U.S. Department of Labor

Wage and Hour Division
Washington, DC 20210

FMLA2024-01-A

November 8, 2024

Ms. Mary E. McGowan
Chief Executive Officer
Foundation for Sarcoidosis Research
320 W. Ohio Street
Suite 300
Chicago, IL 60654

Dear Ms. McGowan:

This letter responds to your request for an opinion concerning whether an employee may use leave under the Family and Medical Leave Act (FMLA) for the treatment of a serious health condition when treatment is provided as part of a clinical trial. We conclude that, under the circumstances outlined below, this is a permissible use of FMLA leave. As discussed below, the term "treatment" is broadly defined under the FMLA to include medical interventions that may or may not be effective in every case. When all other FMLA eligibility requirements are met, a serious health condition that involves either inpatient care or continuing treatment by a health care provider, including when such care or treatment involves an individual's voluntary participation in a clinical trial, qualifies the employee to use FMLA leave.

This opinion is based exclusively on the facts you have presented. You represent that you do not seek this opinion for any party that the Wage and Hour Division (WHD) is currently investigating or for any litigation that commenced prior to your request.

BACKGROUND

Your request for an opinion is on behalf of an organization dedicated to finding a cure for a disease that can be long-term and severe, and to improving care for affected individuals through research, education, and support. According to the National Institutes of Health (NIH), a clinical trial is a "research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes."[1] Patient participation in clinical trials, you explain, is "a critical component" of your research goals.

You write that when your organization surveyed African Americans to increase their participation in clinical trials, you learned that concern about taking time off work is a

[1] National Institutes of Health, NIH Clinical Research Trials and You, https://www.nih.gov/health-information/nih-clinical-research-trials-you/glossary-common-terms#clinicaltrial (last reviewed July 2, 2024).

"significant barrier" to participation. You ask for confirmation that FMLA leave is available for those participating in such trials "regardless of whether the individual receives the applicable experimental treatment." "[C]larifying access," you note, "is a critical aspect to ensuring equitable access to clinical trials since underserved and under-resourced patients face the most significant risks from job or benefit loss."

Your request appears to be focused on an individual's ability to take FMLA leave to participate in a clinical trial addressing their own serious health condition, so this letter addresses that scenario.[2] *See* 29 U.S.C. § 2612(a)(1)(D).

GENERAL LEGAL PRINCIPLES AND ANALYSIS

The FMLA provides eligible employees of covered employers with job-protected leave for qualifying family and medical reasons and requires continuation of their group health benefits under the same conditions as if they had not taken leave. Eligible employees may take up to 12 workweeks of leave in a 12-month period due to their own serious health condition. FMLA leave may be unpaid or used at the same time as employer-provided paid leave. Employees must be restored to the same or a virtually identical position when they return to work after FMLA leave. Employees have the right to take FMLA leave all at once, or, when medically necessary, in separate blocks of time or by reducing the time they work each day or week.

Among other qualifying reasons for leave, an eligible employee has the right to use FMLA leave "[b]ecause of a serious health condition that makes the employee unable to perform the functions of the position of such employee." 29 U.S.C. § 2612(a)(1)(D). Where an individual seeks FMLA leave due to incapacity from a serious health condition, the FMLA regulations specify that "[t]he term incapacity means inability to work, attend school or perform other regular daily activities due to the serious health condition, treatment therefore, or recovery therefrom[,]" and that "[a]n employee who must be absent from work to receive medical treatment for a serious health condition is considered to be unable to perform the essential functions of the position during the absence for treatment." 29 C.F.R. §§ 825.113(b), 825.123(a).

The FMLA defines a serious health condition as an illness, injury, impairment, or physical or mental condition that involves either "inpatient care in a hospital, hospice, or residential medical care facility[,]" or "continuing treatment by a health care provider." 29 U.S.C. § 2611(11). A serious health condition involving "continuing treatment by a health care provider" includes health conditions involving "incapacity and treatment," "pregnancy or prenatal care," "chronic conditions," "permanent or long-term conditions," and "conditions

[2] Where the relevant requirements are otherwise satisfied, this analysis is also applicable to the taking of FMLA leave to care for a family member with a serious health condition, *see* 29 U.S.C. § 2612(a)(1)(C), and to the taking of FMLA military caregiver leave to care for a covered servicemember, *see id.* § 2612(a)(1)(3), where the person being cared for is participating in a clinical trial.

requiring multiple treatments." 29 C.F.R. § 825.115. The regulations specify the requirements to satisfy each of these categories. *Id.*

