An Advocate's Primer on Fighting Barriers to Prescription Drugs for Chronic Conditions Under *Dobbs*

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Introduction

In recent years and especially since the Supreme Court decided *Dobbs v. Jackson Women's Health Organization* in 2022, the United States (U.S.) has experienced a resurgence in reproductive oppression—the regulation and exploitation of people's bodies, sexuality, labor, and reproductive capacities.[1] This oppression is profoundly affecting access to health care for people with disabilities, including chronic conditions.

At the time of this writing, thirteen states have total abortion bans.[2] They are profoundly dangerous for people with disabilities, who were already eleven times more likely to die of pregnancy related complications compared to our non-disabled counterparts before *Dobbs*.[3] To make matters worse, states that ban abortion have some of the highest rates of people with chronic conditions in the country.[4] In addition to heightened risks to maternal health, without abortion access, some people are unable to access the standard of care treatment for chronic conditions. For example, in June 2022, a pregnant woman in Kentucky was unable to access the abortion she needed to obtain the optimal treatment for her cervical cancer: low-dose chemotherapy and a high dose of radiation, which can cause congenital disorders.[5]

Beyond abortion, *Dobbs* has undercut or threatened access to critical prescription drugs that help manage chronic conditions or their symptoms within and beyond states that ban abortion.[6] Health care entities are denying or delaying access to these medications because they can end or cause complications to pregnancies, even though the individuals seeking access are not pregnant.[7] Some may be erecting these barriers to mitigate perceived legal risks prompted by *Dobbs* and the resulting rapidly evolving reproductive legal landscape. *Dobbs* may have emboldened others to discriminate on the basis of sex and intersecting identities (*e.g.*, disability, race). Regardless of the reasons for these barriers, many may violate the Patient Protection and Affordable Care Act (ACA), the Rehabilitation Act, the Medicaid Act, and state laws.

Part I of this *Advocate's Primer* summarizes accounts of barriers to prescription drugs for chronic conditions in the first two years following *Dobbs* and describes other medications at risk. Part II outlines legal strategies for challenging these discriminatory barriers to care.

I. Barriers to Prescription Drugs for Chronic Conditions Under *Dobbs*

Under *Dobbs*, people are experiencing new barriers to critical prescription drugs that help manage chronic conditions or their symptoms and have abortion-inducing or teratogenic (*i.e.*, can cause low-birth weight or congenital disorders) properties. Access to contraceptives (*e.g.*, medications that prevent pregnancy), which are also often used to manage the symptoms of

chronic conditions, are also under threat. In this Part, I provide an overview of prescription drugs for which *Dobbs* threatens or is already affecting access, trends in barriers reported to date, and the resulting harms to people with chronic conditions.

a. Implicated Prescription Drugs

To date, the Supreme Court's decision to overturn the constitutional right to abortion has most extensively undermined access to methotrexate, an essential medication that can extend and save the lives of people with chronic conditions.[8] In 2019, more than 70% of people with a methotrexate prescription were women.[9] In 2021, the year before the Supreme Court ruled in *Dobbs*, pharmacies across the U.S. filled about five million methotrexate prescriptions.[10]

In a reproductive health context, methotrexate is used to end about one in ten ectopic pregnancies, which occur when a fertilized egg grows outside of a person's uterus.[11] Ectopic pregnancies are virtually never viable, are the leading cause of maternal mortality in the first trimester, and can cause future infertility.[12] In this context, methotrexate access is especially critical for people with chronic conditions that increase the risk of ectopic pregnancy, such as endometriosis, Ehlers-Danlos Syndrome (EDS), pelvic inflammatory disease, and some sexually transmitted infections.[13]

However, people primarily take methotrexate for chronic conditions unrelated to pregnancy.[14] Originally developed as a chemotherapy agent, methotrexate helps fight cancers, such as breast cancer, lymphoma, lung cancer, and leukemia.[15] Methotrexate is most widely used as a safe and effective treatment for rheumatoid arthritis (for an estimated 70–80% of cases) and other autoimmune conditions that disproportionately affect women and people assigned female at birth.[16] Providers also prescribe methotrexate off-label (*i.e.*, for uses beyond those that the Food and Drug Administration (FDA) approved and included on the drug label) to treat lupus, Crohn's disease, psoriasis, and other chronic conditions.[17]

Under *Dobbs*, people who are not pregnant are also experiencing barriers to teratogenic (*e.g.*, can cause low birth weight or congenital disorder) medications. Dozens of prescription drugs have teratogenic properties, including numerous medications that help manage chronic conditions (*e.g.*, cancer, seizure disorders, multiple sclerosis) or their symptoms.[18] Prescription drugs with teratogenic properties should not be used during pregnancy. Concurrent use of contraception substantially decreases the risks of low birth weight or congenital disorders associated with these medications.[19]

Dobbs has also harmed access to medications such as misoprostol and mifepristone which, like methotrexate, are used to treat chronic conditions and have abortion-inducing properties. Misoprostol was developed in the 1970s to treat stomach ulcers in people who take certain arthritis or pain medications.[20] In a reproductive health context, it is used for the medical management of miscarriage, labor induction, cervical ripening before surgical procedures, postpartum hemorrhage treatment, and other procedures.[21] It is also used in combination with mifepristone in the most common medication abortion regimen in the U.S.[22] In addition to its ability to block progesterone, a hormone that enables a pregnancy to continue, mifepristone is used to control hyperglycemia from excess cortisol in people with endogenous Cushing's syndrome, a rare and potentially life-threatening chronic condition.[23] Researchers are investigating how mifepristone can fight breast and prostate cancer, post-traumatic stress disorder, depression, substance use disorder, and other conditions.[24] Perhaps due to anti-abortion stigma, at the time of this writing, the media has not reported stories of people who have experienced barriers to these drugs for purposes of chronic condition management.[25]

While contraceptives are best known for their use in a family planning context, they are often widely used on- and off-label to treat symptoms of chronic conditions, such as endometriosis, EDS, postural orthostatic tachycardia syndrome (POTS), and polycystic ovary syndrome.[26] In his concurrence in *Dobbs*, Justice Clarence Thomas suggested that the Court reconsider *Griswold v. Connecticut*, which established the right of married people to obtain contraceptives.[27] In the years since, anti-abortion lawmakers' attacks on contraception have intensified. These attacks often strategically conflate abortion and contraceptives.[28] For example, the myth that certain contraceptive methods induce abortions was foundational to *Burwell v. Hobby Lobby Stores, Inc.*[29] More recently, the Heritage Foundation and their coalition of conservative organizations conflated abortion and emergency contraception in their 2025 Presidential Transition Project known as "Project 2025," an authoritarian playbook "for the next conservative administration."[30] Attacks on contraceptive access not only harm people with disabilities who use contraceptives to prevent pregnancy, but also those who use the medications to manage the symptoms of chronic conditions.

b. Trends in Reported Barriers

1. Entities Creating Barriers

Under *Dobbs*, pharmacies, health care providers, and health insurance companies are denying access to prescription drugs for people with chronic conditions who they perceive as capable of getting pregnant. Major pharmacies such as CVS and Walgreens have denied methotrexate prescriptions or placed them on hold until the prescribing provider confirms the purpose of the prescription.[31] Some health care systems and providers have stopped all refills of methotrexate

"in response to the reversal of *Roe v. Wade*."[32] Some health care providers are refusing to write or refill prescriptions for teratogenic medications to treat chronic conditions.[33] Some insurers have denied coverage for methotrexate.[34]

2. Resulting Harms Reported to Date

These barriers are affecting countless people with disabilities, particularly those who have inflammatory arthritis, lupus, Myasthenia gravis, Crohn's disease, and EDS across the country. They are not only occurring in states that have banned or severely restricted abortion, such as Missouri and Tennessee, but also those in states where people still have a legal right to abortion, such as Maryland, New York, and Virginia.[35] They are also affecting people who likely are not capable of pregnancy, such as those who had a hysterectomy or are partnered with someone who had a vasectomy, as well as children with chronic conditions, including an 8-year-old girl in Texas and an 11-year-old girl in Arizona.[36]

Resulting harms are numerous. First, delays at pharmacies have forced people to go without their prescriptions for days, resulting in painful and potentially dangerous chronic condition flare ups.[37] Provider and insurance refusals have caused years-long delays in access to care for some people with chronic conditions. For example, in Maryland, Myisha Malone-King's rheumatologist and insurance have denied access to methotrexate since *Dobbs* was decided in 2022.[38] Alternative prescription drugs have failed to treat her Crohn's disease effectively. Some provider denials have coerced people into seeking medically unnecessary care. For example, a rheumatologist gave Becky Hubbard, a 46-year-old woman in Tennessee with rheumatoid arthritis and a history of infertility, an ultimatum: if she wanted to stay on methotrexate, she had to take contraceptives, which she had previously experienced adverse side effects from.[39] Hubbard decided to pursue sterilization instead. She went without methotrexate injections for weeks while waiting to see a gynecologist about tubal ligation, and in the interim, weathered severe pain that caused her to fall at her son's birthday party.

Some denials of or delays in access to care have caused people significant emotional distress and financial burdens. For example, Annie England Noblin, a woman with rheumatoid arthritis in Missouri, told the media "[i]t was humiliating to be standing in front of a pharmacist begging for my medication. . . . To be told, essentially, 'We don't trust you to make the appropriate decisions for your health' is horrible."[40] The encounter made her feel as if she were doing "something illegal simply for taking medication to keep [her] alive." Noblin said she would likely switch to another, more expensive medication to prevent future delays.[41] Yet "sticker price" differences, coverage gaps, and differences in how individuals respond to various prescription drugs mean that "alternatives" are often not options.[42]

II. Legal Levers to Address Denials of Care

In this Part, I offer advocates information on federal and state legal levers for fighting the above-described barriers to prescription drugs for chronic conditions.

a. Federal Civil Rights Laws

1. Section 1557 of the ACA

Section 1557 of the ACA prohibits discrimination on the basis of sex, race, color, national origin, disability, age, and any combination thereof in certain health programs and activities.[43] It was the first federal law to broadly prohibit sex discrimination in health care. The law's nondiscrimination requirements apply to health programs and activities that receive federal financial assistance or funding, programs administered by the U.S. Department of Health and Human Services (HHS), and entities created under Title I of the ACA.[44] This includes most health care providers and professionals (*e.g.*, physicians, nurses, pharmacists, and administrative staff); most health care entities (*e.g.*, hospitals, clinics, pharmacies); most health and health-related insurance issuers and plans, including Medicaid managed care plans, Medicare, marketplace health plans, and other private health insurance plans that receive HHS funding; and even some clinical trials. It also applies to state health agencies, such as state Medicaid and Title X agencies, and the federal and state health insurance marketplaces.[45]

Although § 1557 is self-implementing, regulations help clarify the law's protections as well as implementation details. In April 2024, the HHS Office for Civil Rights (OCR) finalized a new rule revising regulations on § 1557.[46] The rule restores and revises the regulatory definition of sex discrimination, which includes but is not limited to discrimination based on sex stereotypes, pregnancy or related conditions, gender identity, sexual orientation, and sex characteristics, including intersex traits.[47] In the preamble, HHS reaffirms that while § 1557 does not require pharmacies to fill prescriptions for the purpose of abortion:

> If a covered entity denies or delays lawful access to medications to support persons with disabilities, treat cancer, or treat an autoimmune condition, that refusal could violate section 1557 if, for example, the refusal is on the basis of a prohibited ground, such as the person's race, age, disability, or sex.[48]

Thus, if a covered entity will not write, cover, or fill a prescription for an individual based on their ability (whether real or perceived) to get pregnant but would write, cover, or fill the same prescription for someone who they do not believe capable of pregnancy, that could constitute prohibited sex discrimination under § 1557. Likewise, if they will not cover or fill a prescription for contraceptives based on the drug's ability to prevent pregnancy even though the drug was prescribed to treat a chronic condition or related symptoms, this may constitute prohibited sex

discrimination under § 1557. For more information on the final rule, *see* the National Health Law Program's (NHeLP) "Questions and Answers on the 2024 Final Rule Addressing Nondiscrimination Protections under the ACA's Section 1557."

