

## Secretary's Report

# HEALTH CARE UNDER ATTACK

An Action Plan to Protect and Strengthen Reproductive Care

A Report Required by Executive Order 14076

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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\* The posted version of the report includes a minor correction, made in November 2022, to avoid confusion.



## MESSAGE FROM SECRETARY

For nearly 50 years, women in America lived in a country that guaranteed them the freedom, privacy, and autonomy to control their own bodies. Women could make decisions on their health care in consultation with their physicians, faith leaders, partners, families or whoever they trusted, without interference from a politician or the government.

On June 24, 2022, the Supreme Court of the United States overturned *Roe v. Wade*, a longstanding precedent, undermining women's privacy, autonomy, health and rights. At the Department of Health and Human Services (HHS), we have been preparing for such a decision for some time.

Earlier this year, on the 49<sup>th</sup> anniversary of *Roe v. Wade*, we launched a Reproductive Healthcare Access Task Force at HHS to plan for every action necessary to protect women's access to reproductive health care in case the unimaginable became a reality. In the time since the Supreme Court ruled in *Dobbs v. Jackson Women's Health*, we have taken several actions to protect Americans' reproductive rights and care:

**Protecting Emergency Medical Care:** HHS <u>issued guidance<sup>1</sup></u> and a <u>letter from Secretary Becerra<sup>2</sup></u> to reaffirm that the Emergency Medical Treatment and Active Labor Act (EMTALA, also known as the Emergency Medical Treatment and Labor Act) protects providers when offering legally-mandated, life- or health-saving abortion services as stabilizing care for emergency medical conditions.<sup>3</sup>

**Safeguarding Information on Health and Rights for Patients and Providers:** HHS <u>launched the</u> <u>ReproductiveRights.gov</u> public awareness website, <sup>4</sup> which includes accurate information about reproductive health, including a Know-Your-Rights patient fact sheet to help patients and providers.

#### Protecting Patients and Providers from Discrimination:

- HHS <u>issued a proposed rule</u> that would strengthen the regulations interpreting the nondiscrimination provision of the Affordable Care Act (ACA) and would reinforce that discrimination on the basis of sex includes discrimination on the basis of pregnancy or related conditions.<sup>5</sup>
- HHS <u>issued guidance</u> to roughly 60,000 U.S. retail pharmacies, clarifying their obligations under federal civil rights laws.<sup>6</sup>

**Protecting Patient Privacy:** HHS <u>issued guidance</u> that clarifies to patients and providers the extent to which federal law and regulations protect individuals' private medical information when seeking abortion and other forms of reproductive health care, as well as when using apps on smartphones.<sup>7</sup>

**Supporting Quality Reproductive Health Care:** HHS <u>announced nearly \$3 million</u> in new funding to bolster training and technical assistance for the nationwide network of Title X family planning providers.<sup>8</sup>

#### **Protecting Access to Birth Control:**



- With the Departments of the Treasury and Labor, <u>we convened a meeting with health insurers</u> <u>and sent them a letter</u>, calling on the industry to commit to meeting their obligations to provide contraceptives as required by the ACA.<sup>9</sup>
- Later, in response to this conversation, <u>we issued guidance to clarify protections for birth control</u> <u>coverage under the ACA</u>.<sup>10</sup> Under the ACA, most private health plans are required to provide birth control and family planning counseling at no additional cost.

This report builds on these efforts and initiatives and outlines an action plan in response to the President's call for us to act. Further, it demonstrates the importance and continued commitment of the Administration in responding to this national crisis.

This is a critical moment in history and how we respond will speak to how we view the rights, dignity, and well-being of women everywhere. Therefore, until the day that the freedom and the autonomy to control their own bodies is afforded to all women in this country once again, we will use every tool at our disposal to protect the reproductive health of women in this country.

Xavier Becerra



## **Executive Summary**

On June 24, 2022, the Supreme Court of the United States upended decades of precedent and wellestablished reproductive and privacy rights when it overturned the constitutional right to safe and legal abortion care recognized by *Roe v. Wade* and *Planned Parenthood v. Casey*.

On July 8, 2022, President Biden issued Executive Order 14076, "<u>Executive Order on Protecting Access to</u> <u>Reproductive Healthcare Services</u>," which among other things, requires the Secretary of Health and Human Services (HHS) to submit a report to the President identifying a plan and supporting actions to:

- Protect and expand access to the full range of reproductive health care, including abortion care;
- Increase outreach and education about access to reproductive health care services, including by launching a public awareness initiative; and
- Ensure all patients receive the full protections for emergency medical care afforded under the law.<sup>11</sup>

On August 3, 2022, President Biden issued Executive Order 14079, "<u>Securing Access to Reproductive and</u> <u>Other Healthcare Services</u>," which applauded the work already in progress by HHS and directed it to:

- Consider additional actions to advance access to reproductive health care services, including through Medicaid for patients traveling out of state for medical care;
- Consider all appropriate actions to ensure health care providers that receive federal financial assistance comply with federal non-discrimination law; and
- Evaluate the adequacy of current interagency data collection and analysis on the effect of access to reproductive healthcare on maternal health outcomes and take actions to improve these efforts.<sup>12</sup>

This report responds to these Executive Orders and outlines actions to protect and expand access to abortion care and other reproductive health care nationwide. It also includes an overview of the historical and legal context relevant to the Executive Orders and current and potential HHS actions to: (a) protect and expand access to abortion care and the full range of reproductive health care services; (b) bolster outreach and education about access to reproductive health care, including medication abortion and contraception; and (c) ensure women, pregnant individuals, and those experiencing pregnancy loss receive the full protections available under federal law with regards to emergency medical care.

In response to the Supreme Court's *Dobbs v. Jackson Women's Health* decision, Secretary Becerra directed HHS to take immediate action to help people across the country as they face this harsh new reality of restricted health care and rights.<sup>13</sup> As a result, HHS took swift, concrete actions to protect access to reproductive health care, consistent with the Administration's priorities.

