A Practical Guide to Understanding Restrictions on Use of Federal Funds for Abortion Services

The landscape for abortion access in the United States has shifted towards a dramatically more restrictive posture with the Supreme Court's June 24, 2022 decision in *Dobbs v. Jackson Women's Health Organization,* abrogating the long-standing constitutional right to abortion, and allowing states the full power to regulate any aspect of abortion not preempted by federal law.[1] In the wake of *Dobbs*, socially conservative state legislatures have enacted criminal prohibitions and other restrictions designed to inhibit access to abortions, yielding a "severe patchwork of rights and protections" that vary across states.[2] As a consequence, the *Dobbs* decision has created profound uncertainty for health care providers, patients, employers, insurers and advocates.

In response, the Biden Administration has deployed its executive authority to preserve access to reproductive services, including directing the U.S. Department of Health and Human Services ("HHS") to protect access to medications approved by the FDA, including drugs used for medical abortion, miscarriage management, and contraception.[3] Further, certain state regulatory agencies have undertaken actions to promote abortion access, such as California Medicaid's decision to permit Section 330-funded providers to receive fee-for-service, state-only Medicaid funding for abortion services.[4]

This guide is intended to address regulatory compliance concerns and other challenges that recipients of federal funding now face in providing, and facilitating access to, abortion services in this emerging post-*Dobbs* environment. The focus is on organizations that receive federal funding under Title X and/or Section 330 of the Public Health Service Act and the laws, regulations, and sub-regulatory agency guidance applicable to such funds when deployed to deliver or reimburse abortion services. If your organization operates in a state that has imposed further abortion restrictions or prohibitions post-*Dobbs*, your organization's ability to provide abortion services may be subject to unique, separately enforceable state-law restrictions and enforcement risks, which fall outside the scope of this guide.

These materials do not constitute legal or accounting advice. **If legal assistance or other expert assistance is required, the services of a competent professional with knowledge of your specific circumstances should be sought.**

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[1] Dobbs v. Jackson Women's Health Org., 142 S. Ct. 2288, 2243 (2022).

[2] Katie Keith, "Status Check on Federal Executive Action on Abortion Access," Health Affairs, Jul. 15, 2022, https://www.healthaffairs.org/do/10.1377/forefront.20220715.799549. As of March 2023, most abortions are now banned in at least thirteen (13) states, although [2] abortion advocates have brought suit subjecting these bans to legal challenge. The New York Times, "Tracking the States Where Abortion is Now Banned," last accessed Mar. 9, 2023, https://www.nytimes.com/interactive/2022/us/abortion-laws-roe-v-wade.html.

[3] See Executive Order 14076 ("Protecting Access to Reproductive Healthcare Services"), Jul. 8, 2022, https://www.whitehouse.gov/briefing-room/presidential-actions/2022/07/08/executive-order-on-protecting-access-to-reproductive-healthcare-services/; Executive Order 14079 ("Securing Access to Reproductive and Other Healthcare Services"), Aug. 3, 2022, https://www.whitehouse.gov/briefing-room/presidential-actions/2022/08/03/executive-order-on-securing-access-to-reproductive-and-other-healthcare-services/. U.S. Department of Health and Human Services, Health Care under Attack: An Action Plan to Protect and Strengthen Reproductive Care, A Report Required by Executive Order 14076, August 2022, https://www.hhs.gov/sites/default/files/hhs-report-reproductive-health.pdf. In addition, HHS has committed to distribute new funding to support abortion access in states where access remains legal, including funds targeted to Title X family planning providers.

[4] California DHCS, "FQHC, RHC, and Tribal Clinic Providers: Abortion Services," Sept. 1, 2022, https://files.medi-cal.ca.gov/pubsdoco/newsroom/newsroom_31873.aspx.