2. Section 504 of the Rehabilitation Act

On May 1, 2024, HHS OCR finalized a new rule on § 504 of the Rehabilitation Act, a federal law that prohibits disability discrimination in programs and activities that receive federal financial assistance or are conducted by a federal agency.[49] The updated regulations apply to each recipient of federal financial assistance from HHS and to the recipient's programs or activities that involve people with disabilities in the U.S.[50] Among other protections, the final rule contains strong protections against discrimination in medical treatment on the basis of disability, including in a sexual and reproductive health context.[51]

Advocacy Tip

If a health care provider accepts Medicare (most do) or Medicaid, they must comply with § 1557 and § 504, even if the individual who experienced discrimination has another form of insurance or is uninsured. If a health care provider does not accept any health insurance, they are not likely covered by § 1557, unless they accept some other form of federal financial assistance.

3. HHS Enforcement Addressing Barriers to Care for Chronic Conditions Under *Dobbs*

Following *Dobbs*, OCR began receiving and investigating complaints against pharmacies, such as CVS and Walgreens, for denying and delaying lawful access to medications that treat chronic conditions on the basis of sex.[52] In July 2022, OCR issued guidance to pharmacies about their obligations to ensure access to comprehensive reproductive health care services, including prescriptions for reproductive and disability-related care post-*Dobbs*.[53] The guidance provided examples of potential violations of § 1557 and § 504, such as a pharmacy denying a methotrexate refill to a person with rheumatoid arthritis based on the medication's alternative use to induce abortions for ectopic pregnancies.

In June 2023, OCR announced that it reached a voluntary resolution agreement with Walgreens and CVS to improve timely access to medications to support people with disabilities, experiencing miscarriages and early pregnancy loss, and who need contraceptive access.[54] The retail pharmacy chains agreed to improve timely access to medications such as methotrexate

and misoprostol for these populations through a number of actions, including creating internal guidance, developing new staff trainings, and monitoring denials of medications related to reproductive health care.

4. Filing a Civil Rights Complaint

Advocates have a number of options to enforce § 1557 and § 504:

Send a letter outlining violations. As a first step, you could send a letter to the covered entity outlining their violation(s) of nondiscrimination requirements. The letter should request that they take proactive steps to correct the violation before any client(s) or potential client(s) are substantially harmed or describe the current harm(s). Starting with a demand letter may or may not be feasible depending on when the discrimination occurred, as individuals have a limited period of time within which they can file an administrative complaint (*see* discussion below). It is important to keep records of any communications with the covered entity, including any documentation you provide.

File a complaint in your federal district court. § 1557 and § 504 provide private rights of action that allow individuals to enforce these rights via the courts.

File an administrative complaint with HHS. You can also enforce rights under § 1557 and § 504 by filing an administrative complaint with HHS OCR. Individuals have 180 days from the date when they knew the covered entity's act or omission (*e.g.*, a refusal to fill, cover, or provide a prescription) occurred to file a complaint.[55] You may file a complaint by mail, fax, e-mail, or via OCR's complaint portal. In your complaint, you must name the health care or social service provider, insurer, or other entity involved and describe the acts or omissions you believe violated civil rights laws or regulations. While more information is better, if you are an individual filing a complaint on your own behalf, you do not need to give many details; a few sentences may be sufficient. For more information, *see* OCR's explainer, "How to File a Civil Rights Complaint."

File a complaint with your state insurance regulator. If you do not reach a favorable resolution or you encounter widespread violations, consider bringing those issues to the attention of your state Attorney General and/or Insurance Commissioner. For more information, *see* the discussion on state insurance regulators on page 18.

What About Health Care Refusal Exemptions?

Federal health care refusal laws, such as the Weldon Amendment and Church Amendments, govern when and how covered entities can refuse to cover, deliver, provide information on, or offer referrals for health care services they find objectionable based on their religious beliefs. These laws contribute to dangerous barriers to essential health care for many populations who are already marginalized and underserved by our health care system. In particular, religious refusals systematically undermine or prevent access to health care for LGBTQI+ people and women, including access to sexual, reproductive, and gender-affirming health care services such as abortion and contraceptives. They also have broad implications for people with disabilities.

Recent final rules set forth HHS's administrative processes for covered entities to request nondiscrimination exemptions. The agency will consider such requests on a case-by-case basis. For more information, *see* the NHeLP's "Questions and Answers on the 2024 Final Rule Addressing Nondiscrimination Protections under the ACA's Section 1557" and "HHS's 2024 Final Rule on Health Care Refusals: What Health Advocates Need to Know."

A covered entity does not qualify for an exemption under federal health care refusal laws if they deny access to a prescription drug intended to help manage a chronic condition or related symptoms based on their misunderstanding of their state's abortion law(s) or objection to providing abortion.

b. Health Insurance Laws

In addition to federal civil rights laws, federal and state health insurance laws may help address some barriers to prescription drugs for chronic conditions under *Dobbs*. Applicable protections will vary depending on the state in which you live, the form of health insurance, the barrier type, and whether the prescription in question is for an on- or off-label drug use.

1. Medicaid Coverage

A. Coverage Requirements and Barriers

As of July 2024, over 72 million people with low incomes in the U.S. received their health insurance through Medicaid.[56] Beneficiaries who experience barriers to coverage for prescription drugs that treat chronic conditions may be able to fight these barriers by enforcing their Medicaid rights. Because all states have opted to cover outpatient prescription drugs, they must cover (with few exceptions) these drugs for "medically accepted indications."

[57] Medically accepted indications include those uses included on the FDA drug label and certain "off-label" uses.[58] FDA drug labels must summarize "essential scientific information needed for the safe and effective use of the drug[,]" such as indications, usage, dosage forms and strength, and adverse interactions.[59] This information is based on the FDA's drug approval and informed by clinical trials, animal research, and other data that the manufacturer submits to the FDA.[60] When a prescription deviates in some manner from what is on the FDA's drug label, such as a prescription for an indication not included on the label, it is considered an "off-label" use.[61] Unfortunately, many indications, even for common uses, do not make it onto FDA drug labels. Sexism in medical research plays a role in these gaps.

How Gender Inequities in Medical Research Affect Medicaid Coverage

In 1977, the FDA recommended excluding women of reproductive age from Phase 1 and early Phase II drug trials, resulting in a dearth of data on how drugs affect cisgender women and people assigned female at birth.[62] In the 1980s, the National Institutes of Health (NIH) and the FDA issued new guidelines to encourage clinical trial investigators to include women, but women continued to be severely unrepresented.[63] In 1993, the FDA finalized new guidelines and formally rescinded the 1977 policy. To ensure robust implementation, Congress directed the NIH to ensure women are included in all clinical research.[64] As of 2000, the NIH had made significant progress, but women and people assigned female at birth are still not equitably included, with implications for which drug uses are FDA-approved and/or included in compendia and which are not.[65] In 2016, Congress enacted the 21st Century Cures Act, which requires the NIH to further its pursuit of "women's health" research.[66]

In November 2023, the Biden-Harris Administration launched the White House Initiative on Women's Health Research to address the continued underfunding of and major gaps in medical research on conditions that only or disproportionately affect women and people assigned female at birth, as well as those that affect them differently than they affect cisgender men.[67] In March 2024, President Biden signed an executive order directing HHS to take additional actions to advance "women's health" research and innovation.[68]

It is our hope that these actions will help address major gender inequities in research and thus in FDA-approved and compendia-supported indications of prescription drugs, strengthening access to care for Medicaid beneficiaries.[69] For example, more research is needed to evaluate and advance access to care for endometriosis, POTS, EDS, and hypermobility spectrum disorder.

Further, off-label uses are frequently used to treat conditions that are considered rare, which often have no or limited FDA-approved treatments.[70] For example, many people, including health care providers, still mistakenly believe that POTS, hypermobile EDS, and hypermobility spectrum disorder are rare conditions.[71] All of these conditions disproportionately affect women and gender-expansive people, for whom systemic sexism can be a profound barrier to diagnosis.[72] To date, there is no FDA-approved treatment for these conditions.[73]

In each of these instances, a drug manufacturer may be unable to gather the volume and types of documentation for FDA approval for a given use.[74] Further, they may not see much financial benefit to be gained by going through the slow and costly process of trying to get the FDA to expand the approved on-label uses of a drug.[75] For these reasons, off-label prescriptions comprise roughly one-fifth of prescriptions in the U.S.[76]

Unfortunately, the Medicaid Act only requires coverage of off-label uses of prescription drugs when their use "is supported by one or more citations included or approved for inclusion in" at least one of the three compendia enumerated in the statute: American Hospital Formulary Service Drug Information, U.S. Pharmacopeia-Drug Information (or successor publications), and DRUGEX Information System.[77] The U.S. Pharmacopeia-Drug Information is no longer in service, and while the U.S. Centers for Medicare and Medicaid Services (CMS) recognized DrugPoints as a successor publication for a time in a Medicare context, it ceased that recognition in 2008.[78] CMS has never clarified whether it still considers DrugPoints as a successor compendium in a Medicaid context and states vary in whether they recognize it for the purpose of determining off-label Medicaid coverage.[79] Unfortunately, the compendia operate under paywalls, making it difficult for Medicaid beneficiaries and advocates alike to assess whether their state must cover a drug for an off-label use.[80]

Advocacy Tip

Inadequate public access to drug compendia remains a major issue, particularly for Medicaid beneficiaries, their advocates, and health care providers. Check whether your local public and university libraries offer public access or can help you identify who does. For ease of access, we compiled highlights from the compendia entries for methotrexate, misoprostol, mifepristone, and popular contraceptive drugs in the Appendix at the end of this *Primer*.

States also vary in when they consider a use to be supported by citation in one of these compendia.[81] As the U.S. District Court for the Southern District of Florida wrote:

> [T]he Medicaid Act directs a state Medicaid agency to determine if a prescription is for a "medically accepted indication" by examining the text of the congressionally-approved

> drug compendia (if not for an FDA-approved use). If the use is supported by a citation in any of the compendia, as the statute mandates, then the state must cover the prescription. This examination . . . leaves no room for the exercise of discretion on the part of the state agency to determine its own criteria for defining whether and how a use is supported by citation. The statute as written eliminates such discretion and results in a single, nationally uniform list of medically accepted indications.[82]

In 2022, the U.S. Court of Appeals for the Eleventh Circuit said that the Medicaid Act requires coverage for "those off-label uses for which an approved medical compendium tends to show or helps prove the efficacy and safety of the prescribed off-label use."[83] Unfortunately, compendia often fail to include established off-label uses.[84] As a result, Medicaid programs may exclude some common off-label uses from coverage, leaving beneficiaries without access.