In the weeks and months to come, access to reproductive health care will continue to face new attacks, in addition to ongoing challenges. Because of the *Dobbs* decision, access to reproductive health care services now depends on where an individual lives to an even greater extent than it did before. The United



States of America has an expanding patchwork of laws, wherein some states criminalize health care providers and others for providing or facilitating medical care—sometimes without meaningful exceptions for the life or health of the woman, or when the pregnancy is a result of rape or incest. Some states and localities have expressed their intention to have prosecutors enforce restrictions against women, health care providers, and others. Further, health care providers in many jurisdictions are facing potential criminal and civil liability as well as loss of licensure for providing necessary abortion related services.

Additional efforts are underway that imperil other basic health care and rights. There have been numerous reports of women denied health- and life-saving emergency care, as providers fearful of legal reprisal delay necessary treatment for patients until their conditions worsen to dangerous levels. There are also reports of women of reproductive age being denied prescription medication at pharmacies— including medication that is used to treat stomach ulcers, lupus, arthritis, and cancer—due to concerns that these medications, some of which can be used in medication abortions, could be used to terminate a pregnancy. Bans and limits are being considered on access to birth control care, including emergency contraception.

This new reality will only worsen health outcomes for women and families, especially individuals who are already underserved in our health care system, including women of color, working families, people with disabilities, and LGBTQI+ patients. The Supreme Court's *Dobbs* decision also renders the United States an outlier globally, putting our nation on a short list of countries seeking to restrict, rather than expand, access to sexual and reproductive health care.<sup>14</sup>

Now, more than ever, the federal government needs to play a critical role helping to ensure access to reproductive health care, including by creating safeguards for providers and patients. HHS will continue to use its authority to protect access to care, including abortion care, and enforce federal law when women's rights to care are violated.



## Introduction

On June 24, 2022, the Supreme Court of the United States eliminated the constitutional right to an abortion in its ruling on *Dobbs v. Jackson Women's Health*, reversing a nearly 50-year precedent established by *Roe v. Wade* and subsequently reaffirmed in *Planned Parenthood v. Casey*—and with it, decades of accepted law. At the time of the *Dobbs* ruling, thirteen states had laws in place to ban abortion under varying circumstances in the event that *Roe v. Wade* and *Planned Parenthood v. Casey* were overturned. Several other states are considering laws to ban or further restrict abortion access in the near future.

The Supreme Court's *Dobbs* ruling and state actions to ban health care have already had dire consequences for women across the country. These restrictions will exacerbate preexisting inequities and worsen maternal health outcomes and fuel a national public health crisis with negative effects on how women access and receive care. These impacts will be felt most acutely by underserved communities, including those with low incomes and people of color. The decision is also an assault on patient privacy and bodily autonomy, with broader implications for the freedoms millions of Americans hold dear. Further, for those states and localities that intend to have prosecutors enforce restrictions against women and others who facilitate their access to health care, this may exacerbate existing disparities in the criminal justice system broadly.

It is well established that both medication and surgical abortions are safe and effective.

There have been several studies examining the impact of abortion on the health and well-being of women. For instance, the National Academies of Science, Engineering, and Medicine (NASEM) conducted a comprehensive review of the literature on the physical and mental health implications of abortion and found consistent, high-quality evidence that, contrary to certain misconceptions, abortion does not increase the risk of breast cancer, secondary infertility, pregnancy-related hypertensive disorders, preterm birth, depression, anxiety, posttraumatic stress disorder, or other mental health harms. Given strong evidence from numerous studies showing that lower socioeconomic status is associated with shorter life expectancy and various forms of morbidity including worse mental health,<sup>15,16,17,18,19</sup> lack of access to abortion may lead to compounding adverse health effects in the future.

This report makes recommendations on actions to help protect access to abortion care, as well as broader reproductive health care services, in the wake of the *Dobbs* decision.



## **SECTION 1. Access to Medication Abortion and Contraception**

## **Abortion Care**

#### Medication Abortion Background:

The use of medication abortion is becoming increasingly common and may help preserve access for women seeking abortions in certain circumstances who may otherwise not have access. The regulatory history of mifepristone, the FDA-approved product for medication abortion, spans more than two decades. On September 28, 2000, FDA approved Mifeprex (mifepristone, 200 mg), in a regimen with another drug (misoprostol), as safe and effective for the medical termination of early pregnancy through seven weeks gestation; and that approval was extended through ten weeks gestation in 2016.<sup>20</sup> Misoprostol is also sometimes prescribed by providers to help women experiencing miscarriages.

### Enforcement Discretion on the REMS—COVID-19

The Mifepristone Risk Evaluation and Mitigation Strategy (REMS) Program currently requires, among other things, that the product be dispensed in-person by a certified prescriber in certain types of health care settings, as well as the use of a Patient Agreement Form.<sup>21</sup>

In April 2021, FDA communicated that, provided all other requirements of the Mifepristone REMS Program are met, the Agency was exercising its enforcement discretion to not pursue violations of the inperson dispensing requirement of the Mifepristone REMS Program during the COVID-19 public health emergency (PHE), including any in-person requirements that may be related to the Patient Agreement Form. The COVID-19 PHE is ongoing, and thus FDA intends to continue to exercise its enforcement discretion in this manner. As a result, pharmacies are dispensing mifepristone to patients by mail on behalf of certified health care prescribers who have purchased the product.

FDA has also undertaken a full review of the Mifepristone REMS Program and has determined that the inperson dispensing requirement is no longer necessary to assure the safe use of mifepristone for medical termination of early pregnancy, provided all the other requirements of the REMS continue to be met and that dispensing pharmacies are certified. **HHS will continue its work to protect access to FDA-regulated products for abortion that have been found to be safe and effective.** 

#### Initiation of the REMS Modification Process

On December 16, 2021, FDA sent REMS modification notification letters to the applicants for Mifeprex and the approved generic version of Mifeprex, Mifepristone Tablets 200 mg, subject to the standard process for this type of REMS modification.<sup>22</sup> In response to these letters, the applicants prepared proposals to modify the REMS and submitted them to FDA. FDA is currently reviewing these REMS modifications. If the REMS modification submissions are approved, the REMS modifications will become effective. Should the submissions be approved consistent with the December 2021 letters to the applicants, people seeking medication abortion will continue to have access to Mifeprex and the approved generic version without in-person dispensing via mail-order pharmacy once the COVID-19 PHE is over.