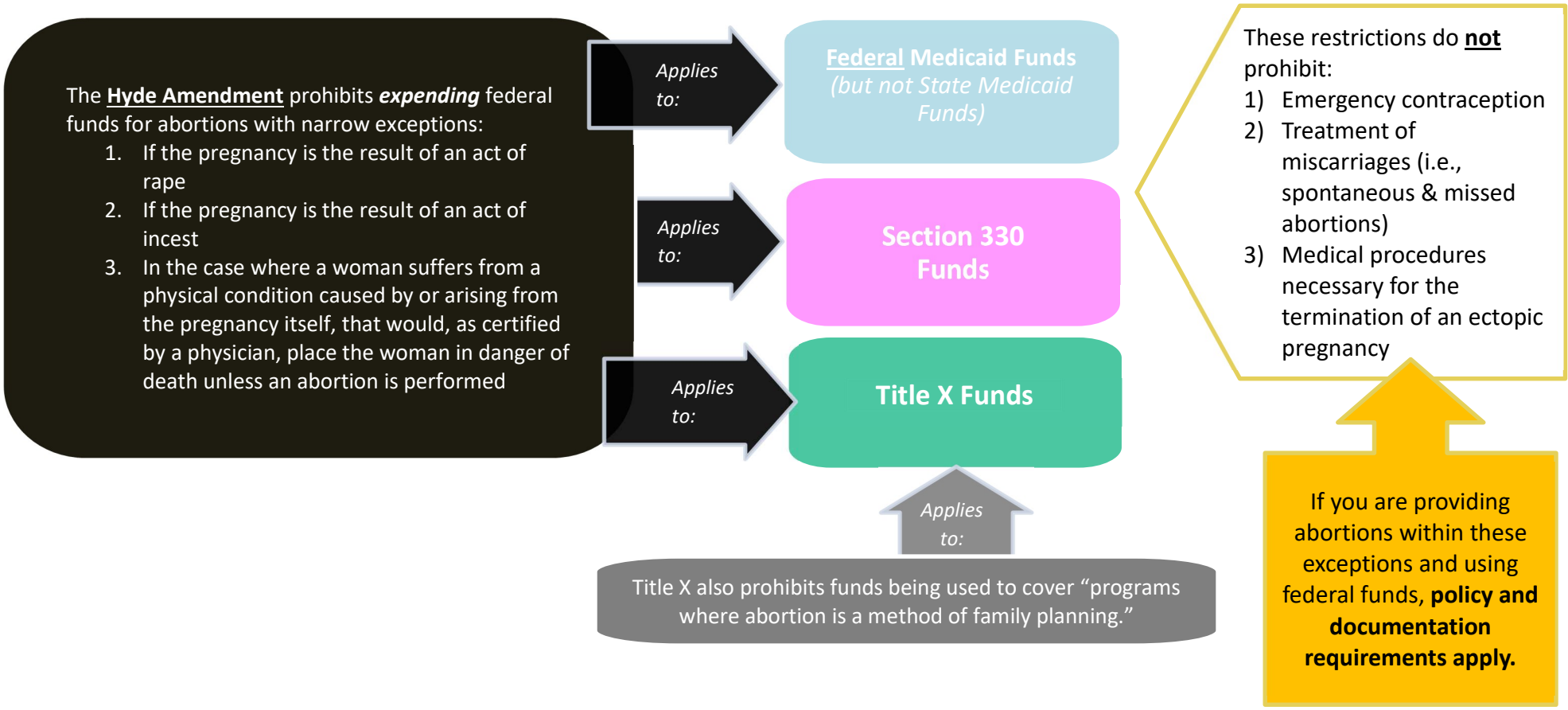
Step 1: Determine what types of federal funds your organization receives.

Different types of federal funding impose different requirements and considerations for providing compliant abortion services.

Type of Federal Funding	Title X *Office of Population Affairs, Department of Health & Human Services (HHS)*	Section 330 *Health Resources and Services Administration (HRSA) Bureau of Primary Health Care, HHS*	Medicaid *Centers for Medicare and Medicaid Services; State Medicaid Agencies*
Recipients	Public or nonprofit private entities	Public or private non-profit Federally Qualified Health Centers (FQHCs)	Medicaid-enrolled providers
Distribution of Funds	Federal grant funds awarded typically to cover **operational costs** (e.g., direct clinical services, general and administrative costs, and entering new contracts with insurers), though may also be used for **capital costs** (facilities, equipment, and information technology)	Federal grant funds awarded to cover costs incurred within the FQHC's defined Scope of Project, which may include **operational costs** (e.g., direct clinical services, general and administrative costs, and entering new contracts with insurers) and **capital costs** (e.g., facilities, including construction and improvement costs, equipment, and information technology)	Reimbursement for covered services

Remember:
There are other types of federal funding not addressed in this guide (e.g., Ryan White) that impose additional restrictions and require different considerations. Entities will need to consider all funding streams received by their organization.