Illustration

These limitations undermine Medicaid coverage for people with chronic conditions, including those who need prescription drugs that treat their conditions or symptoms and have abortion-inducing, teratogenic, or contraceptive properties. For example, millions of people use oral (among other) contraceptives to manage the symptoms of chronic conditions. While the most common reason people use oral contraceptives is to prevent pregnancy, 14% of users—1.5 million women—relied on them for non-contraceptive purposes in 2011.[85] Unfortunately, the FDA has only approved the most popular combination contraceptives and the most popular progestin-only contraceptives for the purposes of contraception and sometimes treating moderate acne, overlooking a myriad of uses for many chronic conditions (*see* Appendix).[86] Further, the compendia often fall short, missing critical off-label uses for prescription drugs.

From 2006–2008, an estimated 4% of people with endometriosis took oral contraceptives to relieve their pain symptoms.[87] Extensive evidence supports this use.[88] The compendia support the use of only some of the most popular oral contraceptives to help manage endometriosis symptoms, creating coverage barriers for Medicaid beneficiaries (*id.*). Further, because people with POTS and EDS frequently experience exacerbated symptoms during menstruation, some take hormonal contraceptives to help manage their symptoms. For people with EDS, contraceptives can help manage common comorbidities such as heavy menstrual bleeding and dysmenorrhea (severe menstrual pain).[89] For people with POTS, which is often comorbid with EDS, contraceptives may help manage Dysautonomia flare-ups (*e.g.*, severe lightheadedness) during menstruation.[90] However, the FDA has not approved EDS or POTS symptom management as uses for at least the 5 most frequently prescribed combination contraceptives

and progestin-only contraceptives, respectively (*id.*). Further, the compendia listed in the Medicaid Act do not include these uses for the most popular oral contraceptives, resulting in potential access barriers for Medicaid beneficiaries.

In order for an outpatient prescription drug to be covered by Medicaid, its manufacturer must also participate in the Medicaid Prescription Drug Rebate Program, the Section 340B Drug Pricing Program, and have a master agreement with the Secretary of Veterans Affairs for the Federal Supply Schedule Program.[91] States must operate drug use review boards to help assess the appropriateness of prescriptions for Medicaid beneficiaries.[92]

States may restrict outpatient prescription drug coverage by limiting the minimum or maximum quantities of a prescription or the number of refills when limitations are necessary to discourage waste, fraud, and abuse.[93] They may exclude or restrict coverage of an outpatient drug if the off-label use for which the drug was prescribed is not a medically accepted indication.[94] States may also impose limited cost-sharing (*e.g.*, deductibles, co-payments, co-insurance) and premiums on certain Medicaid beneficiaries, with some exceptions.[95]

B. Enforcing Medicaid Coverage Requirements

Advocates can enforce federal Medicaid coverage requirements in a number of ways:

File an appeal. Medicaid beneficiaries have a constitutionally protected property interest in their coverage.[96] Under the Medicaid Act, they have due process rights if their benefits are denied, reduced, or terminated.[97] They have a right to an adequate written notice that describes: (1) the adverse action the state Medicaid agency intends to take; (2) the reasons for the intended action (including the legal and factual bases); (3) the specific law or regulations that require or support this action; (4) their right to a fair hearing and the method for requesting one; (5) their right to represent themselves or be represented by legal counsel, a relative, or another authorized representative; (6) the availability of legal services agencies and other sources of representation; and (7) the situations under which they can receive aid paid pending a determination (*i.e.*, continued benefits pending the outcome of an appeal if they request a hearing, such as continued prescription drug coverage).[98] The state Medicaid agency or Medicaid managed care plan must generally send the notice at least ten days before the date of the action.[99]

The Medicaid Act requires that individuals have a reasonable period of time (as established by the state agency and not to exceed ninety days from the date that the notice was mailed) to request a fair hearing.[100] State agencies and managed care organizations must generally provide a hearing upon request, except when there is an automatic change in coverage due

solely to a change in state or federal law.[101] The Medicaid Act provides beneficiaries with a number of key procedural rights for fair hearings, such as an opportunity to review all policies and documents that informed the decision and their case files.[102] The hearing must be conducted by an impartial hearing officer and occur at a reasonable time, place, and date.[103] State agencies must provide a qualified interpreter to those with limited English proficiency.[104]

In the case of prescription drug denials that involve medical issues (*e.g.*, which indications are medically accepted for a given diagnosis, a medical review team's decision), if the hearing officer deems a medical assessment from an additional person necessary, the agency must secure that assessment at its own expense and add it to the record.[105] The beneficiary (and their authorized representative) has a right to establish all pertinent facts and circumstances (including through their own witnesses), confront and question opposing witnesses, and present their argument without interference.[106] The hearing officer must base their decision solely on the legal rules and evidence presented at the hearing and provide their decision in writing within ninety days of the request for a hearing.[107] If the hearing decision is adverse to the beneficiary, they have a right to seek judicial review in state court, as available.[108]

File a complaint with your state insurance regulator. Consider bringing violations of Medicaid coverage requirements to the attention of your state Attorney General and/or Insurance Commissioner. For more information, *see* the discussion on state insurance regulators on page 18.

2. Essential Health Benefits

A. Essential Health Benefits Coverage Requirements for Qualified Health Plans

At present, we have limited information on the circumstances surrounding insurance barriers to prescription drugs for chronic conditions under *Dobbs*. Whether these denials are all on the basis of sex or some plans are withdrawing coverage of these drugs for all enrollees remains to be seen. If private health plans are engaging in the latter, their enrollees may be able to enforce federal coverage rights under the ACA's Essential Health Benefits (EHB) requirements. For purposes of this section, I focus on EHB requirements in Qualified Health Plans (QHPs) sold through state or federal health insurance marketplaces.[109]

Non-grandfathered health plans in the individual markets (*e.g.*, individual plans available through the marketplaces), small group markets, and Medicaid alternative benefit plans (ABPs) (*e.g.*, for Medicaid expansion beneficiaries) must cover EHBs, a set of ten health care service

categories, including prescription drugs and preventive services, with limits on cost-sharing.[110] The EHB standard for preventive services requires coverage of FDA-approved contraceptive methods without cost-sharing.[111]

In contrast, the separate EHB standard for prescription drugs requires that QHPs cover at least one drug per the USP Medicare Model Guidelines classification system (USP MMG) *or* the same number of drugs in each USP category and class as the state's EHB base-benchmark plan.[112] QHP coverage requirements for off-label uses of drugs vary by state, and where no protections exist, people with chronic conditions may face additional coverage barriers.[113]

Because the U.S. Pharmacopeial Convention designed the USP MMG for the Medicare Part D program and its beneficiaries, it does not adequately classify and categorize drugs for the broader populations who rely on health plans subject to EHB standards.[114] Perhaps due to ableist assumptions about sexual and reproductive health, it also fails to adequately classify and categorize medications that Medicare Part D beneficiaries who are disabled and in their reproductive years may need. For example, the USP MMG fails to cover a number of sexual and reproductive health-related prescription drugs, including some of the drugs that *Dobbs* has chilled access to.[115]

QHP Pharmacy and Therapeutics (P&T) Committees are charged with helping to ensure that plan formularies are up to date and adequately meet enrollees' needs. They must meet at least quarterly to review plan formularies, prior authorization criteria and other medical management strategies, and document the rationale for all decisions regarding formulary drug list development or revision.[116] Thus, P&T Committees must review, approve, and document the rationale for any changes to outpatient drug formularies because of *Dobbs*.

Although federal regulations only permit QHP issuers to modify plan benefits, including formularies, at the time of open enrollment, advocates report numerous incidents where issuers adversely change benefits in the course of a plan year, such as by imposing prior authorization requirements or dropping drugs altogether.[117] It remains to be seen whether *Dobbs* will induce such mid-year changes. Due to a lack of formulary transparency in many states, many people comparing QHP options side-by-side in the marketplace may lack adequate information about whether the prescriptions they need are covered by each plan.[118] Nevertheless, federal regulations require a QHP to publish an up-to-date, accurate, and complete list of all covered drugs on its formulary list in a manner that is accessible to plan enrollees, prospective enrollees, the public, and other stakeholders.[119]

When an enrollee's QHP does not include the prescription drug they need in its formulary, they have a right to request an exception and gain access to it if the use is "clinically appropriate."[120] Unfortunately, there is a lack of transparency on how plans and external reviewers determine "clinically appropriate" uses. QHPs must have an expedited exception process for exigent circumstances when an enrollee has a health condition that may seriously jeopardize their health, life, or ability to regain maximum function or when an enrollee is currently undergoing a course of treatment using a non-formulary drug.[121] This expedited exemption process may particularly help people who face prescription drug coverage losses due to mid-year formulary changes.

B. Enforcing and Defending EHB Coverage Requirements

Advocates can enforce and defend EHB prescription drug requirements in a number of ways:

Send a letter outlining violations. As a first step, you can opt to send a letter to the entity denying or limiting coverage outlining violation(s) of EHB prescription drug coverage or formulary transparency requirements. The letter should request that they take proactive steps to correct the violation before any client(s) or potential client(s) are substantially harmed or describe the current harm(s). It is important to keep records of any communications with the covered entity, including any documentation you provide.

Appeal coverage denials. When a QHP denies an enrollee coverage for a drug included in its formulary, the enrollee has a right to appeal the decision.[122] If they receive an adverse determination after their internal appeal, they have a right to an external review.[123] When a QHP denies an enrollee's exception request for a non-formulary drug, the enrollee also has a right to request a secondary external review by an independent review organization, though plan processes vary.[124]

File a complaint with your state insurance regulator. Consider bringing violations of transparency requirements or coverage restrictions to the attention of your state Attorney General and/or Insurance Commissioner. For more information, *see* the discussion on state insurance regulators on page 18.

Represent Consumers on QHP P&T Committees. CMS recently revised the minimum membership standards for QHP P&T Committees.[125] For plan years beginning on or after January 1, 2026, P&T committees must include at least one patient representative.[126] Advocates serving in this capacity could monitor and oppose any proposed changes to a QHP formulary in light of the changing legal landscape for abortion.

Contraceptive Coverage Exemptions in Private Health Insurance

Some private health plans, such as self-funded student health plans and grandfathered plans (*i.e.*, plans that have not substantially changed since March 23, 2010) are exempted from the ACA's contraceptive coverage mandate by statute.[127] Federal regulations also establish exemptions to the requirement for group health plans established, maintained, provided, offered, or arranged for by certain employers and colleges and universities with sincerely held moral objections to coverage or payments for some or all contraceptive services.[128]

3. State Contraceptive Equity Laws

Contraceptive equity "is a policy framework under which contraceptive care is easily accessible and covered at no cost in all health programs."[129] State contraceptive equity laws can play a critical role in filling gaps in contraceptive access that remain despite the ACA.[130] They apply to most commercial plans, all plans purchased through the ACA's marketplaces, Medicaid ABPs, and Medicaid managed care plans and have three major components:

- Expanding the range of contraceptive methods and services covered with no cost-sharing;
- Limiting medical management (*i.e.*, utilization controls); and
- Creating gender equity in contraceptive coverage.