FDA will continue the REMS modification process and review the applicants' proposed changes to the REMS related to removing the in-person dispensing requirement.

### Federal Preemption—Protecting Access to Medication Abortion

The Attorney General of the United States made clear that states may not ban mifepristone based on disagreement with FDA's expert judgment about its safety and efficacy.<sup>23</sup> HHS is working with the U.S. Department of Justice (DOJ) to help ensure access to care and preserve FDA's role in determining what is safe and effective for patients.

## **Coverage of Abortion Services**

### The Hyde Amendment

The Hyde Amendment permits use of federal funds for abortions only in limited circumstances: when the pregnancy is the result of rape or incest, or when the woman suffers from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself that would place the woman in danger of death unless an abortion is performed. The Hyde Amendment applies to federal funds in programs and activities across HHS, including Medicaid, Medicare, the Children's Health Insurance Program, and others.<sup>24,25</sup>

In the wake of the *Dobbs* decision, the Centers for Medicare and Medicaid Services (CMS) continues to evaluate the impact of Hyde restrictions on coverage and further steps to expand care. To that end, the Centers for Medicare & Medicaid Services (CMS) continues to evaluate the effect of *Dobbs* and will work to ensure states provide reproductive health care in federally funded programs, consistent with applicable Hyde Amendment restrictions.

The Hyde Amendment disproportionately impacts access to abortion for low-income communities, people of color, and people with disabilities nationwide for whom Medicaid is the primary source of coverage for health care.<sup>26, 27</sup>

CMS will work with states to advance access to reproductive health care, including to the extent permitted by federal law, through Medicaid for patients traveling across state lines for medical care consistent with President Biden's Executive Order 14079. It took a first step on this action in releasing a letter to states, inviting them to work with HHS on Medicaid waivers to increase access to reproductive health care within the legal limits of the Medicaid Act.

## Federal Protections for Family Planning and Birth Control Care

#### Reproductive Health Care Coverage—Private Market and Medicaid

#### Private Market

The Affordable Care Act (ACA) helps make prevention services affordable and accessible for all Americans by requiring most employer health plans and other health insurance plans to provide coverage to their enrollees for certain recommended preventive services at no additional cost. A recent HHS report



estimated that more than 58 million women were benefiting from these provisions.<sup>28</sup> The recommended preventive services include preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration (HRSA). The Women's Preventive Services Initiative reviews and recommends updates to the guidelines, including contraception and contraceptive counseling. The guidelines were last updated in December of 2021, effective for plan years starting on or after December 30, 2022, and are reviewed on an annual basis.<sup>29</sup>

Following President Biden's July 2022 Executive Order on ensuring access to reproductive health care, HHS, alongside the Departments of Labor and of the Treasury (the Departments), released <u>guidance</u> to clarify protections for birth control coverage under the ACA.<sup>30</sup> Under the ACA, most private health plans are required to provide coverage of birth control and family planning counseling at no additional cost. This guidance followed action in June, when the three Departments sent a <u>letter</u> to health insurers and employer health plan organizations,<sup>31</sup> and the Departments convened a meeting with them, calling on the industry to commit to meeting their obligations to provide coverage for contraceptive services at no additional cost as required by the ACA. **HHS will enforce the law to ensure access to birth control coverage under the ACA and continue to work to ensure that patients understand their coverage rights.** 

#### Medicaid

Medicaid plays a critical role in helping to ensure access to reproductive health care for the populations it serves, including women's preventive care, family planning, and pregnancy-related care such as prenatal care, childbirth, and postpartum care. Nearly all women use some form of family planning during their reproductive years, and Medicaid is the largest source of public funding for family planning services nationally.<sup>32</sup> The mandatory Medicaid family planning benefit provides coverage for services and supplies to prevent or delay pregnancy and may include education and counseling in the method of contraception desired or currently in use by the individual, a medical visit to change the method of contraception, and infertility treatment. States receive an enhanced federal matching rate of 90 percent for expenditures for family planning services and supplies. **CMS will continue to work with states to expand access to reproductive health care**.

## Federal Family Planning Programs – Title X, Community Health Centers and More

The Office of the Assistant Secretary for Health runs the Title X program, which supports high-quality, family planning services, and preventive care including breast and cervical cancer screening, contraceptive counseling and care, sexually transmitted infection testing and treatment, and HIV screening. In October 2021, HHS issued a final rule to strengthen the nation's family planning program with nationally recognized standards of care. Subsequently, HHS awarded more than \$270 million to support family planning service delivery, and more than \$16 million to support telehealth enhancement and expansion. A critical part of this was funding released in Fall 2021 to help clinics in dire need as a result of the Texas abortion ban, SB 8. This funding went to support clinics in eight states. **HHS is considering other grants to help with training and capacity for clinics on sexual and reproductive health and will make family planning care a priority in its programs and services, as well as considering options to make family planning a specific condition for certain grants.** 

As a result of state abortion bans, abortion providers are closing their doors and patients are at risk of losing access to providers they trust and the care they need. On June 29, 2022, HHS further issued guidance to clinics, providers, others on how Title X projects can support pregnant clients and use funds to respond to changing reproductive health care needs. **HHS is evaluating the opportunity to provide** 



grants to clinics to support patient navigation and ongoing clinic stability in underserved areas that may face closure from revenue losses and state bans. Further, HHS will continue to work to make more funding available under the Title X program to help clinics with capacity limitations and support increased needs in providing Title X services to patients who travel from states where clinics have closed due to bans on abortion. HHS has also made clear to Congress that more funding is needed for the Title X program given the capacity issues in both states with bans and those without restrictions on reproductive health care.

