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District Court Issues Nationwide Injunction Barring Enforcement of Portion of ACA Preventive Services Mandate

A Federal District Court judge in Texas on March 30, 2023 issued a nationwide injunction barring enforcement of a key portion of the Affordable Care Act's (ACA) preventive services mandate. The injunction also prevents enforcement of the mandate with respect to certain preventive drugs for individuals at high risk of HIV infection against those with religious objections. The U.S. Department of Justice (DOJ) has appealed the district court's ruling to the 5th Circuit Court of Appeals.

What Does This Mean for Employers and Group Health Plans?

While the potential implications of this case are huge, the practical immediate impact is very limited.

As discussed more below, the district court's ruling invalidates only a portion of the ACA's preventive services mandate. Even if the district court's decision is ultimately upheld, significant portions of the ACA preventive services mandate will continue to apply.

As noted above, the DOJ already has appealed the district court's decision to the 5th Circuit Court of Appeals. The 5th Circuit could choose to lift the injunction while the case is pending. If it keeps the injunction in place, DOJ could appeal that decision to the U.S. Supreme Court.

Fully-insured plans will still be required to comply with relevant state insurance laws, including in some cases preventive services mandates, even if the injunction remains in place and/or the district court's decision is ultimately upheld.

If the injunction remains in place, self-insured plans may have the option of changing the terms of coverage for affected preventive services while the substantive case is pending. However, they will not be required to do so (subject to a caveat for high-deductible health plans (HDHPs), discussed below). And even those that want to make changes may not want to do anything in the middle of a plan year.

Special considerations apply to health savings account (HSA)-compatible HDHPs. In general, HDHPs may not provide coverage below the minimum HDHP deductible. However, there is an exception for certain preventive health services, which can be provided on a first-dollar basis.

Pursuant to IRS Notice 2013-58, HDHPs can provide first-dollar coverage for any preventive health services required by the ACA preventive services mandate pursuant to this exception. If the injunction remains in place and/or the district court's decision is upheld, HDHPs may – unless the IRS issues guidance stating otherwise – need to be amended to conform to the updated ACA preventive services mandate.

Overview of the ACA Preventive Services Mandate

In general, the ACA requires group health plans to cover the following preventive services without cost-sharing:

- Evidence-based items or services with an A or B rating by the United States Preventive Services Task Force (USPSTF)

- Immunizations for routine use as recommended by the Centers for Disease Control's Advisory Committee on Immunization Practices (ACIP)
- Preventive care and screenings for children as provided for in guidelines supported by the Health Resources and Services Administration (HRSA)
- Preventive care and screenings for women as provided for in guidelines supported by the HRSA

The USPSTF periodically updates its ratings. In 2019, USPSTF issued an A rating for preexposure prophylaxis (PrEP) drugs. These drugs are designed for use by individuals who are at higher risk of HIV infection. **The A rating for PrEP drugs means group health plans are now required to cover them without any cost-sharing.**

District Court Ruling

The Texas district court generally held that the preventive services mandate with respect to USPSTF ratings of A or B issued on or after March 23, 2010 (the date the ACA was enacted) violates the Constitution's Appointments Clause. This leaves the mandate in place with respect to preventive services with a USPSTF rating of A or B issued before March 23, 2010, as well as with respect to preventive services recommended by ACIP and HRSA.

Separately, the district court also ruled the PrEP mandate violates the Religious Freedom Restoration Act (RFRA), which generally prohibits the government from "substantially burdening" an individual's exercise of religion. As such the district court determined the PrEP mandate could not be enforced against those with religious objections.

What's Next

As noted, the DOJ already has appealed the district court's decision to the 5th Circuit Court of Appeals.

Rewards Policy Insider will publish updates as they happen.

IRS Explains Rules for Reimbursing Nutrition and Wellness Expenses by HSAs, HRAs, and Health FSAs

In a set of Frequently Asked Questions (FAQs) released on March 17, the IRS explained the rules for determining if certain nutrition and wellness-related expenses are reimbursable as "medical care" expenses by health savings accounts (HSAs), health reimbursement arrangements (HRAs), and health flexible spending arrangements (Health FSAs). While the FAQs mostly reiterate well-established principles, they are still a useful tool for employers and plan administrators that sometimes need help making tough calls regarding

whether certain expenses are medical care expenses or not and explaining those decisions to participants.

What are "Medical Care" Expenses?

