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FMLA Leave May Be Used to Participate in Clinical Trials

The Wage and Hour Division (WHD) of the U.S. Department of Labor (DOL) has issued [Opinion Letter FMLA2024-01-A](#), stating that leave under the federal Family and Medical Leave Act (FMLA) may be used by employees to participate in treatment that is part of a clinical trial.

The letter was issued Nov. 8, 2024, in response to a request from an organization working toward finding a cure for a specific disease and relying on clinical trials to achieve that goal. The letter said that concern about taking time off work is a significant barrier to African Americans' participation in the organization's clinical trials. The opinion is limited to situations where an eligible employee of a covered employer takes FMLA leave to participate in a clinical trial addressing their own serious health condition.

WHD Analysis Under the FMLA

The FMLA allows employees otherwise eligible for leave to use the leave because of (among other reasons) a serious health condition that makes them unable to perform the functions of their position at work. "Continuing treatment by a health care provider" satisfies the definition of "serious health condition" under the statute. Noting the broad definition of "continuing treatment" in the FMLA regulations, the WHD concluded that the medical interventions involved in clinical trials, which include prescription medication and the use of medical equipment, meet that definition. The WHD also said that because the regulations do not require the treatment to be efficacious, clinical trials may be experimental, use placebos or have unproven efficacy and still qualify as continuing treatment under the FMLA.

The WHD further examined the history of the regulations—specifically, the DOL's deliberate choice not to exclude voluntary treatments from FMLA coverage—and concluded that the fact that treatment is optional, voluntary or elective also does not factor into the determination of whether an employee may take FMLA leave to receive the treatment. An eligible employee's participation in a clinical trial would, therefore, not be excluded from FMLA coverage on that basis.

FMLA

The FMLA provides up to 12 weeks per year of unpaid leave to eligible employees of covered employers for specific family and medical reasons. Generally, private employers are covered if they have 50 or more employees. To be eligible, employees must have worked for the employer for at least 12 months, have worked for the employer for at least 1,250 hours during the 12 months preceding leave, and work at a location within 75 miles of which the employer has at least 50 employees.

HIGHLIGHTS

- The DOL issued an opinion letter addressing whether an employee eligible for FMLA leave could take that leave to participate in a clinical trial.
- According to the letter, such employees may take FMLA leave to participate in clinical trials to treat their serious health conditions.
- The letter said neither the experimental nature of the treatment, the possible use of placebos, the treatment's unproven efficacy nor the voluntary nature of the treatment would preclude it from qualifying as continuing treatment under the FMLA.

Provided by Salus Group

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