In addition to helping clinics navigate the post-*Dobbs* reality, **HHS** is also working to support more training and resources to help providers build capacity and expertise as the need for family planning care and patient information continues to grow. HRSA plans an initiative for the fall of 2022 to increase capacity for recipients of the Ryan White HIV/AIDS Program to implement evidence-informed interventions and promising strategies around reproductive health care needs for people with HIV. This will include preventive screenings, education (including pre-conception counseling), family planning, and other reproductive health care needs for people with HIV, as well as post-natal care. CDC serves as a source of clinical guidance for health care providers and provides evidence-based guidance to reduce medical barriers to contraception access and use.<sup>33</sup> CDC anticipates issuing an updated Contraceptive Guidance for Health Care Providers and has conducted the initial steps for this update—including soliciting public comments and conducting systematic reviews.

HRSA runs our nation's health centers program. These centers provide primary and preventive health services to underserved communities, including family planning services. Services include patient-centered counseling, contraceptive services (including the full range of FDA-approved methods), pregnancy testing and counseling, assistance for patients who want to conceive, basic infertility services and screening for sexually transmitted infections. It is critical that these providers stay up to date on reproductive health care and are able to continue providing services that meet the necessary standard of care. HRSA is in the process of updating its technical assistance guide and HHS will update and expand technical assistance guidance for Title X and community health center providers.



## Section 2: Access to Care Under the Law

## **Nondiscriminatory Access to Healthcare**

Since the *Dobbs* decision, there have been an uptick in cases around the country where people—especially women of reproductive age—have been denied care, including medical care that is not directly related to reproductive health. Such incidents have happened in pharmacies when persons with disabilities seek their prescribed medications, some have impacted women experiencing miscarriages, and others have been the product of confusion from the decision and resulting denials of care.

The Office for Civil Rights (OCR) enforces a range of federal civil rights laws, including Section 1557 of the ACA (Section 1557),<sup>34</sup> which prohibits discrimination based on sex in health programs and activities. Sex discrimination includes discrimination based on current pregnancy, past pregnancy, and related medical conditions.

Section 1557 and Section 504 of the Rehabilitation Act of 1973 (Section 504) prohibits discrimination on the basis of disability by recipients of federal funding, and Title II of the Americans with Disabilities Act prohibits disability discrimination by state and local government entities. Under these laws, a covered entity cannot deny, exclude, or fail to provide an equal opportunity to benefit from a program, service, or activity, including reproductive health care services to people with disabilities. These laws prohibit discrimination in a covered entity's provision of reproductive health care services, and individuals experiencing discrimination in the provision of such care can <u>file complaints</u> with HHS OCR.<sup>35</sup> OCR is actively monitoring cases around the country and will act against entities not following their obligations under federal law. To that end, the Administration for Community Living (ACL) funds <u>Protection and Advocacy Systems</u> in each state that also can provide legal assistance to individuals with disabilities who face barriers in accessing reproductive health care services.<sup>36</sup>

Pharmacies that receive federal financial assistance are covered entities under Section 1557 and other federal civil rights laws, including Section 504. On July 13, 2022, OCR released <u>guidance to pharmacies</u> on their obligations under federal civil rights laws to ensure nondiscriminatory access to pharmacy services.<sup>37</sup> The guidance reminds covered pharmacies that they may not discriminate on the grounds prohibited by Section 1557 and Section 504, including with regard to supplying medications; making determinations regarding the suitability of a prescribed medication for a patient; or advising patients about medications and how to take them.

On August 3, 2022, President Biden signed Executive Order 14079 on "Securing Access to Reproductive and Other Healthcare Services," which directed OCR to consider all appropriate actions to advance the prompt understanding of and compliance with nondiscrimination law in obtaining medical care. This includes providing technical assistance to providers, convening providers to increase awareness of the law, and working to promote compliance. **OCR will take further action in response to this Executive Order to promote compliance, including vigorous enforcement of federal civil rights laws.** As part of this important work, **OCR will continue to provide technical assistance to providers on their obligations under federal civil rights law and will convene providers to help ensure providers understand their obligations under federal civil rights laws.** 

On August 4, 2022, OCR published a <u>notice of proposed rulemaking (NPRM) on Section 1557 of the</u> <u>Affordable Care Act</u>.<sup>38</sup> The proposed rule, among other things, implements the statutory prohibition on



discrimination on the basis of sex in federal health programs and activities. The NPRM recognizes discrimination on the basis of pregnancy or related conditions as a form of prohibited sex discrimination and seeks comment on whether the Final Rule should include a stand-alone provision to this effect and what impact, if any, the *Dobbs* decision has on the implementation of Section 1557 and the implementing regulations.

## **Access to Emergency Medical Care**

The Emergency Medical Treatment and Labor Act (EMTALA) requires that all patients who present at an emergency department of a hospital that receives Medicare funds and who request examination or treatment shall receive an appropriate medical screening examination, stabilizing treatment, and transfer if necessary, irrespective of any directly conflicting state laws or mandates. CMS released guidance on September 17, 2021, and again on July 11, 2022, emphasizing that under EMTALA, a health care provider has a legal duty to provide stabilizing medical treatment to a patient who presents to the emergency department and is found to have an emergency medical condition, and that requirement preempts any directly conflicting state law or mandate that might otherwise prohibit such treatment. <sup>39</sup> HHS will continue to make information available to help patients and providers understand this important right and provide technical assistance and information to providers on their obligations under EMTALA.<sup>40</sup>

As indicated in CMS guidance, the determination of an emergency medical condition is the responsibility of the examining physician or other qualified medical personnel. Emergency medical conditions involving pregnant patients may include but are not limited to ectopic pregnancy, complications of pregnancy loss, or emergent hypertensive disorders, such as severe preeclampsia. Any state laws or mandates that employ a more restrictive definition of an emergency medical condition that directly conflicts with the EMTALA definition are preempted by the EMTALA statute to the extent of this conflict.