Step 2: Understand that the restrictions apply to the use of federal funds for abortion services.



Remember:
The Hyde Amendment restricts federally funded entities' ability to use funds for abortions (apart from the above exceptions), but does not restrict entities from providing abortions using other funding sources.

Step 3: Understand the framework for navigating these restrictions based on the funding type received.

Title X

- Pursuant to current guidance, recipients of Title X funds may provide abortion services using other funding sources so long as these abortion services are "***separate and distinct***" from the recipient's Title X services[5]
  - Title X recipients should monitor guidance, as political conditions change (and prior, now-superseded Trump-era HHS guidance imposed much stricter requirements)
- Title X funding recipients may comply by:
  - Separating operations legally (e.g., by creating a separate entity)

    OR
  - Separating operations through a **cost allocation plan** that makes it possible to distinguish between the Title X supported activities and non-Title X abortion-related activities, provided that:
    - The cost allocation plan is sufficiently robust: separate "bookkeeping entries alone" or "mere technical allocation of funds" would be insufficient
    - Recipients ensure that abortion services are not so large or so intimately related to all aspects of the Title X program as to make it **difficult or impossible** to separate the eligible from the non-eligible items of cost

Section 330

- No official guidance has been promulgated to date for FQHCs that seek to provide abortion services
- However, no law, regulation or express agency guidance prohibits FQHCs from furnishing abortion services, provided that such services are carried out as "**other lines of business**" that are not included in the scope of their Section 330 project grant
  - "Other lines of business" refers to operations, sites, services, activities, or patient populations that are not within the HRSA-approved Scope of Project, and the costs of these activities are not included in the annual operating budget of the Health Center Program project
- FQHC funding recipients must comply by:
  - **Ensuring that Section 330 funds** and other grant-related income are **not used inappropriately to support costs outside the approved Scope of Project**
    - In many cases, this can be accomplished through a **cost allocation plan**; however, see limitations described in Step 4
    - Ensuring that the **revenue generated from such other lines of business and/or additional, non-federal funding sources is sufficient to support all costs of abortion services**

[5] See HHS, Final Rule, Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services, 86 FR 56144 (October 7, 2021).

Step 4: Understand the practical application of restrictions on use of federal funds for abortions.

Remember that if your organization receives both Title X and Section 330 funds, you need to evaluate compliance under both frameworks.

Common Questions	Title X	Section 330
May my organization use the **same legal entity** to provide abortion services?	✅ Yes, per guidance, so long as the provision of abortion services is **separate and distinct** from the Title X program. Even so, creating a separate organizational framework may be helpful for some organizations to facilitate tracking of these services and documenting their separation more easily from Title X services. In evaluating this option, consider the volume of abortion services to be provided, given that creating a separate organizational framework may entail significant effort and expense. Note that even if a separate organization is created, any shared general or administrative joint costs (e.g., shared administrative and management staff salaries, leave and benefits) will still need to be allocated via a **cost allocation plan.**	✅ Yes, there is no requirement to create a separate legal entity to carry out other lines of business, including abortion services. Creating a separate organizational framework is not required; however, depending on the Scope of Project awarded, (e.g., if the grant applies to capital expenditures), it may be administratively easier to create a separate organizational framework that does not use any Section 330 funds. More information about **cost allocation plans** and relevant resources may be found in **Step 5.**
May my organization provide abortion services through the **same healthcare professionals** that provide federally funded services?	✅ Yes, per guidance, provided that the provision of abortion services is demonstrably **separate and distinct** from the Title X program through adoption of, and documented adherence to, a **cost allocation plan.**	✅ Yes, if the FQHC ensures and documents that the fully loaded costs associated with healthcare professionals' provision of abortion services are properly allocated to non-330 funding sources via a **cost allocation plan.**
May my organization use the **same administrative staff** to support abortion services that support federally funded services?	✅ Yes, per guidance, provided that the provision of abortion services is **separate and distinct** from the Title X program through a **cost allocation plan.** Note that time and effort (or activity) reports can be used to implement cost allocation plans, but are not in themselves sufficient to serve as a cost allocation plan since they do not address overhead costs, such as salaries, benefits, leave, etc.	✅ Yes, if the FQHC ensures and documents that the costs associated with administrative staff support for abortion services are properly allocated to non-330 funding sources **via a cost allocation plan.**

