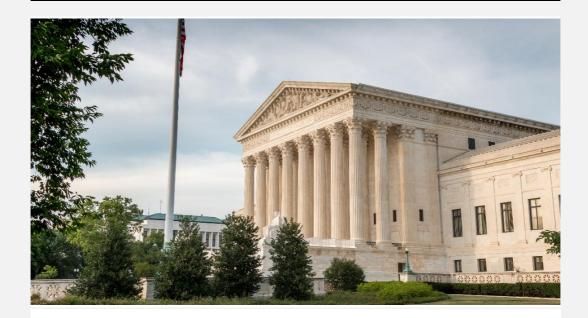
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In this Issue:

- 1. DOL Issues Final Rule on Worker Classification under the Fair Labor Standards Act
- 2. <u>First-Ever HHS Settlement for HIPAA-Related Phishing Cyber-</u> Attack Serves as Reminder of HIPAA Rules
- 3. Supreme Court to Weigh in on Abortion Again in FDA Approval of "Abortion Pill"

DOL Issues Final Rule on Worker Classification under the Fair Labor Standards Act The Department of Labor's Wage and Hour Division issued final regulations on the standard to be used for determining if workers are employees or independent contractors for purposes of the Fair Labor Standards Act ("FLSA") on January 9, 2024, and simultaneously withdrew the current rule – which was issued exactly 3 years and 2 days earlier. The new final rule takes effect on March 11, 2024.

Overview of Final Rule

Like the current rule, the new rule focuses on the so-called "economic realities" test. That is, a worker is an "employee" – and thus protected by the FLSA – if they are, as a matter of economic reality, economically dependent on the employer for work. The difference between the two rules lies in how this economic reality determination is made.

Under current rules, issued at the very end of the Trump Administration, two "core factors" relating to control and opportunity for profit and loss are weighted more heavily than other factors used to determine if the worker is economically dependent on the employer. The Biden Administration has taken the position that this position is inconsistent with the text of the FLSA and the way the courts have interpreted it.

The new rule will apply 6 factors to analyze employee or independent contractor status under the FLSA:

- (1) opportunity for profit or loss depending on managerial skill;
- (2) investments by the worker and the potential employer;
- (3) degree of permanence of the work relationship;
- (4) nature and degree of control;
- (5) extent to which the work performed is an integral part of the potential employer's business; and
- (6) skill and initiative.

The new final rule does not assign any predetermined weight to any single factor or set of factors. It also provides that additional factors may be relevant if such factors in some way indicate whether the worker is in business for themself (i.e., an independent contractor), as opposed to being economically dependent on the employer for work.

Impact on Worker Classification

For those who believe the current rule makes it easier for employers to classify certain workers as independent contractors, the new rule represents an effort to swing the pendulum back in favor of workers who want to be classified as employees. Whether that will indeed be the case remains to be seen.

On a practical level, employers will now need to begin the process of reevaluating the standards and procedures they use to determine if a worker is an independent contractor – and making whatever changes are needed to ensure consistency with the new final rule. They also will need to review the status of current independent contractors and determine if any should be reclassified as employees under the new rules.

Significantly, employers also should note that the final rule is relevant only to worker classification for purposes of the FLSA. It does not affect other worker classification laws, including the Internal Revenue Code and state wage and hour rules.

First-Ever HHS Settlement for HIPAA-Related Phishing Cyber-Attack Serves as Reminder of HIPAA Rules

In December, the Department of Health and Human Services ("HHS") Office for Civil Rights ("OCR") announced that it had reached a settlement with a medical group involving violations of the Health Insurance Portability and Accountability Act ("HIPAA") following a "phishing" attack. This marks the first-ever settlement OCR has resolved involving a phishing attack under the HIPAA rules.

Overview of Settlement

Under HIPAA's Privacy Rule, covered entities (e.g., health plans and most health care providers) must protect the privacy of individuals' protected health information ("PHI") and follow certain limits on the use and disclosure of PHI. Similarly, HIPAA's Security Rule requires covered entities to implement safeguards to protect electronic PHI. HIPAA's Breach Notification Rule requires covered entities to notify HHS and any affected individuals when their PHI has been compromised.

On December 7, 2023, OCR <u>announced a settlement</u> with a Louisiana-based medical group that specializes in emergency medicine, occupational medicine, and lab testing. As a result of a "phishing" attack on the group, the PHI of nearly 35,000 individuals was exposed to a hacker. Phishing is a common type of cybersecurity attack which is designed to fool individuals into volunteering personal or financial information, usually through fraudulent emails or other messages.

