemic, state Medicaid and Children's Health Insurance Program (CHIP) agencies were not permitted to end coverage for individuals who were enrolled in Medicaid or CHIP even if their income changed or they ceased to meet eligibility requirements. This restriction ended on March 31, 2023. State Medicaid and CHIP

agencies are now performing eligibility audits and may disenroll individuals who do not timely confirm their continued eligibility. The Biden administration estimates that tens of millions of people will have their Medicaid or CHIP eligibility cancelled over the coming months.

Employees who have previously declined coverage under a group health plan must be given at least 60 days from the date Medicaid or CHIP coverage ends for the employee or a dependent (because the individual ceases to be eligible for the Medicaid or CHIP coverage) to elect to enroll in the group health plan. This is referred to as a HIPAA special enrollment right.

The deadline to exercise a HIPAA special enrollment right is temporarily extended under the emergency relief issued by the U.S. Department of Labor (DOL) during the COVID-19 pandemic. Consequently, if Medicaid or CHIP coverage ends for an employee or dependent on or before July 10, 2023, the employee will have until September 8, 2023 to exercise their HIPAA special enrollment right to enroll in the group health plan. For coverage ending after that date, the normal 60 day rule will apply (unless your plan permits a longer period).

The DOL, Internal Revenue Service and U.S. Department of Health and Human Services (the tri-agencies) are encouraging employers to be aware of the state agencies' return to normal operations and the commencement of eligible audits. The tri-agencies are also hoping that employers will take steps to educate their employees who may be enrolled in Medicaid or CHIP coverage about the need to update their contact information with the applicable state agency and to respond to any communication that the employee receives from the state agency to ensure that coverage is not dropped because the otherwise eligible employee fails to timely respond to a request for information. We note that no education effort is legally required.

Contact your Vorys attorney if you would like assistance crafting an employee communication on this issue.