Common Questions	Title X	Section 330
May my organization provide abortion services in the **same facility** as federally-funded services (e.g., co-location)? **Real Property** means (under Federal Cost Principles) land, including land improvements, structures and appurtenances thereto, but excludes moveable machinery and equipment	✅ Yes, guidance under the Biden Administration expressly contemplates that Title X-supported activities and abortion activities **may share facilities, including a common waiting room and separate space within a single physician facility**, subject to the precise allocation and pro-ration of costs via a **cost allocation plan**.	This depends on whether your facility was **built, purchased, refurbished, or improved with Section 330 dollars.** ***If your facility was built, purchased, refurbished, or improved with Section 330 dollars (or you cannot prove otherwise):*** ❌ Use of a facility **built, purchased, refurbished, or improved with Section 330 dollars likely creates significant risk of non-compliance.** Any real property **built, purchased, refurbished, or improved** with a Federal grant has a **Federal interest,** which means that the property must be used for the purpose authorized by the grant, and recipients may not dispose of or encumber the title of such real property except as instructed.[6] In this situation FQHCs may **lease a separate facility using non-330 funding** for the provision of abortion services, such as an office space for in-office consultation and prescriptions for medication abortion, or **deploy non-330 funding to purchase and operate a mobile clinic**. FQHCs may also use **telehealth for a provider to furnish medication abortion assistance and advice to a patient remotely**, without being physically present in real property purchased with Section 330 funds so long as the provider complies with licensing and reimbursement requirements for telehealth. ***If you can prove with documentation that your facility was <u>not</u> built, purchased, refurbished, or improved with Section 330 dollars:*** ✅ Yes, organizations can use the same facility to carry out other lines of business, including abortion services, by documenting use in a **cost allocation plan.**

[6] See 45 CFR § 75.323; 2 CFR § 200.311.

Common Questions	Title X	Section 330
May my organization use the **same equipment (including electronic health records (EHR) systems)** when providing abortion services and federally funded services?	✅ Likely yes, per guidance, provided that the provision of abortion services is **separate and distinct** from the Title X program through a **cost allocation plan,** which charges **user fees** to the abortion program for such use.	✅ Likely yes, if your organization follows applicable requirements, which will depend on whether the equipment in question was **purchased with Section 330 dollars.** If you can prove with documentation that the equipment was not purchased with Section 330 dollars, then your organization would merely use the same equipment to carry out "other lines of business," including abortion services, by documenting such use in a **cost allocation plan.** If your equipment was purchased with Section 330 dollars (or you cannot prove otherwise), you may use the equipment to provide abortion services if: 1) The **equipment has "excess capacity"** for additional use after factoring in (i) the use for which the equipment was originally purchased (e.g., in furtherance of Section 330-supported services), and (ii) any other use that may be required to support other Federal grants; organizations must ensure that any use by the abortion program of such equipment will not **interfere** with the use for which the equipment was purchased. 2) The organization charges the non-federally funded program (here, the abortion program) appropriate **user fees for such use**, which should be documented in and consistent with a detailed **cost allocation plan**.[7]

Equipment means (under Federal Cost Principles) tangible personal property (including IT systems) having a useful life of >1 year and a per-unit acquisition cost generally ≥ $5,000. ***Most EHR systems likely meet this definition of equipment.***

Note of Caution: Be certain, in determining an appropriate user fee to charge for use of equipment, to base the fee upon an appropriate cost allocation plan; reliance on a "fair charge," "standard charge" or other estimate or proxy for the actual, fully loaded cost poses audit risk.

[7] See 2 CFR 200.313.

