

LEADING CHANGE

Revolutionizing Employee Benefits and Health Management

Final Rule Addresses Reproductive Health and HIPAA

The U.S. Department of Health and Human Services (specifically the Office for Civil Rights "OCR") recently published a final rule updating the HIPAA Privacy Rule to address the privacy of "reproductive health information." Covered entities, including group health plans and their business associates, have until December 23, 2024, to comply with most aspects of the Final Rule, with the exception of the Notice of Privacy Practices (NOPP) requirements, which must be in place by February 16, 2026.

The new definition of "reproductive health care" takes effect June 25, 2024, and includes male as well as female reproductive health. Specifically, the Final Rule defines "reproductive health care" as "health care ... that affects the health of an individual in matters relating to the reproductive system and its functions and processes." According to the OCR, reproductive health care includes such services as contraception, preconception screening and counseling, pregnancy screening, miscarriage management, fertility and infertility diagnosis and treatment, and broad care related to the reproductive system (e.g., perimenopause, menopause, and mammography). Male reproductive health may include vasectomies and ED treatments.

Under the new Final Rule, by the December 23, 2024, the compliance deadline, Regulated Entities (that includes Group Health Plans and their business associates among others) may NOT use or disclose PHI (Protected Health Information) for either of the following purposes:

- To conduct a criminal, civil, or administrative investigation into or to impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating "reproductive health care," where such health care is lawful under the circumstances in which it is provided.
- To identify any person for the purpose of conducting such investigation or imposing such liability.

Once the Final Rule takes effect, upon receiving a request for PHI potentially related to reproductive health care for health oversight activities, judicial and administrative proceedings, law enforcement purposes, and/or authorized duties and activities of coroners and medical examiners, the Regulated Entity must obtain a signed, written attestation from the person or entity making the request that the intended use or disclosure of the requested PHI is not for one of the prohibited purposes described above. OCR has said it will publish a model form of attestation, which must be a standalone document, before the compliance deadline. Source: <u>Akerman</u>



Summer 2024

Most Employers Offer Mental Health Benefits

A survey from April 2024 by the American Psychiatric Association found 67% of working adults know how to access mental health care services through work. However, 2 in 5 employed adults worry about retaliation or being fired if they take time off for their mental health or seek mental health care.



Despite their fears of retaliation for addressing their mental health, 59% of respondents agreed they could discuss mental health openly with coworkers, and 58% agreed they could discuss their mental health openly with supervisors.

Forty-two percent of working adults reported experiencing burnout ("a state of emotional, mental, and physical exhaustion brought on by prolonged stress") within the past six months, and nearly half of respondents said that they "always" or "sometimes" struggle to get away from their work at the end of the day.

Employers offer a variety of options to access mental health services. Nearly 1/3 of working adults indicated that they have access to sufficient mental health coverage through their employer, 30% can access an EAP, and 28% have access to telehealth services that offer virtual counseling by phone, app, or video. *Source:* <u>APA</u>

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News & Notes

Summer 2024

Lawmakers Agree, Pharmaceutical Patent Reform Is Needed

In a time when it is hard to find bipartisan consensus among lawmakers, there's widespread agreement in Congress for pharmaceutical patent reform. The steep prices of brand-name drugs in the United States are owed in part to anticompetitive tactics used by pharmaceutical manufacturers to extend their monopoly pricing power and obstruct cheaper generics and biosimilars from entering the market.

Several different studies illustrate how commonly these anti-competitive tactics are used. The first study showed that 74% of new drug patents issued (2005 to 2015) were for drugs already on the market. In another study of the 100 best-selling drugs, nearly 80% received an additional patent to extend their monopoly period beyond what was originally intended.

Here is how pharmaceutical firms manipulate the patent system to prolong their monopolies and block lower-cost generic and biosimilar competition from entering the market:

- Product hopping: when a company switches a patient population from a branded product whose patent is expiring and therefore facing imminent competition to a different formulation of the original drug that has a later expiring patent.
- Patent thickets: references the numerous patents drug companies may file to create hurdles to market entry for prospective generic or biosimilar competitors.
- Pay-for-delay deals: Brand name drug manufacturers induce competitors to delay selling a generic or biosimilar version of a drug. Source: *Forbes*

The Effects of Dementia on Personal Finance

New research shows that long before people develop dementia, they begin falling behind on financial obligations. The research was performed by economists and medical experts combining Medicare records with data from the credit bureau, Equifax, to study how people's borrowing behavior changed in the years before and after a diagnosis of Alzheimer's or a similar disorder. The study expands on past research through its sheer scale: Researchers had access to health and financial data on nearly 2.5 million older Americans.

What they found was striking: Credit scores among people who later develop dementia begin falling sharply long before their disease is formally identified. A year before diagnosis, these people were 17.2 percent more likely to be delinquent on their mortgage payments than before the onset of the disease, and 34.3 percent more likely to be delinquent on their credit card bills. The issues start even earlier: The study finds evidence of people falling behind on their debts five years before diagnosis.

The research adds to a growing body of work documenting what many Alzheimer's patients and their families already know: Decision-making, including on financial matters, often begins to deteriorate long before a diagnosis is made or even suspected. People who are starting to experience cognitive decline may miss payments, make impulsive purchases or put money into risky investments they would not have considered before the disease. Interestingly, the issues stem from more than forgetfulness. Cognitive decline changes tolerance for risk, making these people vulnerable to scams and fraud.

Source: <u>NY Times</u>

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