Some state contraceptive equity laws, such as those in Connecticut, Massachusetts, and New York, include provisions that protect access to contraceptive drugs for uses beyond contraception.[131] For example, Massachusetts's law bars covered plans from excluding coverage for contraceptive drugs, devices, and products and procedures prescribed for non-contraceptive purposes, "including, but not limited to, decreasing the risk of ovarian cancer, eliminating symptoms of menopause or providing contraception that is necessary to preserve the life or health of the enrollee or the enrollee's covered spouse or covered dependents."[132]

If a health plan denies access to a contraceptive because it was prescribed for a non-contraceptive purpose, check if your state has a contraceptive equity law and if so, whether it contains specific protections for uses beyond contraception.[133] These laws may include exemptions for religious objections. NHeLP's "Contraceptive Equity in Action: A Toolkit for State Implementation" offers advocates in states with contraceptive equity laws best practices for evaluating potential claims and enforcement.

File a Complaint with Your State Insurance Regulator.

If you are unable to reach a favorable Medicaid, EHB, or state contraceptive equity law enforcement outcome through an administrative appeal or litigation, or if you recognize a pattern of insurance denials and limitations for prescription drugs to treat chronic conditions after *Dobbs*, consider submitting a complaint to your state's department of insurance (DOI).[134] This option can be particularly helpful if you have filed a complaint (*e.g.*, with HHS OCR or your state Medicaid agency) but have encountered a delay, denial, or unsatisfactory resolution. To locate your state DOI's complaint portal, visit https://content.naic.org/consumer and select your state under "File a Complaint."

Conclusion

Amid escalating attacks on sexual and reproductive rights in the U.S., people are facing increasing barriers to prescription drugs that help manage their chronic conditions or related symptoms. These barriers may violate civil rights and coverage laws. Advocates have a number of avenues to enforce related rights. We hope that this *Primer* proves a useful resource to advocates serving people with disabilities caught in the fallout from *Dobbs*.

Appendix: On- and Off-Label Uses for Select Reproductive Health-Related Prescription Drugs

For purposes of this Appendix, we surveyed on-and-off label uses for a sample of prescription drugs that are used in both reproductive health and chronic condition management contexts: methotrexate, misoprostol, mifepristone, and select combination estrogen-progestin and progestin-only contraceptives. To complete this survey, we examined the FDA labels and related entries in the compendia that all states accept, the American Hospital Formulary Service—Drug Information (AHFS-DI), and Drugdex.[135] We bolded uses related to sexual and reproductive health.

a. Methotrexate

METHOTREXATE
On-Label Uses
Treatment for acute lymphoblastic leukemia; Mycosis fungoides; Non-Hodgkin's lymphoma; Rheumatoid arthritis; Polyarticular juvenile idiopathic arthritis; Severe psoriasis[136]
Off-Label Uses in Compendia
AHFSDI:[137] Trophoblastic neoplasms (effective mostly in patients whose onset of disease was shortly before chemotherapy); Leukemias (effective mostly in acute lymphocytic leukemia); Osteosarcoma;[138] **Breast cancer** (effective in combination chemotherapy for premenopausal and postmenopausal patients); Lymphoma (effective in Burkitt's lymphoma, advanced stage lymphosarcoma, mycosis fungoides, but not Hodgkin's disease); Psoriasis (evidence is inconclusive); Rheumatoid arthritis (effective in certain combos); Head and neck cancer (research is insufficient); Crohn's disease (more effective than placebo); Advanced bladder cancer; Recurrent small cell lung cancer; Variety of solid tumors; Psoriatic arthritis (effective in patients who are unresponsive to conventional therapy); Systemic lupus erythematosus; Vasculitis; Dermatomyositis; Polymyositis; Wegener's granulomatosis; Variety of dermatologic and chronic refractory ocular diseases
DRUGDEX:[139] Oral tablet*:* Acute lymphoid leukemia, as part of a combination chemotherapy maintenance regimen (adult, effective) (pediatric, effective); Juvenile idiopathic arthritis, active, polyarticular, in patients with an insufficient response or intolerance to first-line therapy, including full-dose NSAIDs (pediatric, effective); Mycosis fungoides, alone or in combination with other chemotherapy agents (adult, effective); Non-Hodgkin's lymphoma, relapsed or refractory, as part of a metronomic combination chemotherapy regimen (adult, effective); Psoriasis, severe (adult, effective); Psoriasis severe; recalcitrant disabling (adult, effective); Rheumatoid arthritis (adult, effective); Rheumatoid

arthritis, severe, in patients with an insufficient response or intolerance to first-line therapy, including full-dose NSAIDs (adult, effective) Injection: Rheumatoid arthritis, severe, in patients with an insufficient response or intolerance to first-line therapy, including full-dose NSAIDs (adult, effective); Psoriasis severe; recalcitrant disabling (adult, effective) Non-FDA Uses: Behcet's syndrome (adult, evidence favors efficacy) (pediatric, evidence favors efficacy); Eosinophilic granulomatosis with polyangiitis (adult, evidence favors efficacy); Gout, refractory to conventional therapy, in combination with pegloticase (adult, effective); Granulomatosis with polyangiitis (adult, evidence favors efficacy); Microscopic polyangiitis (adult, evidence favors efficacy); Polyarteritis nodosa (adult, evidence favors efficacy) (pediatric, evidence favors efficacy); Psoriasis, moderate to severe (pediatric, evidence favors efficacy); Ulcerative colitis, moderate to severe, in combination with TNF-alpha antagonists, vedolizumab, or Ustekinumab (adult, evidence is inconclusive); Ulcerative colitis, moderate to severe, monotherapy for induction or maintenance therapy
METHOTREXATE SODIUM
On-Label Uses
Treatment for acute lymphoblastic leukemia; Mycosis fungoides; Non-Hodgkins lymphoma; Rheumatoid arthritis; Polyarticular juvenile idiopathic arthritis; Severe psoriasis[140]
Off-Label Uses in Compendia
AHFSDI:[141] Trophoblastic neoplasms (effective mostly in patients whose onset of disease was shortly before chemotherapy); Leukemias (effective mostly in acute lymphocytic leukemia); Osteosarcoma; **Breast cancer** (effective in combination chemotherapy for premenopausal and postmenopausal patients); Lymphoma (effective in Burkitt's lymphoma, advanced stage lymphosarcoma, mycosis fungoides, but not Hodgkin's disease); Psoriasis (evidence is inconclusive); Rheumatoid arthritis (effective in certain combos); Head and neck cancer (research is insufficient); Crohn's disease (more effective than placebo); Advanced bladder cancer; Recurrent small cell lung cancer; Variety of solid tumors; Psoriatic arthritis (effective in patients who are unresponsive to conventional therapy); Systemic lupus erythematosus; Vasculitis; Dermatomyositis; Polymyositis; Wegener's granulomatosis; Variety of dermatologic and chronic refractory ocular diseases
DRUGDEX:[142] Injection: Acute lymphoid leukemia (adult, evidence favors efficacy) (pediatric, evidence favors efficacy); **Breast cancer** (adult, evidence favors efficacy); Gestational trophoblastic neoplasia, including gestational choriocarcinoma, chorioadenoma destruens, and hydatidiform mole (adult, evidence favors efficacy); Head and neck cancer, epidermoids type (alone or in combination with other chemotherapy agents) (adult, evidence favors efficacy); Lung cancer, alone or in combination with other chemotherapy agents (adult, evidence favors efficacy); Meningeal leukemia; treatment and prophylaxis (adult,

evidence favors efficacy) (pediatric, evidence favors efficacy); Mycosis fungoides, advanced (alone or in combination with other chemotherapy agents) (adult, evidence favors efficacy); Non-Hodgkin's lymphoma, advanced (adult, evidence favors efficacy) (pediatric, evidence favors efficacy); Osteosarcoma, adjuvant (adult, evidence favors efficacy) (pediatric, evidence favors efficacy); Polyarticular juvenile idiopathic arthritis (pediatric, evidence favors efficacy); Psoriasis, severe (adult, effective); Rheumatoid arthritis (adult, effective)
Non-FDA Uses: Asthma (adult, evidence favors efficacy); Behcet's syndrome (adult, evidence favors efficacy) (pediatric, evidence favors efficacy); Bullous pemphigoid (adult, evidence favors efficacy); Carcinoma of penis (adult, evidence favors efficacy);
Carcinoma of stomach, first line, in combination with 5-fluorouacil and doxorubicin (adult, evidence is inconclusive); Carcinoma of urinary bladder (adult, evidence favors efficacy); Chronic myeloid leukemia (adult, evidence favors efficacy); Cutaneous lupus erythematosus (adult, evidence favors efficacy); Dermatomyositis (adult, evidence is inconclusive); **Ectopic pregnancy** (adult, evidence favors efficacy); Eosinophilic granulomatosis with polyangiitis (adult, evidence favors efficacy); Felty's syndrome (adult, evidence favors efficacy); Gout, refractory to conventional therapy, in combination with pegloticase (adult, effective); Graft versus host disease; prophylaxis (adult, evidence favors efficacy); Granulomatosis with polyangiitis (adult, evidence favors efficacy); Hodgkin's disease (adult, evidence favors efficacy); Immune effector cell-associated neurotoxicity syndrome; Labyrinthine disorder (adult, evidence in inconclusive); Lipoid dermatoarthritis (adult, evidence is inconclusive); Lymphomatoid papulosis (adult, evidence is inconclusive); Malignant epithelial tumor of ovary (adult, evidence favors efficacy); Malignant lymphoma—malignant tumor of meninges (pediatric, evidence favors efficacy); Malignant lymphoma of the eye region, intraocular (adult, evidence favors efficacy); Malignant meningitis, non-lymphomatous (adult, evidence is inconclusive); Mantle cell lymphoma (adult, evidence is inconclusive); Microscopic polyangiitis (adult, evidence favors efficacy); Multiple sclerosis (adult, evidence is inconclusive); Myasthenia gravis, generalized (adult, evidence is inconclusive); Polyarteritis nodosa (adult, evidence favors efficacy) (pediatric, evidence favors efficacy); Polymyalgia rheumatica (adult, evidence is inconclusive); Primary biliary cholangitis (adult, evidence is inconclusive); Primary central nervous system lymphoma (adult, effective); Psoriasis, moderate to severe (pediatric, evidence favors efficacy); Psoriatic arthritis (adult, evidence is inconclusive); Rheumatoid arthritis, severe, active, in patients failing or intolerant to first-line therapy, including full-dose NSAIDs; Sarcoidosis, adjunct (adult, evidence favors efficacy) (pediatric, evidence is inconclusive); Sezary's disease (adult, evidence is inconclusive); Soft tissue sarcoma (adult, evidence favors efficacy); Systemic lupus erythematosus (adult, evidence favors efficacy); Systemic onset juvenile chronic arthritis (adult, evidence is inconclusive); Takayasu's disease (adult, evidence is inconclusive); Temporal arteritis (adult, evidence is inconclusive); **Abortion** (adult, evidence favors efficacy); Ulcerative colitis, moderate to severe, in