Common Questions	Title X	Section 330
May my organization use the **same store of supplies** when providing abortion services and federally funded services? **Supplies** means (under HHS Federal Principles) tangible personal property other than equipment.	✅ Yes, per guidance, provided that the provision of abortion services is **separate and distinct** from the Title X program through a **cost allocation plan.** In practice, some Title X providers may choose to use separate supplies where such supplies are used primarily in providing abortion services (e.g., medication abortion drugs), and use a **cost allocation plan** to allocate supplies that are used in the provision of all services (e.g., exam room supplies). Alternatively, a Title X recipient may buy a separate set of supplies that it maintains in a physically separate fashion from its inventory of federally funded supplies.	✅ Yes, if the FQHC ensures and documents that the costs associated with supplies are properly allocated to non-330 funding sources via a **cost allocation plan**. Drugs dispensed for a medication abortion (mifepristone & misoprostol) are considered "supplies"
May organizations that receive Title X or Section 330 funding **refer patients receiving federally funded services** for abortions?	✅ Yes, although Title X recipients **may not make warm referrals**. Per 2020 HHS guidance, "[w]hile a Title X project may provide a referral for abortion, which may include providing a patient with the name, address, telephone number, and other relevant factual information (such as whether the provider accepts Medicaid, charges, etc.) about an abortion provider, **the project may not take further affirmative action** (such as negotiating a fee reduction, making an appointment, providing transportation) **to secure abortion services for the patient**."[8]	✅ Yes, there is no prohibition (or issued guidance) with respect to the referral of abortion services by FQHC providers or staff, where the costs of such providers or staff are covered by Section 330 grant funding.[9] While some Section 330 recipients choose to follow the Title X standards prohibiting warm referrals, other FQHCs frequently assist in referrals for abortion services, including making appointments directly into clinics that provide abortion services.

[8] In 2021, HHS readopted a Final Rule from 2000 to ensure access to "equitable, affordable, client-centered, quality family planning services for client." The 2021 Final Rule revoked the 2019 regulations, including removing restrictions on nondirective options counseling and referrals for abortion services.
65 FR at 41281 (July 3, 2000). The final rule goes on to say "The Department believes that offering pregnant clients the opportunity to receive neutral, factual information and nondirective counseling on all pregnancy options—and providing referral upon request for option(s) the client wishes to receive—are critical for the delivery of quality, client-centered care. The Department agrees that restoring this provision will remove unnecessary limitations governing the patient-provider relationship and will enable healthcare providers to offer complete and medically accurate information and counseling to their clients."

[9] Note that while no guidance has been issued with respect to the referral of abortion services, the Office of General Counsel for HHS has issued a slip opinion affirming HHS's view that the Hyde Amendment "permit[s] expenditures to fund transportation for women seeking abortions where HHS otherwise possesses the requisite authority and appropriations." Application of the Hyde Amendment to the Provision of Transportation for Women Seeking Abortions, No. 46 slip op. O.L.C. __ (Sept. 27, 2022), https://www.justice.gov/d9/2022-11/2022-09-27-hyde_amendment_application_to_hhs_transportation.pdf.

Step 5: Establishing a Cost Allocation Plan.

As described in Steps 3 & 4, federal funding recipients that provide abortion services may, where appropriate and feasible, use a cost allocation plan to demonstrate that federal funds are not used to cover the costs of abortion services. The below chart summarizes basic considerations for establishing a cost allocation plan. **We caution that your organization will need to engage appropriate accounting experts and auditor oversight to establish a cost allocation plan that works for your organization**.[10]

1. Identify "Fully-Loaded Costs" Relating to the Provision of Abortion Services

- Organizations must identify the "fully loaded costs," or the total costs incurred to provide abortion services, including direct costs and indirect costs
- **Direct costs** consist of "those costs that can be **identified specifically with a particular final cost objective"** e.g., the provision of abortion services, "or that can be **directly assigned to such activities relatively easily with a high degree of accuracy**"
  - Examples of direct costs may include:
    - **Employee Compensation & Benefits** of healthcare providers and staff providing abortion services
    - **Supplies**, like drugs used in a medical abortion
  - Direct costs whose benefit can be specifically identified with **more than one funding source or program** are **joint direct costs**
    - For example, the employee compensation and benefits expense of clinical service providers who provide services paid for or mandated by a federal grant and also provide abortion services may constitute **joint direct costs**
- **Indirect costs** are costs that are "incurred for common or joint objectives and **cannot be readily identified with a particular final cost objective**"
  - Indirect costs are reimbursed at a **negotiated cost rate**, which represents an agreed-upon percentage on top of direct cost classified within two broad categories:
    - **Facilities**, which may include depreciation on buildings, rent, equipment and capital improvements; interest on debt associated with certain buildings, equipment and capital improvements; and operations and maintenance expenses
    - **Administration**, which includes general expenses such as a director's office, governance, accounting, and salaries of