The regulations further provide that "[t]he term 'treatment' includes (but is not limited to) examinations to determine if a serious health condition exists and evaluations of the condition[,]" and that a "regimen of continuing treatment includes, for example, a course of prescription medication (e.g., an antibiotic) or therapy requiring special equipment to resolve or alleviate the health condition (e.g., oxygen)." 29 C.F.R. § 825.113(c). In contrast, treatment does not include routine physical examinations, and a regimen of continuing treatment does not include, standing alone, the taking of over-the-counter medications or activities such as bed rest that can be initiated without a visit to a health care provider. *Id.*

An employee may be required by an employer to submit a certification (as set out in 29 C.F.R. §§ 825.102 and 825.125) to support the need for FMLA leave for the employee's own serious health condition. The employer may require the certification to include "whether medication has been prescribed, any referrals for evaluation or treatment (physical therapy, for example) or any other regimen of continuing treatment" and, for intermittent or reduced schedule leave for planned medical treatment, "information sufficient to establish the medical necessity for such intermittent or reduced schedule leave and an estimate of the dates and duration of such treatments and any periods of recovery." *Id.* §§ 825.306(a)(3), 825.306(a)(6).

OPINION

Eligible employees may take FMLA leave for the treatment of a serious health condition when treatment is part of a clinical trial.[3]

The FMLA regulations define "continuing treatment" very broadly, establishing only the general principles that a regimen of continuing treatment includes, for example, prescription medication or therapy requiring the use of specialized equipment, but not, ordinarily, routine physical examinations, or over-the-counter medications "that can be initiated without a visit to a health care provider." 29 C.F.R. § 825.113(c). The medical interventions generally involved in clinical trials are similar to the former examples, often involving prescription medication, equipment, or other significant interventions. That such interventions may be experimental (or involve the use of placebos) does not suggest otherwise, as the regulatory definition does not contain any requirement that the treatment meet a certain level of efficacy or that it achieves a certain result.

This interpretation is consistent with the Department's deliberate choice to broadly define "treatment" in its regulations at 29 C.F.R. § 825.113. In 1995, in implementing the FMLA regulations, the Department explained that it chose a broad definition because it "did not wish to encourage employers to second-guess a health care provider's judgment that a treatment is

[3] This opinion presumes that the employee is eligible for FMLA leave and is seeking leave for a qualifying serious health condition, and that other general requirements for use of FMLA leave have been satisfied.

advisable (e.g. orthoscopic knee surgery on an out-patient basis) by questioning whether it is 'necessary.'" 60 Fed. Reg. 2180, 2192, 2195 (Jan. 6, 1995). Previously, the Department had considered prohibiting the taking of leave for "voluntary" treatments that were not "medically necessary," but it ultimately determined that the term "voluntary" was "inappropriate because all treatments and surgery are voluntary." *Id.* at 2195. Instead, the Department chose to make a specific exclusion solely for certain types of routine cosmetic treatments, and here too, included exceptions where such treatment is for a serious health condition (e.g., there is inpatient care, complications develop, or the treatment involves restorative dental or plastic surgery after an injury or removal of cancerous growths). *Id*; 29 C.F.R. § 825.113(d). Accordingly, 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 treatment. Similarly, it is the Department's determination that it is also not relevant whether a course of treatment is new, experimental, a placebo, or proven to meet certain criteria for efficacy.

The FMLA and the implementing regulations neither require nor permit an employer to inquire into the effectiveness of a particular treatment for purposes of determining whether an employee may take FMLA leave to receive that treatment. Through the appropriate certification process, and only in response to an employee's leave request and consistent with regulatory guidelines, an employer may verify that an employee has a serious health condition that involves treatment. The FMLA regulations set forth the precise scope of the information that employers may request and that employees must provide. 29 C.F.R. § 825.306. Those regulations do not require an employee to disclose specific details about prescribed medication or their precise treatment plan.

The above principles may be illustrated by the following examples:

> *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.*
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> *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.*

In summary, treatment for a serious health condition that is rendered as part of a clinical trial can be a qualifying reason for FMLA leave.

This opinion is based exclusively on the facts and circumstances described in your request and is given based on your representation, express or implied, that you have provided a full and fair description of all the facts and circumstances that would be pertinent to our consideration of the question presented. Existence of any other factual or historical background not contained in your letter might require a conclusion different from the one expressed herein.

We trust that this letter is responsive to your inquiry.

Sincerely,

Jessica Looman

Jessica Looman
Administrator