combination with TNF-alpha antagonists, vedolizumab, or Ustekinumab (adult, evidence is inconclusive); Ulcerative colitis, moderate to severe, monotherapy for induction or maintenance therapy (adult, ineffective); Urothelial carcinoma (adult, evidence favors efficacy); Uveitis (adult, evidence favors efficacy); Vasculitis, cerebral (adult, evidence is inconclusive)

b. Misoprostol

On-Label Uses
Reducing risk of NSAID-induced gastric ulcers in certain patients[143]
Off-Label Uses in Compendia
AHFSDI:[144] Prevention of NSAID-induced ulcers (efficacy evidence inconclusive); Short term, benign gastric ulcer (same to less efficacy than other similar drugs); Duodenal ulcer (same to less efficacy than other similar drugs); **Abortion**; **Other obstetric uses**; Management of fat malabsorption associated with cystic fibrosis; Management of hemorrhagic gastritis, reflux esophagitis, alcohol-induced gastritis, NSAIA-induced nephropathy
DRUGDEX:[145] Oral Tablet: NSAID-induced gastric ulcer, prophylaxis (adult, effective) Non-FDA Uses: **Cervical ripening procedure—hysteroscopy** (adult, evidence favors efficacy); **Cervical ripening procedure—induction of labor** (adult, evidence favors efficacy); Constipation (adult, evidence favors efficacy); Drug-induced gastrointestinal disturbance; **Female infertility** (adult, evidence favors efficacy); Gastric ulcer: prophylaxis (adult, effective); Hemorrhagic gastritis, acute (evidence is inconclusive); **Missed miscarriage, less than 14 weeks gestation** (adult, evidence favors efficacy); Non-steroidal anti-inflammatory drug adverse reaction—ulcer of duodenum, prophylaxis (adult, evidence favors efficacy); **Postpartum hemorrhage** (adult, evidence favors efficacy); **Postpartum hemorrhage; prophylaxis** (adult, evidence favors efficacy); **Radiation proctitis** (evidence is inconclusive); **Abortion** (adult, evidence favors efficacy); Ulcer of duodenum (adult, evidence favors efficacy); **Undelivered in utero fetal death, 14 to 18 weeks gestation** (adult, evidence favors efficacy); Upper gastrointestinal bleeding, drug-induced; adjunct (evidence is inconclusive)

c. Mifepristone

On-Label Uses
Abortion;[146] Control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type two diabetes mellitus or glucose intolerance or have failed or are not candidates for surgery.[147]
Off-Label Uses in Compendia
AHFSDI:[148] **Abortion** (effective when oral mifepristone is followed by oral misoprostol); Hyperglycemia secondary to Cushing's syndrome
DRUGDEX:[149] Oral Tablet: Hyperglycemia—Idiopathic Cushing's syndrome, in patient who have failed surgery or are ineligible for surgery (adults, effective); **Abortion; in regimen with misoprostol** (adults effective) (pediatric effective); Alzheimer's disease, mild to moderate (efficacy evidence is inconclusive); **Breast cancer** (efficacy evidence is inconclusive); **Contraception** (efficacy is inconclusive); Cushing's syndrome (efficacy evidence is inconclusive); Depression (efficacy evidence is inconclusive); **Dilation of cervical canal** (adult, evidence favors efficacy); **Endometriosis** (adult, evidence favors efficacy); **Induction of labor** (adult, evidence favors efficacy); **Irregular periods** (adult, evidence favors efficacy); **Missed miscarriage, less than 14 weeks gestation; in regimen with misoprostol** (adult, evidence favors efficacy); **Ovarian cancer, refractory** (adult, evidence favors efficacy); **Postcoital contraception** (adult, evidence favors efficacy); **Undelivered in utero fetal death, 14 to 28 weeks gestation, in regimen with misoprostol** (adult, evidence favors efficacy); **Uterine leiomyoma** (adult, evidence favors efficacy)

d. Oral Contraceptives

This section summarizes findings from the compendia entries relevant to the five most commonly prescribed combination and progestin-only contraceptive pills in 2022. I identified these drugs using IQVIA Dynamic Prescription Data. Because the data include both generics and brand name drugs, some of the applicable compendia entries are the same.

1. Combination Oral Contraceptives

PRODUCT NAME On-Label Uses	Off-Label Uses in Compendia
LO LOESTRIN FE **Contraceptive**[150]	**AHFSDI**:[151] **Contraception** (effective); **Postcoital contraception** (effective but not as effective as other forms of long-term contraception); **Contraception and folate supplementation**; Acne vulgaris (effective,

	specifically Yaz and Beyaz); **Premenstrual dysphoric disorder** (more effective than placebo with Yaz); **Endometriosis or dysfunctional uterine bleeding**
	DRUGDEX:[152] Oral Tablet: **Contraception** (adult, effective in women with BMI lower than 35 kg/m(2)) (pediatric, effective)
DROSPIRENONE/ ETHINYL ESTRADIOL **Contraceptive**, moderate acne[153]	**AHFSDI**: N/A
	DRUGDEX:[154] Oral Tablet: **Contraception** (adult, effective) (pediatric, effective); Moderate acne (adult, effective) (pediatric 14 years+, effective); **Premenstrual dysphoric disorder**
SPRINTEC 28 (norgestimate and ethinyl estradiol tablets) **Contraceptive**[155]	**AHFSDI**: N/A
	DRUGDEX:[156] Oral Tablet: Acne (adult, effective) (pediatric, effective); **Contraception** (adult, effective) (pediatric, effective)
BLISOVI FE 1/20 (norethindrone acetate and ethinyl estradiol tablets USP and ferrous fumarate tablets) **Contraceptive**[157]	**AHFSDI**: N/A
	DRUGDEX:[158] Oral Tablet: **Contraception** (adult, effective) (pediatric, effective)
NORGESTIMATE/ETHINYL ESTRADIOL **Contraceptive**, moderate acne if desire contraceptive 15+[159]	*See* compendia entry for Sprintec 28

2. Progestin-only Oral Contraceptives

PRODUCT NAME On-Label Uses	Off-Label Uses in Compendia
NORETHINDRONE **Contraceptive**[160]	**AHFSDI**: N/A
	DRUGEX:[161] Oral Tablet: **Contraception** (adult, effective) (pediatric, effective)
SLYND (drospirenone) **Contraceptive**[162]	**AHFSDI**: N/A
	DRUGDEX[163]:

	Oral Tablet: **Contraception** (adult, effective) (pediatric, effective)
HEATHER **Contraceptive**[164]	*See* Norethindrone
ERRIN **Contraceptive**[165]	*See* Norethindrone
JENCYCLA **Contraceptive**[166]	*See* Norethindrone

ENDNOTES

*As a multiply disabled woman with chronic conditions, including some described in this paper, it is my hope that this *Primer* will arm advocates with the legal tools they need to fight some of the prescription drug denials affecting our community under *Dobbs*. Thank you to Kavisha Prajapati for their assistance developing the Appendix; Natasha Rappazzo, Rebecca Abraham, and Fiona Fitzgerald for their media research assistance; and Julia Strasser, Ellen Schenk, Lauren Stiles, and Dr. Jeff Boris for their invaluable technical guidance. I also thank my colleagues Wayne Turner, Christina Piecora, and Cat Duffy for consulting on topics within their areas of expertise and Fabiola De Liban, Jennifer Lav, Wayne Turner, and Mara Youdelman for their review of this *Primer* in whole or in part. I have made every effort to offer up-to-date and accurate information based on existing legal, medical, and media resources.

[1] Loretta Ross, *What is Reproductive Justice?* in REPRODUCTIVE JUSTICE BRIEFING BOOK: A PRIMER ON REPRODUCTIVE JUSTICE AND SOCIAL CHANGE 4 (2007), https://www.law.berkeley.edu/php-programs/courses/fileDL.php?fID=4051; Dobbs v. Jackson Women's Health Org., 142 S. Ct. 2228 (2022).

[2] Guttmacher, State Bans on Abortion Throughout Pregnancy (last visited Oct. 7, 2024), https://www.guttmacher.org/state-policy/explore/state-policies-abortion-bans.

[3] Jessica L. Gleason et al., *Risk of Adverse Maternal Outcomes in Pregnant Women with Disabilities*, JAMA NETWORK OPEN (Dec. 2021), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2787181.

[4] Agency for Healthcare Res. & Qual., Chronic Conditions (defining a chronic condition as one "that lasts 12 months or longer and meets one or both of the following tests: (a) it places limitations on self-care, independent living, and social interactions; (b) it results in the need for ongoing intervention with medical products, services, and special equipment."), https://www.ahrq.gov/topics/chronic-conditions.html (last visited Sep. 3, 2024); Asha Hassan et al., *Dobbs and Disability: Implications of Abortion Restrictions for People with Chronic Conditions*, 58(1) HEALTH SERV. RES. 197 (Feb. 2023), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9836943/.

[5] Jeannie Baumann, *Abortion Restrictions Weakening Cancer Care, Other Treatments*, BLOOMBERG LAW, Aug. 14, 2023 (5:04 AM EDT), https://news.bloomberglaw.com/pharma-and-life-sciences/abortion-restrictions-weakening-cancer-care-other-treatments?context=search&index=0.

[6] *See* Part I, infra.

[7] *Id*.

[8] World Health Org., Model List of Essential Medicines, https://list.essentialmeds.org/ (last visited Aug. 8, 2024); Meghan Holohan, *Methotrexate, used on autoimmune diseases, can induce abortion. Some patients can't get it*, TODAY, July 8, 2022, (2:40 EDT), https://www.today.com/health/health/methotrexate-abortion-ban-rcna36764.

[9] NHeLP strives to use gender inclusive language to accurately reflect the scope of people with various sexual and reproductive health care needs and related experiences. We employ "women" in limited instances when necessary to accurately reference gendered legal terms or research and to honor how advocates or groups self-identify. More inclusive policy language and research are needed to better serve, understand, and illuminate the needs of all people

who need equitable access to health care, including sexual and reproductive care. Brittni Frederiksen et al., *Abortion Bans May Limit Essential Medications for Women with Chronic Conditions*, KFF (Nov. 2022), https://www.kff.org/womens-health-policy/issue-brief/abortion-bans-may-limit-essential-medications-for-women-with-chronic-conditions/.

[10] Annalisa Merelli, *Rheumatology patients are already having trouble accessing essential drugs because of abortion bans*, QUARTZ, July 6, 2022, https://qz.com/2185205/abortion-bans-are-stopping-treatments-for-arthritis-and-lupus-too.

[11] *See, e.g.*, Katie MacBride, *Overturning Roe Leaves People With Autoimmune Conditions in Danger*, INVERSE, July 22, 2022, https://www.inverse.com/mind-body/overturning-roe-methotrexate (stating that methotrexate can only be used off-label for 10% of ectopic pregnancies because you have to catch the condition within the first six weeks of pregnancy for this treatment to work).

[12] Kellie Mullany, *Overview of Ectopic Pregnancy Diagnosis, Management, and Innovation*, 14 WOMEN'S HEALTH (LOND.) 1 (2023), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10071153/#:~:text=Ectopic%20pregnancies%20are%20the%20leading,abdominal%20pain%20and%20vaginal%20bleeding.