[10] For further information on cost allocation, please see Office of Management and Budget, Circular No. A-122, Cost Principles for Non-Profit Organizations, available at https://georgewbush-whitehouse.archives.gov/omb/circulars/a122/a122.html ("**OMB Circular A-122**").

administrative and clerical staff

- Recipients have discretion to classify costs as either direct or indirect, i.e., a type of cost may be direct with respect to one function, but indirect with respect to another function; however, federal regulations require consistent treatment such that each item of cost incurred for the same purpose must be treated the same in like circumstances, as either direct or indirect, to avoid potential "double-charging" of federal grants

2. Determine Cost Allocation Methods

- Title X and Section 330 funding recipients that seek to provide abortion services must determine what costs may be allocable to their grant funds, and what costs must be allocable to other sources of revenue
- Per federal guidance, a cost is allocable to a **Federal grant** if it is treated consistently with other costs incurred for the same purpose in like circumstances and if it:

  (1) Is incurred specifically for the grant (e.g., a **direct cost**),

  (2) Benefits both the grant and other work and can be distributed in reasonable proportion to the benefits received (e.g., a **joint direct cost**), or

  (3) Is necessary to the overall operation of the organization, although a direct relationship to any particular cost objective cannot be shown (an **indirect cost**)

- Joint costs must be allocated by cost allocation methods that are reasonable and justifiable. Common examples include:
  - FTE or staff time
  - Usable square footage
  - Number of patients served
  - "Units" of services, such as usual and customary charges, visits/encounters, and relative value units (RVUs)
  - (For indirect costs) percentage of total direct costs
- Allocation calculations may be performed manually, or automated through accounting systems; however, the formulas should be reviewed and updated if the program changes (i.e., staff reassignments or program growth)
- Documentation of the organization's cost allocation plan is key to ensure consistency and demonstrate the organization's approach if related costs are ever questioned in a grant audit

Remember: Time and effort (or activity) reports can be used to implement cost allocation plans, but are not in themselves sufficient to serve as a cost allocation plan since they do not address overhead costs, such as salaries, benefits, leave, etc.

3. Secure Sufficient Funding for Abortion Services

- Federal funding recipients cannot use federal funding to cover the costs of abortion services, and must ensure other revenue from other sources is sufficient to cover such costs – even where such costs are a very small percentage of the recipient's total budget
- Section 330 recipients must determine their Section 330 program income, which includes all grant-supported activities or earned as a result of the award (including, for example, higher reimbursement obtained via the entity's FQHC status and profits from the 340B program)
  - Note that FQHCs may not use reimbursement from the Medicaid PPS rate for services in support of "other lines of business"
    - However, some state Medicaid agencies, like California, have set up alternative billing options for FQHCs to receive fee-for-service, state-only Medicaid reimbursement for abortion services[11]
    - Bottom line: different states will have different requirements and restrictions
  - Note that it is an unresolved legal question regarding whether FQHCs may use excess program income, e.g., program income generated in excess of what is projected in the program budget, to provide abortion services – until this ambiguity is resolved, it is recommended that FQHCs do not rely on excess program income to demonstrate sufficient revenue to cover costs of abortion services

4. Continuous Review & Audits

- Cost allocation plans should ideally be reviewed no fewer than four times a year by a CPA who is experienced in HRSA audits with respect to abortion services
- Consider having your organization's auditor specifically review and bless your allocation of costs for abortion services to provide further documentation supporting the reasonableness of your approach, especially if the federal political climate changes

[11] California DHCS, "FQHC, RHC, and Tribal Clinic Providers: Abortion Services," Sept. 1, 2022, https://files.medi-cal.ca.gov/pubsdoco/newsroom/newsroom_31873.aspx.