Subject to certain exceptions, Health FSAs and HRAs can only reimburse an expense if it is an expense for "medical care" that otherwise would be deductible under Code Section 213. HSA distributions technically can be used for any reason, but the reimbursement amount may (but for a few exceptions) be treated as taxable income and subject to a 20% excise tax if it is not for a Code Section 213 "medical care" expense.

The general rule is that "medical care" expenses generally refers to amounts paid for the "diagnosis, cure, mitigation, treatment, or prevention of disease, or for the purpose of affecting any structure or function of the body." As the FAQs point out, this includes routine physicals, eye exams, and dental exams, because all involve a diagnosis of "whether a disease or illness is present." However, expenses incurred for things that are merely beneficial to an individual's general health are not "medical care" expenses.

Expenses for Treating Mental Health and Substance Use Disorders

The FAQs confirm that the costs associated with therapy generally are "medical care" expenses, but only if the therapy is to treat a diagnosed mental illness. The cost of marriage counseling is not a "medical care" expense, according to the FAQs.

A related question that often comes up is whether the cost of programs to treat drug-related substance abuse, alcohol abuse, or smoking are "medical care" expenses. The FAQs confirm these are all reimbursable because each treats a disease – i.e., substance use disorder, alcohol use disorder, and tobacco use disorder, respectively.

Nutrition and Weight Loss Expenses

Nutritional counseling might be used to treat a specific physician-diagnosed disease, such as diabetes or obesity. If so, the cost is a "medical care" expense.

Likewise, the cost of nutritional supplements is a "medical care" expense so long as the supplements are recommended by a medical practitioner for the treatment of a physician diagnosed medical condition.

However, if nutritional counseling or nutritional supplements are just for the purpose of improving overall health, the associated costs are not "medical care" expenses.

Some diet programs include special foods and beverages to help participants achieve their goals. Individuals participating in these programs generally may not use their HSAs, Health FSAs, or HRAs to purchase these products. But the FAQs outline an exception to this general rule if each of the following three criteria is satisfied:

1. The food or beverage doesn't satisfy normal nutritional needs;
2. The food or beverage alleviates or treats an illness; and
3. The need for the food or beverage is substantiated by a physician.

All three of these conditions must be met for the expense to be considered a "medical care" expense.

Gym Memberships and Exercise Classes

As a general matter, gym membership fees are not "medical care" expenses because going to the gym is typically about improving someone's overall health and wellbeing. But the FAQs do note that if someone is joining the gym to treat a physician-diagnosed illness (such as obesity or heart disease), then the fees are eligible for reimbursement by an HSA, HRA, or Health FSA.

By comparison, swimming or dancing classes are not reimbursable even if recommended by a doctor.

Abortion News Roundup: Post-Roe, State Legislatures, Officials, and Courts Test New Restrictions on Medication Abortions

Following the Supreme Court's decision in June 2022 overturning *Roe v. Wade*, the landscape of state abortion law and policy has been evolving rapidly. This article focuses on three major recent developments that employers and group health plans should watch closely: (1) a new Wyoming law specifically banning abortion pills; (2) a Texas case challenging the FDA's approval of mifepristone; and (3) a major retail pharmacy's decision to refrain from distributing abortion pills in states where officials have raised objections.

Wyoming Becomes First State to Explicitly Ban Abortion Pills

On March 17, 2023, Wyoming became the first state in the nation to enact a law explicitly banning abortion pills. Under the new law, it is unlawful to prescribe, dispense, distribute, sell, or use any drug for the purpose of procuring or performing an abortion. The law provides limited exceptions, allowing abortion where it is necessary to protect the pregnant person from a physical condition that substantially endangers life or health, or if the pregnancy is the result of incest or sexual assault. The law, which is slated to go into effect on July 1, 2023, is already facing at least one challenge in court that was brought by a group seeking to open an abortion clinic in the state.

In the meantime, abortion currently remains legal up until viability in Wyoming. A trigger law that would ban nearly all abortions in the state has been blocked for several months pending the outcome of a challenge alleging that it violates the state constitution. Separately, on the same day that Governor Mark Gordon (R) signed the new abortion pill ban into law, he also allowed another near-total

abortion ban to go into effect without his signature. That law was swiftly blocked by a judge while the litigation proceeds.

Although some other states have also effectively outlawed all or most abortion services, or otherwise restricted the use of abortion pills, Wyoming is the first state to explicitly target and prohibit the use of such medication. But it is unlikely that Wyoming will be the last. State legislatures looking to prohibit abortions in a post-*Roe* world are increasingly targeting medication abortions, which account for the majority of all abortions in the United States.