[13] For additional methotrexate uses, see the Appendix. *See, e.g.*, Bradley S. Hurst et al., *Obstetric and Gynecological Challenges in Women with Ehlers-Danlos Syndrome*, 123(3) OBSTET. GYNECOL. 506–513 (Mar. 2014), https://pubmed.ncbi.nlm.nih.gov/24499752/; Am. Col. Obstet. & Gynecol., Ectopic Pregnancy, https://www.acog.org/womens-health/faqs/ectopic-pregnancy (last visited Aug. 8, 2024).

[14] Meghan Holohan, *supra* note 8.

[15] Frederiksen et al., *supra* note 9; Sonja Sharp, *Post-*Roe*, Many Autoimmune Patients Lose Access to 'Gold Standard' Drug*, L.A. TIMES, July 11, 2022 (5:00 AM PT), https://www.latimes.com/california/story/2022-07-11/post-roe-many-autoimmune-patients-lose-access-to-gold-standard-drug.

[16] *Id.*; MacBride, *supra* note 11.

[17] U.K. Nat'l Health Serv., Methotrexate, https://www.nhs.uk/medicines/methotrexate/ (last visited Aug. 8, 2024).

[18] Eleanor Bilma Schwarz et al., *Documentation of Contraception and Pregnancy When Prescribing Potentially Teratogenic Medications for Reproductive-Age Women*, 147(b) ANN. INTERN. MED. 370 (Sep. 2010), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2941151/; Guoda Varytė et al., *Pregnancy and Multiple Sclerosis: An Update*, 33(b) CURR. OPIN. OBSTET. GYNECOL. 378 (Oct. 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8452312/; J. Arnon et al., *Genetic and Teratogenic Effects of Cancer Treatments on Gametes and Embryos*, 7(4) HUMAN REPRO. UPDATE 394, 399 (2001), https://pubmed.ncbi.nlm.nih.gov/11476352/; Evan Gedzelman & Kimford J. Meador, *Antiepileptic Drugs in Women with Epilepsy During Pregnancy*, 3(2) THER. ADV. DRUG. SAF. 71 (Apr. 2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4110845/.

[19] Schwarz, *supra* note 20, at 370.

[20] Kate Baggaley, Abortion Bans are Impeding Access to Ulcer, Arthritis, and Cancer Medications, POPULAR SCIENCE, Aug. 1, 2022, https://www.popsci.com/health/abortion-ban-impeding-medication-access/.

[21] Frederiksen et al., *supra* note 9; see also World Health Org., *supra* note 8.

[22] FDA, Highlights of Prescribing Information for Mifeprex® (Mifepristone), https://www.accessdata.fda.gov/spl/data/f827a5f5-c021-61dd-e053-6294a90a94d9/f827a5f5-c021-61dd-e053-6294a90a94d9.xml (last visited July 24, 2024); *see also* World Health Org., *supra* note 8.
[23] FDA, Highlights of Prescribing Information for KORLYM® (mifepristone), https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/202107s008lbl.pdf.
[24] Caroline Hopkins, *The 'Abortion Pill' May Treat Dozens of Diseases, but* Roe *Reversal Might Upend Research*, NBC NEWS (June 25, 2022, 4:30 AM EDT), https://www.nbcnews.com/health/health-news/abortion-pill-may-treat-dozens-diseases-roe-reversal-might-upend-resea-rcna34812.
[25] Maya Yang, *Republican Abortion Bans Restrict Women's Access to Other Essential Medicine*, THE GUARDIAN, Sept. 26, 2022 (1:00 PM), https://www.theguardian.com/world/2022/sep/26/us-abortion-bans-restrict-access-essential-medications (reporting per the Global Healthy Living Foundation people are facing new access barriers to misoprostol prescriptions for chronic conditions following *Dobbs*. The Global Healthy Living Foundation did not respond to my outreach for further details on these barriers).
[26] For discussion regarding on- and off-label uses of contraception, *see* discussion *infra* in section b.1.
[27] *Dobbs* Thomas Concurrence 3 ("in future cases, we should consider all of this Court's substantive due process precedents, including *Griswold* . . . ").
[28] *See, e.g.*, Alina Salagincoff & Usha Ranji, *A Focus on Contraception in the Wake of Dobbs*, 33(4) WOMEN'S HEALTH ISSUES, 343 (July–Aug. 2023), https://www.whijournal.com/article/S1049-3867(23)00082-8/fulltext.
[29] Burwell v. Hobby Lobby Stores, Inc., 573 U.S. 682 (2014); *id.* (explaining that Hobby Lobby's owners challenged the ACA's contraceptive coverage mandate by arguing that intrauterine devices (IUDs) and emergency contraception induce abortions).
[30] Kevin D. Roberts, *Forward* in MANDATE FOR LEADERSHIP: THE CONSERVATIVE PROMISE (PROJECT 2025 PRESIDENTIAL TRANSITION PROJECT) xiii (Paul Dans & Steven Groves, 2023) (hereinafter "PROJECT 2025"); Roger Severino, *Department of Health and Human Services* in PROJECT 2025 485 (Paul Dans & Steven Groves, 2023) (recommending that the next conservative administration "eliminate the week-after-pill fro the contraceptive mandate as a potential abortifacient").
[31] *See, e.g.*, Erica Jalal, *Patients Being Barred From Medication No Longer Used for Abortion Post Roe*, ABC NEWS, July 14, 2022 (2:01 AM ET), https://abcnews.go.com/Health/patients-barred-medication-longer-abortion-post-roe/story?id=86755133 (describing how a CVS in Tennessee placed a person's methotrexate prescription "on hold or denied" while the prescribing physician confirmed the purpose of the prescription, forcing her to go without her prescription for 3 days and causing a painful inflammatory arthritis flare up in the interim).
[32] Rebecca Flood, *Anger as Woman Denied 'Abortifacient' Medication After Roe v. Wade Ruling*, NEWSWEEK, July 4, 2022 (11:13 AM), https://www.newsweek.com/anger-woman-denied-abortifacient-medication-roe-v-wade-abortion-1721428; Sharp, *supra* note 15.
[33] 573 U.S. 682 (2014).
[34] Liz Plank, *Abortion Bans are Stopping These Women from Getting Medication for their Chronic Illness*, MSNBC, July 11, 2022 (4:53 PM), https://www.msnbc.com/opinion/msnbc-

opinion/post-roe-abortions-aren-t-only-healthcare-being-denied-women-n1296928.
[35] *See, e.g.*, *id.* (discussing barriers in Maryland); Adrianna Hopkins, *How abortion bans are affecting access to treatments for chronic illnesses*, ABC 15 News, July 21, 2022 (10:45 AM), https://wpde.coinm/news/nation-world/how-abortion-bans-are-affecting-access-to-treatments-for-chronic-illnesses-methotrexate-medication-department-of-health-and-human-services-secretary-xavier-becerra-supreme-court-overturning-roe-v-wade-1973-decision (discussing barriers in Virginia); Rose Horowitch, *State Abortion Bans Prevent Women from Getting Essential Medication*, REUTERS, July 14, 2022 (9:07 PM EDT), https://www.reuters.com/world/us/state-abortion-bans-prevent-women-getting-essential-medication-2022-07-14/ (discussing barriers in Missouri); Jalal, *supra* note 31 (discussing barriers in Tennessee); Giulia Carbonaro, *Arizona Teen Denied Lifesaving Medication Due to State's Abortion Ban*, NEWSWEEK, Oct. 3, 2022 (4:26 AM), https://www.newsweek.com/arizona-teen-denied-life-saving-medication-state-abortion-ban-1748264 (discussing barriers in Arizona); Complaint at 4, Tara Rule v. Jonathan Braiman et al., No. 1:2023cv01218 (N.D.N.Y. 2023) (on file with author) (discussing barriers in New York State).
[36] *See, e.g.*, Sharp, *supra* note 15; Carbonaro, *supra* note 35; Complaint at 4, *supra* note 35.
[37] *Id.*
[38] Plank, *supra* note 34; Ellen Matloff, *One Year After Dobbs Decision, Women Blocked from Meds for Conditions Unrelated to Abortion*, FORBES, June 23, 2023 (12:08 PM), https://www.forbes.com/sites/ellenmatloff/2023/06/23/one-year-after-dobbs-decision-women-blocked-from-meds-for-conditions-unrelated-to-abortion/; Email from Myisha Malone-King, Patient Advocate, to Madeline Morcelle, Senior Attorney, Nat'l Health Law Prog., (Oct. 9, 2024, 06:18 ET) (on file with author).
[39] Katie Shepherd & Frances Stead Sellers, *Abortion Bans Complicate Access To Drugs For Cancer, Arthritis, Even Ulcers*, WASH. POST, Aug. 8, 2022 (11:10 AM), https://www.washingtonpost.com/health/2022/08/08/abortion-bans-methotrexate-mifepristone-rheumatoid-arthritis/?utm_source=substack&utm_medium=email.
[40] *Id.*; Bethany Dawson, *Woman Describes How She Was Humiliated at a Walgreens as Autoimmune Patients Become Collateral Damage in the U.S. Abortion Crackdown*, BUSINESS INSIDER, July 31, 2022 (8:57 AM EDT), https://www.businessinsider.com/roe-v-wade-autoimmune-patients-collateral-damage-of-abortion-ban-2022-7.
[41] Horowitch, *supra* note 35.
[42] See Jalal, *supra* note 31; Jen Christensen, *Women with Chronic Conditions Struggle to Find Medications After Abortion Laws Limit Access*, CNN, July, 22, 2022 (7:11 AM EDT), https://www.cnn.com/2022/07/22/health/abortion-law-medications-methotrexate/index.html (explaining that Dr. Mehret Birru Talabi, a rheumatologist and assistant professor at the University at Pittsburg, has heard from a number of patients unable to get refills of medications such as methotrexate that can end pregnancies or cause congenital disabilities, and that this is "really a travesty, because some of these patients have diseases that are well-managed by these particular medications . . . . Just the idea that your reproductive health status might undermine your care and your treatment, even if you're not pregnant—it's really disheartening."); Kylie Cheung, Woman with Severe Chronic Pain Was Denied Medication for Being 'Childbearing Age,' JEZEBEL, Sep. 22, 2022 (6:35 PM), https://jezebel.com/woman-with-severe-chronic-pain-was-denied-medication-fo-1849569187 (describing the case of Tara Rule,

who had already exhausted non-teratogenic prescription drugs for her cluster headaches associated with EDS and was already taking another teratogenic medication when a neurologist refused to prescribe her a teratogenic medication for her cluster headaches); *see* Yang, *supra* note 25; Humira Prices, Coupons, Copay Cards & Patient Assistance, DRUGS.COM, (explaining that Humira, a brand-name alternative to methotrexate, can cost roughly $7,300 a month without insurance) https://www.drugs.com/price-guide/humira (last visited Oct. 7, 2024).

[43] 42 U.S.C. § 18116; Mara Youdelman, Madeline T. Morcelle, Wayne Turner, & Jennifer Lav, Nat'l Health Law Prog., *Questions and Answers on the 2024 Final Rule Addressing Nondiscrimination Protections Under the ACA's Section 1557* 3, 7 (May 9, 2024), https://healthlaw.org/wp-content/uploads/2024/05/1557-Reg-Revision-QA-FINAL-May-8-2024.pdf; 42 U.S.C. § 18116; *see generally* U.S. Dep't of Health & Human Servs., Nondiscrimination in Health Programs and Activities, Final Rule, 89 Fed. Reg. 37522 (May 6, 2024) (hereinafter "2024 § 1557 Final Rule"), https://www.federalregister.gov/documents/2024/05/06/2024-08711/nondiscrimination-in-health-programs-and-activities#:~:text=The%20Department%20of%20Health%20and%20Human%20Services%20(HHS%20or%20the,certain%20health%20programs%20and%20activities.