The course of treatment necessary to stabilize such emergency medical conditions is also under the purview of the physician or other qualified medical personnel. Stabilizing treatment could include medical and/or surgical interventions (e.g., abortion, removal of one or both fallopian tubes, anti-hypertensive therapy, methotrexate therapy, etc.), irrespective of any directly conflicting state laws or mandates.

Thus, if a physician believes that a pregnant patient presenting at an emergency department, including certain labor and delivery departments, is experiencing an emergency medical condition as defined by EMTALA, and that abortion is the stabilizing treatment necessary to resolve the emergency medical condition, the physician must ensure that the patient receives that treatment. And when a state law directly conflicts with EMTALA because it prohibits abortion and does not include an exception for the life and health of the pregnant woman—or draws the exception more narrowly than EMTALA's emergency medical condition definition—that state law is preempted in the area of this direct conflict.

The enforcement of EMTALA is generally a complaint-driven process. **HHS will continue to enforce EMTALA and investigate complaints where consistent with law.** 



## Investigating

CMS investigations of a hospital's policies, procedures and processes, or the actions of medical personnel, are initiated by a complaint. Complaints can be filed in each state. CMS may also open an investigation based on public reports.

## Enforcement

If the results of a complaint investigation indicate that a hospital violated one or more of the provisions of EMTALA, a hospital may be subject to termination of its Medicare provider agreement and/or the imposition of civil monetary penalties. Civil monetary penalties and exclusion from Medicare and Medicaid participation may be imposed against individual physicians for EMTALA violations. Furthermore, where a state purports to prohibit providers from offering the emergency care that EMTALA requires, HHS will not hesitate to refer the matter to the DOJ to take appropriate legal action. On August 2, 2022, the United States sued the State of Idaho over a law that imposes a ban on abortion.<sup>41</sup> Under the Idaho law, a prosecutor can indict, arrest and prosecute a physician merely by showing that an abortion has been performed, without regard to the circumstances. A physician who provides an abortion in Idaho can ultimately avoid criminal liability only by establishing as an affirmative defense that "the abortion, the pregnant patient (or, in some circumstances, their parent or guardian) reported an "act of rape or incest" against the patient to a specified agency and provided a copy of the report to the physician. The Idaho law provides no defense for an abortion necessary to protect the health of the pregnant patient.

Idaho's criminal prohibition of all abortions, subject only to the statute's two limited affirmative defenses, directly conflicts with EMTALA and stands as an obstacle to the accomplishment of EMTALA's federal objectives of providing stabilizing care and treatment to anyone who needs it. On August 24, 2022, the United States, represented in this matter by HHS alongside DOJ, was awarded a preliminary injunction prohibiting enforcement of the Idaho law to the extent of its conflict with EMTALA. **HHS will continue to enforce the law as appropriate.** 



## **Section 3: Protecting Patient Privacy**

Recent reports indicate that state Attorneys General and other state actors may seek to use patient data to track women seeking reproductive health care, violating patient trust and privacy and creating dangerous and untenable situations for patients who are already facing limited options. Further, there have been reports about the risks posed by smart phones and mobile applications that allow patient data related to reproductive health to be shared, such as period trackers and geolocation data. These data may be used against patients and may also lead patients to feel stigma when accessing care or to not seek care at all.

The complexity of protecting the privacy of patients' reproductive health data is compounded by the dynamic nature of electronic health information and the ways it is encoded within health information technology systems. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) plays an important role in patient privacy. Information relating to a patient's sexual and reproductive health can be directly accessed or indirectly inferred based on a wide range of data points that can be included within a patient's longitudinal care record. For example, a medication list could be used to infer medical or surgical abortion care. It is essential to protect the entirety of a patient's health information.

## **HIPAA Compliance**

OCR issued <u>guidance</u> on June 29, 2022, to help protect patients seeking reproductive health care, as well as their health care providers.<sup>42</sup> The guidance addresses how the HIPAA Privacy Rule protects individuals' private medical information ("protected health information," or PHI) relating to abortion and other sexual and reproductive health care—making it clear that HIPAA does not require providers to disclose private medical information to third parties. **HHS will continue to rigorously enforce the HIPAA Privacy, Security, and Breach Notification Rules to help protect patients seeking reproductive health care.** 

OCR also issued <u>guidance</u> outlining best practices for consumers that addresses the extent to which private medical information is protected on personal cell phones and tablets.<sup>43</sup> This guidance explains that, in most cases, the HIPAA Privacy, Security, and Breach Notification Rules do not protect the privacy or security of individuals' health information when they access or store the information on personal cell phones or tablets. This guidance provides tips about steps an individual can take to decrease how their cell phone or tablet collects and shares their health and other personal information without the individual's knowledge. HHS will continue to issue guidance, technical assistance, and support to help protect the privacy of individuals' PHI related to abortion and other sexual and reproductive health care and will provide further guidance and policies to safeguard patient privacy.

The Office of the National Coordinator for Health IT (ONC) certification and information blocking regulations already provide for protection of patient privacy and choice when it comes to sharing electronic health information. HHS will continue to publish guidance reinforcing health care providers' awareness of the ways in which information blocking regulations support their ability to provide care while protecting patient privacy.

Protecting patient privacy is a critical priority for HHS, which has already begun this important work. **HHS** will also host public meetings with providers and others in the health care system, including health



information technology developers and other stakeholders, to encourage awareness of how patients can obtain their electronic health information and make informed choices about whether to share it with others (including the use of mobile health applications).



## Section 4: Improving Awareness, Education and Access to Accurate Information

This section describes actions HHS has taken or will take to provide education and outreach to individuals on how to access reproductive health care services and about their rights relating to privacy, as well as outreach to key partners on the Administration's actions in response to the *Dobbs* decision.