Step 6: Additional Considerations

Malpractice Insurance

Ensure that appropriate "gap" or "wraparound" malpractice insurance to cover abortion procedures is obtained as an additional expense (and note that, for FQHCs, Federal Tort Claims Act coverage will not apply to the provision of abortion services).

Out-of-State Patients

Given the patchwork of state laws restricting abortion across the U.S., your organization should work with counsel to evaluate and mitigate the unique risks presented when providing abortion services to out-of-state patients, with particular attention to medication abortions or other abortion services that can be initiated in one state but completed in another.

Unique Patient and Staff Confidentiality/Privacy Concerns

Special policies and procedures should be developed to address considerations including but not limited to: abortion services for minors, record requests and subpoenas, dealing with protestors, adding security for the facility and staff, conscientious objections from clinical staff, and obtaining and maintaining informed consent.

Restrictive Private Agreements

Many FQHCs contract with additional providers to provide the full array of "required services." Consider whether affiliation agreements entered into by your organization contain limitations on whether affiliated providers will perform certain abortion-related services.

Mifepristone

The FDA originally imposed risk evaluation and mitigation strategies ("REMS") that required provider agreements and other medically questionable standards and requirements in order to purchase or dispense mifepristone.

However, the FDA recently revised the REMS requirements in January 2023 to permanently remove the requirement that mifepristone be dispensed in a clinic, medical office, or hospital, which means that mifepristone can now be dispensed via mail. A new process was also added for retail pharmacies to become certified to dispense directly to patients.

Litigation continues over the FDA's approval of, and actions related to, mifepristone.[12] For now, all existing FDA approvals for mifepristone, including Mifeprex, and generic mifepristone, as well as the January 2023 REMS program, remain in effect. However, organizations that prescribe mifepristone as part of a medical abortion regimen will need to continue to carefully monitor legal developments.

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[12] On April 7, 2023, two federal district courts, located in the Northern District of Texas and the Eastern District of Washington, respectively, issued conflicting preliminary orders relating to the U.S. Food and Drug Administration's ("FDA") approval and oversight of mifepristone for use in medication abortion. Litigation in both cases continues.

First, in *Alliance for Hippocratic Medicine ("AHM") v. FDA*, the U.S. District Court for the Northern District of Texas issued a preliminary injunction that imposed an unprecedented nationwide "stay" of the FDA's prior approvals issued with respect to mifepristone, including the initial approval dating back more than two decades, subject to a seven-day delay in enforcement of the order to enable the federal government to seek emergency appellate relief. On April 12, 2023, the U.S. Court of Appeals for the Fifth Circuit granted a partial stay pending appeal, which would have maintained the FDA's approval of Mifeprex (the branded version of mifepristone manufactured by Danco Laboratories), but only under the conditions specified in the FDA-approved labeling and REMS in effect prior to 2016, with the district court's stay of the FDA's subsequent approval of generic mifepristone in 2019 continuing in effect. On April 21, 2023, however, the Supreme Court granted the FDA's and Danco Laboratories' applications for a stay pending disposition of the appeal in the Fifth Circuit and a potential petition for certiorari to the Supreme Court. The effect of the Supreme Court's brief order is that no part of the Northern District of Texas's April 7 order is currently in effect, and the matter has been remanded to the Fifth Circuit to decide the merits of the FDA's and Danco's appeals.

In *Washington v. FDA*, the U.S. District Court for the Eastern District of Washington issued a preliminary injunction enjoining FDA from "altering the status quo and rights as it relates to the availability of Mifepristone" under the current FDA-approved REMS in 17 states and the District of Columbia. The Eastern District of Washington also granted a motion to clarify that its order applies "irrespective of" the district court and Fifth Circuit rulings in *AHM v. FDA*, and also denied a motion to intervene by several additional states that wished to argue that FDA's January 2023 mifepristone REMS changes were unlawful.

Additional litigation relating to the FDA's approvals and actions of mifepristone, pursued by the manufacturer of generic mifepristone, GenBioPro, as well as a North Carolina physician, is currently pending.