

Granting FMLA Leave for Clinical Trials: Five Key Points from the DOL's New Guidance for Employers

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Takeaways

- Employees who meet all other FMLA requirements may take FMLA leave for clinical trial treatment of a serious health condition, regardless of whether the treatment is experimental or involves placebos.
- Employers may not ask about the effectiveness of a treatment, the specific medications prescribed, or the detailed treatment plan when determining if an employee is eligible to take FMLA leave.

Link

[FMLA2024-01-A](#)

Article

The U.S. Department of Labor's Wage and Hour Division issued an [opinion letter](#) on Nov. 8, 2024, affirming that employees may use Family and Medical Leave Act (FMLA) leave when participating in clinical trials. This is significant guidance for employers, as it clarifies the scope of permitted uses of FMLA leave to include medical interventions provided as part of clinical trials, regardless of whether the treatment is experimental or involves placebos.

The DOL provides two useful examples:

1. Janelle has sarcoidosis, an inflammatory autoimmune disease that affects her breathing. Janelle receives treatment for sarcoidosis at least twice a year and, as such, the condition qualifies as a chronic serious health condition under the FMLA. Janelle meets the FMLA eligibility criteria. Janelle is interested in volunteering to participate in a clinical trial for the treatment of sarcoidosis but is concerned that if she changes her current treatment plan the amount of time she needs to take off work may change. Under the FMLA, Janelle may use FMLA leave to receive treatment in the clinical trial and recover from treatment, including if there are changes in treatment or in her response to treatment due to her participation in the clinical trial.
2. Bernard has cancer and is participating in a clinical trial for a new drug intended to help patients manage side effects from chemotherapy. Bernard meets the FMLA eligibility criteria. In the clinical trial, Bernard does not know whether he has been prescribed the new drug or a placebo. Bernard may use FMLA leave intermittently for time spent receiving chemotherapy and participating in the clinical trial, including recovery time.

Highlights from the DOL's opinion letter include:

1. **FMLA Requirements:** Employees who meet all other FMLA requirements may take

FMLA leave for the treatment of a serious health condition when treatment is part of a clinical trial.

2. **Caring for a Family Member:** Leave also extends to caring for a family member with a serious health condition and taking FMLA military caregiver leave to care for a covered service member when the person being cared for is participating in a clinical trial.
3. **Broad Definition of Treatment:** The FMLA defines “treatment” broadly, encompassing medical interventions that may or may not be effective in every case. It is not relevant whether a course of treatment is new, experimental, a placebo or proven to meet certain criteria for efficacy.
4. **Optional, Voluntary or Elective Treatments:** The fact that treatment is considered optional, voluntary or elective – as may generally be the case with clinical trial participation – is not a factor in the determination of whether an employee may take FMLA leave to receive it. This is in contrast to elective procedures for cosmetic treatments, such as most treatments for acne or plastic surgery, which generally are not administered for serious health conditions and do not qualify for FMLA leave.
5. **Employer Inquiries and Certification:** Employers may not ask about the effectiveness of a treatment, the specific medications prescribed or the detailed treatment plan when determining if an employee is eligible to take FMLA leave. The certification process for FMLA leave remains unchanged. Employers may only verify that an employee has a serious health condition requiring “treatment” by a healthcare provider when responding to a leave request.

State Leave Laws

The new opinion letter may also affect state leave entitlements. Many state family and medical leave insurance programs, for example, mirror FMLA’s definition of “serious health condition” or “treatment” for purposes of eligibility for leave.

For additional guidance navigating the FMLA, please contact a Jackson Lewis attorney.

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