## Federal Resources and Information—ReproductiveRights.gov

HHS has launched ReproductiveRights.gov, a website that serves as a central location for information on federal reproductive rights, including rights associated with accessing abortion, birth control, and other preventive services. This site provides accurate information in an accessible format to consumers to help them understand their rights to emergency care, birth control, medication, abortion services, and other preventive health services in one location. It also provides information for individuals who do not have health insurance, including information on how to locate Title X Family Planning Clinics, health centers, and Ryan White HIV/AIDS Programs. Additionally, the public can find information regarding filing a complaint with HHS OCR if a person's civil rights or health information privacy rights are violated. This website will continue to add timely, relevant information on a range of reproductive health issues to reflect the shifting environment, and efforts are underway to ensure that materials are accessible to individuals with limited English proficiency.

Reproductiverights.gov is also cross-linked with the DOJ's Reproductive Rights website, which provides information about federal legal protections for accessing reproductive health services.<sup>44</sup> DOJ's website provides helpful <u>information</u> for clinics and individuals seeking access to reproductive health services, such as the Freedom to Access Clinic Entrances (FACE) and how to report property damage, violence or threats of violence directed at providers.<sup>45</sup>

HHS will continue to add timely, relevant information on a range of reproductive health issues to the website.

## **Outreach Efforts**

**HHS launched a campaign to ensure the public has information on how to access birth control.** Specifically, this campaign aims to provide patients and consumers with information regarding the requirement for most health insurance plans to cover the full range of FDA-approved contraceptives including emergency contraceptives and intrauterine devices with no cost to the consumer. Additionally, information will be provided to notify the public of the ability to access, depending on income, no-cost or low-cost contraceptive services, as well as cervical cancer screenings, sexually transmitted infection (including HIV) testing, and referrals for abortion and other patient care.

**OCR plans to convene with health care providers to discuss federal civil rights and health privacy obligations.** This will facilitate OCR's efforts to provide informative and timely guidance to covered entities and is in furtherance of President Biden's Executive Order <u>14079</u>. Through these convenings OCR will provide support in complying with the law and also help inform areas where additional policy changes or technical assistance may be helpful to advance reproductive health care.



The HHS Reproductive Access Task Force also met with advocacy organizations, providers, civil rights groups, medical experts, and faith-based partners to better understand and respond to needs following *Dobbs*. These efforts helped inform HHS's early action in response to the *Dobbs* decision. Further, HHS will leverage external relationships in communities across the country to improve education and understanding about women's preventive health services, including birth control coverage and family planning care, at Title X clinics, community health centers, and other HHS programs and services nationwide using its existing network of providers to expand information and access to coverage for patients.

## **Countering Inaccurate Information**

The Office of the Surgeon General has addressed the challenges of inaccurate health information with the release of the Surgeon General's Advisory on Health Misinformation in July of 2021.<sup>46</sup> This advisory outlined the harms of inaccurate health information and the ways individuals, health professionals, technology platforms, and many others can combat it. In November of 2021, the Office of the Surgeon General released a Community Toolkit for Addressing Health Misinformation to help educate the public on ways to identify and appropriately engage with others about inaccurate health information.<sup>47</sup> Thousands of individuals, community leaders, educators, and health workers have used the toolkit for teaching and training. These efforts will continue to create a safer information environment to inform health decisions, including those on reproductive health. **HHS will work with providers and patients nationwide to counter inaccurate information.** 



## **Section 5: Improving Data and Research**

Restrictions on abortions will likely have significant impacts on maternal health outcomes. This section briefly reviews data sources that are available to monitor maternal health outcomes and track access to reproductive health services. The Department is making a number of investments to improve maternal health data infrastructure. Some of this work is improving electronic health records data and linking mothers with their children to support longitudinal studies on maternal health.<sup>48,49</sup> On August 3, 2022, as part of Executive Order 14079 on Securing Access to Reproductive and Other Healthcare Services, HHS was directed to evaluate the adequacy of research, data collection, and data analysis and interpretation efforts at the National Institutes of Health (NIH), the CDC, and other relevant HHS components in accurately measuring the effect of access to reproductive health care on maternal health outcomes and other health outcomes.

The Department is taking additional steps to increase its monitoring and data collection to better understand the impact on health disparities and equity as well as determine areas with needs for increased federal resources and support to protect access to health care and patient privacy. **HHS is actively exploring approaches to improve its ability to track and understand the implications of lack of access to abortion through improved comprehensive and timely data.** 

## **Tracking Maternal Mortality and Morbidity Data**

Measures of maternal mortality and severe maternal morbidity are reported on an annual basis including the CDC's maternal mortality rate and pregnancy-related mortality ratio, and severe maternal morbidity rates measured by the Agency for Healthcare Research and Quality (AHRQ). **HHS will continue these reporting systems to better understand the impact of abortion bans on maternal mortality and morbidity.** 

## **Tracking Abortion Data**

The CDC collects data that states may voluntarily report on legal abortions, which includes information on the number and type of abortions and on basic characteristics of the women who receive them.<sup>50</sup> Given the voluntary nature of this data collection, these data are not complete. The CDC also runs the <u>Pregnancy</u> <u>Mortality Surveillance System</u>.<sup>51</sup> This system monitors the impact of abortion deaths from legal abortions, illegal abortions, or abortion arising from miscarriages or pregnancy related complications. These data are also available in the <u>Abortion Surveillance Report</u>.<sup>52</sup>

## **Family Planning Data**

Self-reported information directly from women about access to and use of services such as family planning and contraception is another relevant data resource. **Early reporting suggests that there have been changes in the types of contraceptive methods some women are seeking since the** *Dobbs* **decision was announced with as much as 21 percent of women reporting that they changed their contraception method in the preceding month.**<sup>53</sup> The CDC's <u>Pregnancy Risk Assessment Monitoring System</u> collects state-level population-based data on maternal attitudes and experiences before, during, and shortly after pregnancy, as well as pregnancy intention and contraceptive use.<sup>54</sup> The CDC also conducts the National Survey of Family Growth, which collects information about fertility, contraceptive-use, pregnancy-



intention, adoption-intention, and pregnancy, among other related topics which will help measure the impact of the *Dobbs* decision on health care decisions in family planning care.