In 2021, the medical group was the victim of a successful phishing attack, which allowed a hacker to gain access to an email account that contained electronic PHI. As a result of its investigation, OCR discovered that the group failed to conduct the proper risk analyses to identify the threats to its systems which left its PHI vulnerable. OCR also found that the group had no policies in place to regularly review its system for maintaining and storing PHI and other information. The group is required to pay \$480,000 and develop a corrective action plan, including establishing security measures and training staff members.

Big Picture

With breaches of healthcare data on the rise, it is vital that covered entities remain on top of their responsibilities under the Privacy Rule, Security Rule, and Breach Notification Rule. In the press release for the settlement, an OCR official warned that phishing is the most common way that hackers gain access to health care systems to steal data. In order to avoid their own OCR investigation, covered entities should periodically review and update their security procedures that cover PHI. This settlement is a clear indication that OCR is on the lookout for phishing attacks targeting PHI.

For plan sponsors, these HIPAA rules may apply in some circumstances. For instance, employers with self-insured plans are not considered covered entities, but the plan itself would be considered a covered entity. It is crucial that employers understand whether and how they are covered by HIPAA in order to avoid running afoul of the rules protecting PHI.

Supreme Court to Weigh in on Abortion Again in FDA Approval of "Abortion Pill"

The Supreme Court is slated to weigh in on abortion rights for the first time since it struck down the constitutional right to abortion in 2022. In December, the court agreed to hear a case challenging the Food and Drug Administration's ("FDA") approval of mifepristone, a drug commonly used in early-stage abortions.

Background

Following the overturning of the constitutional right to abortion in *Dobbs v. Jackson Women's Health Organization*, many different methods of abortion became the subject of scrutiny in states where abortion has become more restricted. The drug mifepristone, which is typically used in combination with another drug to induce early-stage abortions, is the subject of multiple ongoing lawsuits brought in 2023 to challenge the FDA's approval of the drug. Mifepristone was first approved by the FDA in 2000, and in recent years the agency has allowed access to the medication through telemedicine and by mail.

In FDA v. Alliance for Hippocratic Medicine, a group of plaintiffs are challenging the FDA's decades-old approval of mifepristone on the grounds that the agency exceeded its authority in approving the drug by failing to follow the proper procedures for drug approvals. In April 2023, a Texas district court issued an order suspending the FDA's approval, noting that the suspension would be in the public interest in order to stop "unsafe" drugs from entering the market. On appeal, the Fifth Circuit sustained parts of the lower court's decision, ruling that mifepristone could continue to be available, but only through the first seven weeks of pregnancy and not through the mail. The Fifth Circuit's decision was later paused by the Supreme Court pending further review.

In a second, related case, *Danco Laboratories v. Alliance for Hippocratic Medicine*, the Biden Administration and the manufacturer of the name-brand version of mifepristone approached the Supreme Court in September 2023 asking it to weigh in on the first case, particularly with respect to whether the plaintiffs had the legal right to bring the case in the first place.

Looking Ahead

On December 13, 2023, the Supreme Court consolidated the two cases and agreed to hear the challenge to the FDA's approval of mifepristone. As with many high-profile cases – such as the *Dobbs* decision – it is widely expected that the Supreme Court will issue its opinion late into its term, possibly in the last days of June 2024. These cases have implications well beyond just abortion – they are also a test of a court's power to weigh in on the FDA's approval of a drug, which appears to be a novel issue.

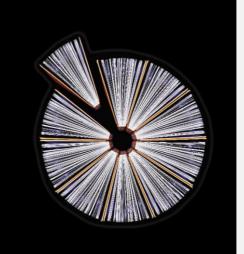
In a sign that abortion-related litigation will not slow down in 2024, an ongoing legal challenge to the federal Emergency Medical Treatment and Labor Act ("EMTALA") will also be the subject of Supreme Court review this year. EMTALA, which was enacted in 1986, generally requires doctors to treat emergency medical conditions regardless of ability to pay. In one case challenging the EMTALA out of Texas, on January 2, 2024, a panel of judges on the Fifth Circuit held that the law does not require hospitals and doctors to perform emergency abortions. In a second case in Idaho, the Biden Administration sued the state on the grounds that its restrictive abortion law violates EMTALA and successfully struck down part of the Idaho law. On January 5, 2024, the Supreme Court agreed to temporarily permit Idaho to enforce the entirety of its abortion law and announced that it will hear the case itself in April.



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