[44] *Id.* at 3.

[45] 45 C.F.R. § 92.2; 89(88); 89 Fed. Reg. 37655 (explaining that other federal agencies apply § 1557 to recipients of their department's federal financial assistance).

[46] 2024 § 1557 Final Rule, 45 C.F.R. §§ 92.2(a)(2).

[47] 45 C.F.R. § 92.101(a)(2).

[48] 89 Fed. Reg. 37636.

[49] 29 U.S.C. § 794; U.S. Dep't of Health & Human Servs., Nondiscrimination on the Basis of Disability in Programs or Activities Receiving Federal Financial Assistance, 89 Fed. Reg. 40066 (May 9, 2024).

[50] 45 C.F.R. § 84.2(a).

[51] 45 C.F.R. § 84.56.

[52] HHS, HHS Office for Civil Rights Resolves Complaints with CVS and Walgreens to Ensure Timely Access to Medications for Women and Support Persons with Disabilities (June 16, 2023), https://www.hhs.gov/civil-rights/for-providers/compliance-enforcement/agreements/cvs-walgreens/index.html (last visited June 17, 2024).

[53] In September 2023, OCR revised the guidance to clarify that it does not require pharmacies to fill prescriptions for the purpose of abortion. HHS, Guidance to Nation's Retail Pharmacies: Obligations under Federal Civil Rights Laws to Ensure Access to Comprehensive Reproductive Health Care (July 2022), https://www.hhs.gov/about/news/2022/07/13/hhs-issues-guidance-nations-retail-pharmacies-clarifying-their-obligations-ensure-access-comprehensive-reproductive-health-care-services.html; HHS, Guidance to Nation's Retail Pharmacies under Federal Civil Rights Laws to Ensure Nondiscriminatory Access to Health Care at Pharmacies (Sep. 2023), https://www.hhs.gov/civil-rights/for-individuals/special-topics/reproductive-healthcare/pharmacies-guidance/index.html.

[54] *See* HHS, *supra* note 53.

[55] HHS, How to File a Civil Rights Complaint (Nov. 2, 2020), https://www.hhs.gov/civil-

rights/filing-a-complaint/complaint-process/index.html (last visited June 17, 2024).
[56] CMS, July 2024 Medicaid & CHIP Enrollment Data Highlights, https://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-enrollment-data/report-highlights/index.html (last visited Nov. 4, 2024).
[57] 42 U.S.C. § 1396r-8(d)(1)(B)(i); CMS, Prescription Drugs, https://www.medicaid.gov/medicaid/prescription-drugs/index.html (last visited Apr. 1, 2024).
[58] *Id.* § 1396r-8(k)(6) (a medically accepted indication is: (1) any covered outpatient drug approved by the FDA under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.); or (2) an off-label use supported by one or more citations included or approved for inclusion in the American Hospital Formulary Service Drug Information; United States Pharmacopeia-Drug Information; and DRUGDEX Information System compendia, though United States Pharmacopeia-Drug Information is no longer in service).
[59] 21 C.F.R. § 201.56(d)(1).
[60] Abbi Coursolle, Nat'l Health Law Prog., *More Transparency Needed to Ensure Medicaid Beneficiaries Have Access to Necessary Off-Label Prescription Drugs* 1 (Apr. 7, 2022), https://healthlaw.org/resource/more-transparency-needed-to-ensure-medicaid-beneficiaries-have-access-to-necessary-off-label-prescription-drugs/.
[61] *Id.*
[62] HHS Nat'l Inst's of Health, NIH Inclusion Outreach Toolkit: How to Engage, Recruit, and Retain Women in Clinical Research, https://orwh.od.nih.gov/toolkit/recruitment/history (Apr. 11, 2024).
[63] HHS Office on Women's Health, Policy of Inclusion of Women in Clinical Trials, https://www.womenshealth.gov/30-achievements/04 (last visited Apr. 11, 2024).
[64] *Id.*; NIH Revitalization Act of 1993 (Public Law 103-43).
[65] *See* HHS Office on Women's Health*, supra* note 63.
[66] 21st Century Cures Act (Public Law 114-255).
[67] *See generally*, The White House, The White House Initiative on Women's Health Research, https://www.whitehouse.gov/womenshealthresearch/ (last visited Aug. 8, 2024).
[68] President Joseph Biden, Executive Order on Advancing Women's Health Research and Innovation, Mar. 18, 2024, https://www.whitehouse.gov/briefing-room/presidential-actions/2024/03/18/executive-order-on-advancing-womens-health-research-and-innovation/.
[69] *See, e.g.*, World Health Org., Endometriosis, https://www.who.int/news-room/fact-sheets/detail/endometriosis (last visited Apr. 11, 2024); Kate M. Bourne et al., *Symptom Presentation and Access to Medical Care in Patients with Postural Orthostatic Tachycardia Syndrome: Role of Sex*, 3(12) CJC Open S44–S52 (Dec. 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8712580/ (stating that more than 85% of POTS patients are women); Joanne C. Demmler et al., *Diagnosed Prevalence of Ehlers-Danlos Syndrome and Hypermobility Spectrum Disorder in Wales, UK: a National Electronic Cohort Study and Case-Control Comparison*, 9(11) BMJ Open e031365 (2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6858200/.
[70] *See* Coursolle, *supra* note 60, at 2.
[71] Dysautonomia Internat'l, 10 Facts Doctors Should Know About POTS, https://www.dysautonomiainternational.org/page.php?ID=180 (last visited Apr. 10, 2024) (explaining that POTS affects 1–3 million people in the U.S.); The Ehlers-Danlos Society, Are

the Ehlers-Danlos Syndromes and Hypermobility Spectrum Disorders Rare or Common?, https://www.ehlers-danlos.com/is-eds-rare-or-common/ (last visited Apr. 10, 2024) (discussing how hypermobile EDS and hypermobility spectrum disorder are not rare and that prevalence figures are likely underestimates due to underdiagnoses).
[72] Madeline T. Morcelle, Nat'l Health Law Prog., *How the Proposed Section 1557 Rule Addresses Discrimination Based on Sex Stereotypes* (Sep. 27, 2022), https://healthlaw.org/how-the-proposed-section-1557-rule-addresses-discrimination-based-on-sex-stereotypes-2/.
[73] *See* Rebecca S. Steinberg et al., *Narrative Review of Postural Orthostatic Tachycardia Syndrome: Associated Conditions and Management Strategies*, 17(13) U.S. CARDIOLOGY REV. (2023), https://www.uscjournal.com/articles/narrative-review-postural-orthostatic-tachycardia-syndrome-associated-conditions-and.
[74] *See* Coursolle, *supra* note 60, at 2.
[75] *Id.*
[76] HHS Agency for Healthcare Res. & Qual., *Off-Label Drugs: What You Need to Know*, https://www.ahrq.gov/patients-consumers/patient-involvement/off-label-drug-usage.html (last visited Apr. 11, 2024).
[77] 42 U.S.C. § 1396r-8(k)(6); Coursolle, *supra* note 60, at 3.
[78] *Id.*
[79] *Id.*
[80] *Id.* at 4; *see e.g.*, AHFS-DI, AHFS Clinical Drug Information, https://www.ahfsdruginformation.com/ahfs-clinical-drug-information/ (last visited Apr. 11, 2024) (stating that a one year, single user subscription starts at $90).
[81] *Id.*
[82] *Edmonds v. Levine*, 417 F. Supp. 2d 1323, 1325 (S.D. Fla. 2006).
[83] *Dobson v. Sect'y Health & Hum. Servs.*, No. 20-11996, 2022 WL 424813 at *1 (Feb. 11, 2022 11th Cir.).
[84] *See, e.g.*, Lisa M. Potter et al., *Transplant Recipients are Vulnerable to Coverage Denial Under Medicare Part D*, 18 Am. J. Transplantation 1502, 1502 (2018) (finding that there is "a substantial gap between what is considered standard of care for transplant recipients" and the uses listed in the compendia); Coursolle, *supra* note 60, at 7.
[85] Rachel K. Jones, Guttmacher Inst., *Beyond Birth Control: The Overlooked Benefits of Oral Contraceptive Pills* 3 (Nov. 2011), https://www.guttmacher.org/sites/default/files/pdfs/pubs/Beyond-Birth-Control.pdf.
[86] Call with Christina Piecora, Senior Policy Analyst, Nat'l Health Law Prog. (April 2, 2024) (discussing how these compendia gaps are particularly troublesome for people who have had a partial or full hysterectomy and can no longer become pregnant).
[87] *See, e.g.*, *id.* (estimating that 4%, or 448,000, of the 11.2 million U.S. women aged 15-44 used oral contraceptive pill from 2006–2008); World Health Organization, Endometriosis (Mar. 24, 2023), https://www.who.int/news-room/fact-sheets/detail/endometriosis (last visited Aug. 8, 2024).
[88] *See, e.g.*, Giovanni Grandi et al., *Hormonal Contraception in women with Endometriosis: a Systematic Review*, 24(1) EUR. CONTRACEPT. REPRO. HEALTH CARE 61 (2019), https://pubmed.ncbi.nlm.nih.gov/30664383/; Kevin Cooper et al., *Long Acting Progestogens*

Versus Combined Oral Contraceptive Pill for Preventing Recurrence of Endometriosis Related Pain: the PRE-EMPT Pragmatic, Parallel Group, Open Label, Randomised Control Trial, BMJ (May 2024) https://www.bmj.com/content/385/bmj-2023-079006.

[89] Angela Marie C. Hernandez & Jennifer E. Dietrich, *Gynecological Management of Pediatric and Adolescent Patients with Ehlers-Danlos Syndrome*, 33(3) J. PEDIATRIC & ADOLESCENT GYN. 291 (June 2020), https://www.sciencedirect.com/science/article/abs/pii/S1083318819303808.

[90] *See, e.g.*, Kiffany J. Peggs et al., *Gynecologic Disorders and Menstrual Cycle Lightheadedness in Postural Tachycardia Syndrome*, 118(3) INT. J. GYN. OBSTET. 242 (June 2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3413773/; emails from Dr. Jeffrey Boris, M.D. to Madeline Morcelle, Senior Attorney, Nat'l Health Law Prog. (Apr. 11, 2024, 11:00 and 11:19 EDT) (on file with author) (sharing unpublished research findings that POTS patients assigned female at birth have more symptoms, more severity, and longer symptomatology than patients assigned male at birth and that the vast majority have a worsening of symptoms in the 10 days prior to or 5 days during their menses. Further, indicating that Dr. Boris has seen some patients improve POTS symptoms during menses using hormonal contraceptives).

[91] Michelle Lilienfield, Nat'l Health Law Prog., *Medicaid Outpatient Prescription Drugs* 2 (Nov. 2016), https://healthlaw.org/resource/fact-sheet-medicaid-outpatient-prescription-drugs/.

[92] 42 U.S.C. § 1396r-8(g)(3)(A).