CDC's Behavioral Risk Factor Surveillance System includes questions in the Family Planning Module to understand contraceptive use. Data collected in 2017 and 2019 from 45 jurisdictions were used to estimate the proportion of women aged 18 to 49 years who were at risk for unintended pregnancy and had ongoing or potential need for contraceptive services.<sup>55</sup> The CDC's <u>Youth Risk Behavioral Surveillance</u> <u>System</u> has also monitored health-related behaviors and experiences among high school students, including sexual health behaviors, unintended pregnancy, and sexually transmitted diseases.<sup>56</sup> These data become imperative as we examine national impacts.



## Conclusion

HHS will continue to work to strengthen and expand access to reproductive health care services. As part of this work, the Secretary has directed every part of HHS to evaluate its work and act accordingly. Specifically, the Department is taking all possible steps to increase access to medication abortion and contraception; ensure access to health care under the law; protect patient privacy related to reproductive health; increase awareness, education, and access to accurate information; and expand the collection of accurate data and research in this sphere. HHS will also continue to work across the federal government to provide its expertise and partner with federal partners on its work.

Abortion is health care, and access to it and comprehensive reproductive health services can make a huge difference in a person's life—from the autonomy to make decisions about one's own body to improved health outcomes. This report lays out our current work and actions to address the proliferation of bans and restrictions on reproductive health care nationwide. We will continue this important work until every woman has equal, access to health care, privacy, and reproductive rights.

## References

<sup>1</sup> <u>Memorandum from Ctrs. for Medicare & Medicaid Servs., U.S. Dep't of Health & Human Servs. to State Survey</u> <u>Agency Directors</u> (July 11, 2022).

<sup>2</sup> Letter from Xavier Becerra, Secretary, U.S. Dep't of Health & Human Servs. to Health Care Providers (July 11, 2022).

<sup>3</sup> HHS will comply with the preliminary injunction in *Texas v. Becerra*, No. 5:22-CV-185-H (N.D. Tex.).

<sup>4</sup> <u>ReproductiveRights.gov</u> (last visited Aug. 25, 2022).

<sup>5</sup> Press Release, U.S. Dep't of Health & Human Servs., <u>HHS Announces Proposed Rule to Strengthen</u> <u>Nondiscrimination in Health Care</u> (July 25, 2022).

<sup>6</sup> Press Release, U.S. Dep't of Health & Human Servs., <u>HHS Issues Guidance to the Nation's Retail Pharmacies</u> <u>Clarifying Their Obligations to Ensure Access to Comprehensive Reproductive Health Care Services</u> (July 13, 2022).

<sup>7</sup> Press Release, U.S. Dep't of Health & Human Servs., <u>HHS Issues Guidance to Protect Patient Privacy in Wake of</u> <u>Supreme Court Decision in Roe</u> (June 29, 2022).

<sup>8</sup> Press Release, U.S. Dep't of Health & Human Servs., <u>HHS Announces New Grants to Bolster Family Planner</u> <u>Provider Training</u> (June 30, 2022).

<sup>9</sup> Press Release, U.S. Dep't of Health & Human Servs., <u>Readout: Secretaries Becerra, Walsh Meet with Health</u> <u>Insurers, Employee Benefit Plan Stakeholders to Discuss Birth Control Coverage</u> (June 27, 2022).

<sup>10</sup> Press Release, U.S. Dep't of Health & Human Servs., <u>HHS, DOL, and Treasury Issue Guidance Regarding Birth</u> <u>Control Coverage</u> (July 28, 2022).

<sup>11</sup> Exec. Order No. 14,076, 87 Fed. Reg. 42,053 (July 13, 2022).

<sup>12</sup> Exec. Order No. 14,079, 87 Fed. Reg. 49,505 (Aug. 11, 2022).

<sup>13</sup> Xavier Becerra, Secretary, U.S. Dep't of Health & Human Servs., <u>Remarks at Press Conference in Response to</u> <u>President Biden's Directive Following Overturning of *Roe v. Wade* (June 28, 2022).</u>

<sup>14</sup> <u>Abortion Laws Around the World</u>, N.Y. Times (July 4, 2022).

<sup>15</sup> Raj Chetty et al., <u>The Association Between Income and Life Expectancy in the United States, 2001–2014</u>, 315 J. Am. Med. Ass'n 1750 (2016).

<sup>16</sup> Yan Yu & David R. Williams, <u>Socioeconomic Status and Mental Health</u>, *in* Handbook of the Sociology of Mental Health (Carol S. Aneshensel & Jo C. Phelan eds., 1999).

<sup>17</sup> Russell Ecob & George Davey Smith, <u>Income and Health: What is the Nature of the Relationship?</u>, 48 Soc. Sci. Med. 693 (1999).

<sup>18</sup> Adam Wagstaff, <u>Poverty and Health Sector Inequalities</u>, 80 Bull. World Health Org. 97 (2002).

<sup>19</sup> Gopal K. Singh & Mohammed Siahpush, <u>Widening Socioeconomic Inequalities in U.S. Life Expectancy, 1980–</u> 2000, 35 Int'l J. Epidemiology 969 (2006).

<sup>20</sup> At the time of initial approval, the application was approved under part 314, subpart H (21 C.F.R. part 314, subpart H), which provides for approval with restrictions that are needed to assure the safe use of the drug product. Subsequently, once the Food and Drug Administration Amendments Act of 2007 (FDAAA) was passed, through which the Risk Evaluation and Mitigation Strategy (REMS) authority was created, Mifeprex was identified as one of the products that was deemed to have an approved REMS in effect because Mifeprex had in effect elements to assure safe use.

<sup>21</sup> A REMS is a drug safety program the FDA can require for particular medications with safety concerns to ensure that the benefits outweigh the risks. REMS are designed, for instance, to reinforce safe medication use by preventing, monitoring, or managing a specific risk for a particular drug. For more information, *see* Food & Drug Admin., <u>Risk Evaluation and Mitigation Strategies | REMS</u> (last updated Dec. 17, 2021).