Texas District Court Hears Challenge to FDA's Approval of Abortion Medicine

State legislatures are not the only ones weighing in on the issue of medication abortions. In the Northern District of Texas, arguments were heard on March 15, 2023 in a case challenging the Food and Drug Administration's ("FDA") approval of mifepristone. The drug, which was first approved by the FDA in 2000, is commonly used in combination with another medication to induce early-stage medication abortions. In the case, *Alliance for Hippocratic Medicine v. FDA*, a group called the Alliance Defending Freedom argues that the FDA exceeded its authority by using an accelerated process to approve mifepristone and improperly characterizing pregnancy as an illness. The FDA's accelerated process is typically used to approve drugs for serious conditions that fill an unmet medical need. The FDA, on the other hand, argues that mifepristone was properly approved, and points out that it would be unusual for a drug that has been used safely for over two decades to be pulled from the market.

If the judge does decide to side with the plaintiffs and orders the federal government to take mifepristone off the market – or even issues a preliminary injunction against the FDA – it would affect the use of mifepristone in every state across the country. The judge indicated that he would rule on the case "as soon as possible," but did not give any strong indications during oral arguments on how exactly he would rule.

Major Retail Pharmacy Will Not Dispense Abortion Pills in States Where AGs Voice Objections – Even Where Abortion is Legal

On March 2, 2023, one of the largest pharmacy chains in the nation publicly announced that it would not dispense abortion pills in multiple states where it had received pushback from states' attorneys general.

As discussed above, in January 2023 the FDA finalized a rule allowing pharmacies that obtain certification to dispense mifepristone. (Prior to this rule, generally only clinics and physicians could dispense mifepristone). Shortly thereafter, two major retail pharmacies confirmed plans to seek certification to dispense the drug where it is legally permissible.

In response to the pharmacies' announcements, a group of attorneys general from 20 states – including Alabama, Florida, Georgia, Kentucky, Missouri, Ohio, and Texas – wrote a letter advising the pharmacy chains that it would take actions to uphold a federal law that, in their reading, expressly prohibits using the mail to send or receive any drug that will be used for abortion.

Just months prior, the Biden Administration's Justice Department had released a memorandum opinion for the General Counsel of the U.S. Postal Service noting their opinion that the law the attorneys general cite to in their letter – called the Comstock Act – does not actually prohibit the mailing of drugs that can be used to perform abortions, absent evidence that the recipient intends to use them unlawfully, in part because such drugs can be used in other ways

not related to abortion. The letter from the attorneys general makes clear that the attorneys general would likely be prepared to take legal action against the pharmacy if it violated their interpretation of the Comstock Act by proceeding with its plan to dispense mifepristone, potentially by mail.

Following the letters, one of the pharmacies responded to each of the attorneys general indicating that it does not intend to ship mifepristone to those states from any of its pharmacies. Notably, this list includes multiple states where abortion is still legal in some capacity, such as Alaska, Iowa, and Montana. The pharmacies have received criticism for this decision from other states.

What Does it Mean for Group Health Plans?

The ongoing legal challenge to the FDA's approval of mifepristone has the potential to impact health plan participants' access to this drug nationwide, regardless of whether it otherwise would be covered by the plan. But recent actions by Wyoming to ban mifepristone in that state, and by at least one major retail pharmacy to not dispense mifepristone in states that object, raise more immediate compliance and plan design issues.

For example, can a group health plan – whether fully insured or self-insured – cover mifepristone for participants residing in Wyoming? The Wyoming law doesn't specifically ban insurers from covering mifepristone, but group health plans generally can only cover medicines and drugs that are legally procured.

Nine months after the Supreme Court's decision in Dobbs, the landscape of state abortion laws continues to rapidly evolve, and the changes frequently lead to more questions than answers. Continue following RPI for updates on new developments.

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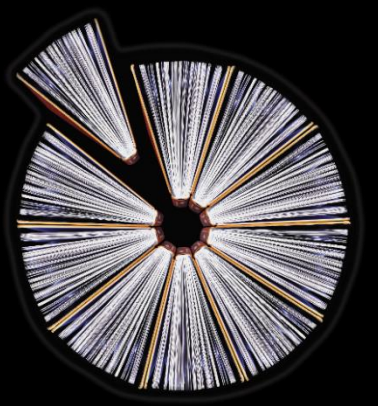

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