[93] 42 U.S.C. § 1386r-8(d)(6). 42 U.S.C. §§ 1396r-8(d)(1)(B), (k)(6).

[94] *See* Coursolle, *supra* note 60, at 8.

[95] Lilienfield, *supra* note 91, at 4.

[96] See U.S. Const., amend. XIV, § 1; *see generally*, Bd. of Regents v. Roth, 408 U.S. 564, 577 (1972); Goldberg v. Kelly, 397 U.S. 254 (1970) (holding that when welfare benefits are terminated, a beneficiary has due process rights to an effective notice and pre-termination hearing).

[97] 42 C.F.R. §§ 431.200(b) (fee-for-service), 438.400(b) (managed care).

[98] 42 C.F.R. §§ 431.210 (fee-for-service), 438.404(b) (managed care); CMS State Medicaid Manual, § 2900.3, available at https://www.cms.gov/Regulations-and-Guidance/guidance/Manuals/Paper-Based-Manuals-Items/CMS021927.html; *see* Kim Lewis et al., Nat'l Health Law Prog., *What Makes Medicaid, Medicaid? Consumer Protections and Due Process*, 16 (2023), https://healthlaw.org/wp-content/uploads/2023/04/Protect-Medicaid-Series-Due-Process-FINAL.pdf (explaining the circumstances in which aid paid pending is available, and clarifying that this protection is unavailable if the sole issue at the hearing is a change in federal or state law policy).

[99] 42 C.F.R. §§ 431.211 (fee-for-service), 438.404 (managed care), 438.420 (managed care).

[100] 42 C.F.R. § 431.221 (explaining that this request can be submitted via internet, phone, mail, in person, or through other commonly available electronic means, but the agency can require that the request be in writing).

[101] A state abortion ban would not trigger such an automatic change in coverage for drugs that can induce abortions, as these drugs can be used for other purposes, such as to treat chronic conditions. Thus, individuals in the state who experience coverage denials have a right to a fair hearing. 42 C.F.R. § 431.220(b).

[102] 42 C.F.R. § 431.242.

[103] 42 C.F.R. § 431.240.
[104] CMS State Medicaid Manual, § 2902.9, https://www.cms.gov/Regulations-and-Guidance/guidance/Manuals/Paper-Based-Manuals-Items/CMS021927.html.
[105] *Id.*
[106] *Id.*
[107] 42 C.F.R. § 431.224(a); *see also* Lewis, *supra* note 98, at 15.
[108] 42 U.S.C. § 1983; *see generally* Jane Perkins, Nat'l Health Law Prog., *Private Enforcement of the Medicaid Act* (Apr. 12, 2024), https://healthlaw.org/resource/private-enforcement-of-the-medicaid-act-pursuant-to-42-usc-1983/.
[109] A Qualified Health Plan is one that is certified by the Health Insurance Marketplace and must meet EHB and other requirements. *See, e.g.*, Wayne Turner, Nat'l Health Law Prog., *Essential Health Benefits Prescription Drug Standard—Formulary Transparency* (May 2015), https://healthlaw.org/resource/ehb-prescription-drug-standard-formulary-transparency/. The ACA has separate preventive services requirements for health insurance across all markets—individual, small group, large group, and self-insured plans. ACA § 1001 (adding § 2713 of the Public Health Services Act) (codified at 42 U.S.C. § 300gg-13(a)). Non-grandfathered plans are required to cover, without cost-sharing, the full range of FDA-approved contraceptive services and supplies. 42 U.S.C. § 300gg–13. This requirement was incorporated into § 715 of the Employee Retirement Income Security Act and applies to many employer-sponsored plans.
[110] See 42 U.S.C. §§ 300gg–6(a), 300gg–13(a)(4); 45 C.F.R. § 147.150; *see also* 29 C.F.R.§ 2590.715-1251(c)(1); CMS, Alternative Benefit Plan Eligibility, https://www.medicaid.gov/medicaid/benefits/alternative-benefit-plans/alternative-benefit-plan-eligibility/index.html (last visited Apr. 11, 2024).
[111] 45 C.F.R. §§ 156.130; 147.130 (describing prohibition on cost-sharing for preventive services); CMS, Dear State Medicaid Director Letter from Vikki Wachino, Director, Center for Medicaid and CHIP Services, to State Health Officials and State Medicaid Directors (SHO # 16-008) 3 (Jun. 14, 2016), https://www.medicaid.gov/federal-policy-guidance/downloads/sho16008.pdf (guidance on Medicaid family planning services and supplies).
[112] 45 C.F.R. § 156.122(a)(1). Nat'l Health Law Prog., *Comments on US Pharmacopeia Drug Classification Update Draft for 2024* 5 (Sep. 2023), https://healthlaw.org/resource/nhelp-comments-on-us-pharmacopeia-drug-classification-update-draft-for-2024/ (explaining that we anticipate that the USP Drug Classification 2025 (USP DC) will eventually supplant the USP Medicare Model Guidelines classification system for purposes of EHB prescription drug coverage determinations).
[113] Some states have enacted "off-label use" laws or regulations to address this situation, but others have not. *See, e.g.*, 39 Oh. Rev. Code § 3923.60.
[114] *Id.* at 1.
[115] *Id.* at 2–3. While the USP DC currently maintains some of the relics of the USP MMG classification system, including its exclusion of a significant number of sexual and reproductive health-related prescription drugs such as contraceptives and medication abortion, unlike the USP MMG, it is updated annually, offering stakeholders more opportunities to shape reforms. Moreover, advocates should note that EHBs must cover a broad range of contraceptives, as delineated by the Health Resources Administration Women's Preventive Services Guidelines.

However, should CMS make a drug classification system the standard for QHP contraceptive coverage in the future, both the current USP MMC and USP DC classification systems would be woefully inadequate.

[116] 45 C.F.R. § 156.122(a)(3); *see also* Wayne Turner, Nat'l Health Law Prog., *Essential Health Benefits Prescription Drug Standard—Pharmacy and Therapeutics Committees* 4–5 (Jul. 2015), https://healthlaw.org/resource/ehb-prescription-drug-standard-formulary-transparency/.

[117] 45 C.F.R. § 147.106(e).

[118] *See, e.g.*, Turner, *supra* note 109.

[119] The public must be able to view this list on the plan's public website through a clearly identifiable link or tab without requiring an individual to create or access an account or enter a policy number. Moreover, if an issuer offers more than one plan, the public must be able to easily discern which formulary drug list applies to which plan. QHPs in the federally facilitated marketplace must make this information available on its website in a HHS-specified format and also submit this information to HHS. 45 C.F.R. § 156.122(d).

[120] 45 C.F.R. § 156.122(c); Michelle Lilienfeld, Nat'l Health Law Prog., *EHB Prescription Drug Standard—Exemptions Process* (May 2015), https://healthlaw.org/resource/ehb-prescription-drug-standard-exceptions-process/.

[121] In these cases, the QHP must notify the enrollee of the coverage determination no more than 24 hours after receipt of the request and must provide coverage for the duration of the exigency. 45 C.F.R. §§ 156.122(c)(1)(i), (iii).

[122] 45 C.F.R. §§ 156.122(c)(3)–(4).

[123] *Id.*

[124] 45 C.F.R. § 156.122(c)(4).

[125] U.S. Dep't of Health & Human Servs., Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2025; Updating Section 1332 Waiver Public Notice Procedures; Medicaid; Consumer Operated and Oriented Plan (CO-OP) Program; and Basic Health Program, 89 Fed. Reg. 26218 (Apr. 15, 2024), https://www.federalregister.gov/documents/2024/04/15/2024-07274/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2025.

[126] 45 C.F.R. § 156.122(a)(3)(i)(E).

[127] 42 U.S.C. §§ 300gg–13(a)(4), 18011.

[128] 45 C.F.R. §§ 147.130(a)(1)(iv), 147.133.

[129] Liz McCaman Taylor, Nat'l Health Law Prog., *Contraceptive Equity in Action: A Toolkit for State Implementation* 6 (July 16, 2019), https://healthlaw.org/resource/contraceptive-equity-in-action-a-toolkit-for-state-implementation/.

[130] *Id.* at 13.

[131] *See, e.g.*, C.T. Gen. Stat. § 38a-503e(e) (2023), https://www.cga.ct.gov/current/pub/chap_700c.htm#sec_38a-503e; N.Y. Ins. L. 3221(16)(G) (2019), https://www.nysenate.gov/legislation/laws/ISC/3221; 32 Mass. Gen. Law. Ann. 28. (2017), https://malegislature.gov/Laws/GeneralLaws/PartI/TitleIV/Chapter32A/Section28.

[132] *See* 32 Mass. Gen. Law. Ann. 28.

[133] For NHeLP's compendium of resources on contraceptive equity laws, including our state contraceptive equity law tracker, *see* Nat'l Health Law Prog., Contraceptive Equity, https://healthlaw.org/contraceptive-equity/ (last visited Oct. 8, 2024).

[134] NAIC, Consumer, https://content.naic.org/consumer (last visited Apr. 11, 2024).
[135] Of note, some states also use DrugPoints as a replacement for the United States Pharmacopeia—Drug Information, which is no longer in service.
[136] FDA, Highlights of Prescribing Information for Methotrexate, https://www.accessdata.fda.gov/spl/data/666230f1-6a5f-43cc-9e9c-7fdb2d8980fc/666230f1-6a5f-43cc-9e9c-7fdb2d8980fc.xml (last visited July 25, 2024).
[137] AHFS Drug Information Compendium, Methotrexate, Methotrexate Sodium (last visited May 29, 2024) (on file with author).
[138] The compendia do not include efficacy notes for some drug uses.
[139] Thomson Micromedex DrugDex® Compendium, Methotrexate (last visited May 29, 2024) (on file with author).
[140] FDA, Highlights of Prescribing Information for Methotrexate Sodium, https://www.accessdata.fda.gov/spl/data/8dde104c-5e16-4d3b-93ae-2a464e033270/8dde104c-5e16-4d3b-93ae-2a464e033270.xml (last visited July 25, 2024).
[141] AHFS Drug Information Compendium, Methotrexate (last visited May 29, 2024) (on file with author).
[142] Thomson Micromedex DrugDex® Compendium, Methotrexate (last visited May 29, 2024) (on file with author).
[143] FDA, Misoprostol Tablets https://www.accessdata.fda.gov/spl/data/fdafd2c5-8c12-4575-a707-bfa7a46cc03c/fdafd2c5-8c12-4575-a707-bfa7a46cc03c.xml (last visited July 25, 2024).
[144] AHFS Drug Information Compendium, Misoprostol (last visited May 29, 2024) (on file with author).
[145] Thomson Micromedex DrugDex® Compendium, for Misoprostol (last visited May 29, 2024) (on file with author).
[146] FDA, *supra* note 22.
[147] FDA, *supra* note 23.
[148] AHFS Drug Information Compendium, Mifepristone (last visited May 29, 2024) (on file with author).
[149] Thomson Micromedex DrugDex® Compendium, Mifepristone (last visited May 29, 2024) (on file with author).
[150] FDA, Highlights of Prescribing Information for Lo Loestrin® Fe https://www.accessdata.fda.gov/spl/data/df0357bd-d2b1-4593-adcc-d8eef3e22260/df0357bd-d2b1-4593-adcc-d8eef3e22260.xml (last visited July 23, 2024).
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