<sup>22</sup> When FDA determines that a REMS must be modified, FDA will notify the applicant of the determination and describe the required change and the type of submission that is needed. For the REMS modifications here, the applicants were required to submit supplemental applications proposing revisions consistent with the FDA



determination. The applications must be reviewed and approved by FDA prior to implementing any changes proposed in the applications.

<sup>23</sup> Press Release, U.S. Dep't of Just., <u>Attorney General Merrick B. Garland Statement on Supreme Court Ruling in</u> <u>Dobbs v. Jackson Women's Health Organization</u> (June 24, 2022).

<sup>24</sup> Alina Salganicoff et al., <u>The Hyde Amendment and Coverage for Abortion Services</u>, Kaiser Fam. Found. (Mar. 5, 2021).

<sup>25</sup> *Id.* ("Because Congress reauthorizes the Hyde Amendment annually as an attachment to the appropriations bill for HHS, it also restricts abortion funding under the Indian Health Service, Medicare, and the Children's Health Insurance Program.").

<sup>26</sup> Ctr. on Budget & Pol'y Priorities, <u>Medicaid Works for People with Disabilities</u> (Aug. 29, 2017).

<sup>27</sup> U.S. Gov't Accountability Off., GAO-19-159, <u>Medicaid: CMS Action Needed to Ensure Compliance with Abortion</u> <u>Coverage Requirements</u> (2019).

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<sup>29</sup> Women's Preventive Services Guidelines, Health Res. & Servs. Admin (last updated Aug. 2022).

<sup>30</sup> Dep't of Labor et al., <u>FAQs About Affordable Care Act Implementation Part 54</u> (July 28, 2022).

<sup>31</sup> Press Release, U.S. Dep't of Health & Human Servs., <u>Secretaries Becerra, Walsh and Yellen Underscore</u>

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<sup>32</sup> Ivette Gomez et al., <u>Medicaid Coverage for Women</u>, Kaiser Fam. Found. (Feb. 17, 2022).

<sup>33</sup> <u>CDC Contraceptive Guidance for Health Care Providers</u>, Ctrs. for Disease Control & Prevention (last updated May 20, 2021).

<sup>34</sup> 42 U.S.C. § 18116.

<sup>35</sup> Complaint Portal Assistant, U.S. Dep't of Health & Human Servs. (last visited Aug. 25, 2022).

<sup>36</sup> <u>Protecting Rights and Preventing Abuse of People with</u> Disabilities, Admin. for Cmty. Living (last updated July 27, 2022).

<sup>37</sup> Off. for C.R., U.S. Dep't of Health & Human Servs., <u>Guidance to Nation's Retail Pharmacies: Obligations Under</u> <u>Federal Civil Rights Laws to Ensure Access to Comprehensive Reproductive Health Care Services</u> (last visited Aug. 25, 2022).

<sup>38</sup> Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. 47,824 (proposed Aug. 4, 2022) (to be codified at 42 C.F.R. 438 *et seq.*).

<sup>39</sup> Memorandum from Ctrs. for Medicare & Medicaid Servs., *supra* note 1.

<sup>40</sup> On August 24, 2022, the Northern District of Texas issued a preliminary injunction prohibiting certain applications of this guidance. *Texas v. Becerra*, No. 5:22-CV-185-H (N.D. Tex.). HHS will comply with the court's injunction.

<sup>41</sup> Press Release, U.S. Dep't of Just., <u>Justice Department Sues Idaho to Protect Reproductive Rights</u> (Aug. 2, 2022).
<sup>42</sup> <u>HIPAA Privacy Rule and Disclosures of Information Relating to Reproductive Health Care</u>, U.S. Dep't of Health & Human Servs. (June 29, 2022).

<sup>43</sup> <u>Protecting the Privacy and Security of Your Health Information When Using Your Personal Cell Phone or Tablet</u>,

U.S. Dep't of Health & Human Servs. (June 29, 2022) ("The HIPAA Rules generally *do not* protect the privacy or security of your health information when it is accessed through or stored on *your* personal cell phones or tablets. The HIPAA Rules apply only when PHI is created, received, maintained, or transmitted by covered entities and business associates.").

<sup>44</sup> <u>Reproductive Rights</u>, U.S. Dep't of Just. (last updated Aug. 2, 2022).

<sup>45</sup> <u>National Task Force on Violence Against Reproductive Health Care Providers</u>, U.S. Dep't of Just. (last updated Sept. 17, 2021).

<sup>46</sup> To view this advisory, *see* Surgeon Gen. of the U.S., <u>Confronting Health Misinformation: The U.S. Surgeon</u> <u>General's Advisory on Building a Health Information Environment</u> (2021).

<sup>47</sup> To view this toolkit, *see* Off. of U.S. Surgeon Gen., <u>A Community Toolkit for Addressing Health Misinformation</u> (2021).

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<sup>51</sup> <u>Pregnancy Mortality Surveillance System</u>, Ctrs. for Disease Control & Prevention (June 22, 2022).

<sup>52</sup> Katherine Kortsmit et al., <u>Abortion Surveillance – United States</u>, 2019, 70 Morbidity & Mortality Wkly. Rpt., Nov. 26, 2021.

<sup>53</sup> Harris Poll, <u>A Notable Sum of Women are Considering Permanent Contraception</u> (July 26, 2022).

<sup>54</sup> Pregnancy Risk Assessment Monitoring System, Ctrs. for Disease Control & Prevention (May 23, 2022).

<sup>55</sup> For the underlying data and the report produced from it estimating the need for contraceptives, *see* Lauren B. Zapata et al., <u>Need for Contraceptive Services Among Women of Reproductive Age – 45 Jurisdictions, United</u>

States, 2017–2019, 70 Morbidity & Mortality Wkly. Rpt., June 25, 2021; Data and Statistics: Need for Contraceptive

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<sup>56</sup> <u>Youth Risk Behavioral Surveillance System</u>, Ctrs. for Disease Control & Prevention (Oct. 27, 2020).