UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

STATE OF NEW YORK
28 Liberty St.
New York, NY 10005

STATE OF MARYLAND
200 Saint Paul Pl.
Baltimore, MD 21202

COMMONWEALTH OF MASSACHUSETTS
One Ashburton Pl.
Boston, MA 02108

STATE OF CALIFORNIA
1300 I Street
Sacramento, CA 95814

STATE OF COLORADO
1300 Broadway
Denver, CO 80203

STATE OF CONNECTICUT
165 Capitol Ave.
Hartford, CT 06106

STATE OF DELAWARE
820 N. French St.
Wilmington, DE 19801

STATE OF HAWAI'I
425 Queen St.
Honolulu, HI 96813

STATE OF ILLINOIS
115 S. LaSalle St.
Chicago, IL 60603

OFFICE OF THE GOVERNOR *ex rel. Andy Beshear, in his official capacity as Governor of the* COMMONWEALTH OF KENTUCKY,
501 High St.
Frankfort, KY 40601

Case No. 1:26-cv-03405

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

STATE OF MAINE
6 State House Station
Augusta, ME 04333

STATE OF MICHIGAN
525 W. Ottawa St.
Lansing, MI 48909

STATE OF MINNESOTA
445 Minnesota St.
St. Paul, MN 55101

STATE OF NEVADA
1 State of Nevada Way, Suite 100
Las Vegas, NV 89119

STATE OF NEW JERSEY
124 Halsey St.
Newark, NJ 07101

STATE OF NEW MEXICO
408 Galisteo St.
Santa Fe, NM 87501

STATE OF OREGON
100 SW Market St.
Portland, OR 97201

JOSH SHAPIRO, *in his official capacity as Governor of the* COMMONWEALTH OF PENNSYLVANIA
30 North 3rd St.
Harrisburg, PA 17101

STATE OF RHODE ISLAND
150 South Main St.
Providence, RI 02903

STATE OF VERMONT
109 State St.
Montpelier, VT 05609

COMMONWEALTH OF VIRGINIA
202 North Ninth St.
Richmond, VA 23219

STATE OF WASHINGTON
800 Fifth Ave.
Seattle, WA 98104

STATE OF WISCONSIN
PO Box 7857
Madison, WI 53707-7857

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Ave. SW
Washington, DC 20201

ROBERT F. KENNEDY, JR., *in his official capacity as the* SECRETARY OF HEALTH AND HUMAN SERVICES,
U.S. Department of Health and Human Services
200 Independence Ave. SW
Washington, DC 20201

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

BRIAN CHRISTINE*, in his official capacity as Assistant Secretary for Health*
Office of the Assistant Secretary for Health
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

OFFICE OF POPULATION AFFAIRS
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

AMY MARGOLIS, *in her official capacity as Deputy Director of OPA*
Office of Population Affairs
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Defendants.

INTRODUCTION

1. Plaintiffs the State of New York, State of Maryland, Commonwealth of Massachusetts, State of California, State of Colorado, State of Connecticut, State of Delaware, State of Hawai‘i, State of Illinois, Office of the Governor, *ex rel.* Andy Beshear, in his official capacity as Governor of the Commonwealth of Kentucky, State of Maine, State of Michigan, State of Minnesota, State of Nevada, State of New Jersey, State of New Mexico, State of Oregon, Josh Shapiro, in his official capacity as Governor of the Commonwealth of Pennsylvania, State of Rhode Island, State of Vermont, Commonwealth of Virginia, State of Washington, and State of Wisconsin, challenge the latest effort by the Trump Administration, through Defendants U.S. Department of Health and Human Services ("HHS" or "the Department") and HHS Secretary Robert F. Kennedy, Jr., to achieve its political agenda by attaching sweeping and often unrelated restrictions to federal funding. Specifically, Plaintiffs challenge terms directing applicants and grantees for federal family planning dollars appropriated under Title X of the Public Health Service Act ("PHSA") to demonstrate "alignment" with the administration's political priorities, including conditions that undermine the program's purpose and conflict with the governing statute and regulations.

2. For over 50 years, Title X has been the only federal funding stream dedicated specifically to providing low-income, uninsured, or underinsured individuals with access to comprehensive family planning services. Title X funds provide crucial access to high-quality family planning and related preventive services to underserved individuals in Plaintiff States and across the United States, including lifesaving cervical cancer testing; testing and treatment for sexually transmitted infections ("STIs") that preserve health and long-term fertility and prevent community spread; and contraception and fertility care that empowers individuals to have children if, when, and how they choose.

3. In July 2026, the Office of Population Affairs ("OPA") published a Notice of Funding Opportunity for Title X grants for the 2027 Fiscal Year (the "2027 NOFO" or "NOFO") (attached as Exhibit A) to establish the competitive terms and conditions governing the 2027–2032 Title X grant cycle and solicit applications. The NOFO instituted new policy priorities for Title X, incorporating several sets of priorities articulated by HHS and various sub-agencies within HHS (collectively, the "Agency Priorities"), including OPA and its parent office, the Office of the Assistant Secretary for Health ("OASH"). Plaintiffs challenge a subset of those Agency Priorities (collectively, "the Challenged Conditions") as incorporated in the NOFO, including mandates to (a) end diversity, equity, and inclusion ("DEI") policies and practices; (b) "end[] support for gender ideology" and to "accurately reflect science, including the biological reality that a person's sex, as either male or female, is unchangeable and determined by objective biology"; (c) end "overmedicalization," a category that the NOFO indicates includes hormonal contraception; (d) "enforce[e] the Hyde Amendment" and "safeguard "life-affirming" program delivery; (e) adopt directive counseling that pushes patients towards parenthood and marriage; and (f) advance miscellaneous priorities such as "[f]urther[ing] our understanding of autism," "[i]nvestigat[ing] and car[ing] for those with Long COVID," "[a]dvanc[ing] the scientific understanding of the agency process," "[e]nd[ing] crime and disorder on America's streets," and improving "oversight of foreign funded institutions" that are irrelevant to Title X.

4. The 2027 NOFO embeds the Agency Priorities into every step of the grant cycle. It directs applicants to address the Agency Priorities in their project proposals; specifies that these submissions will be judged disproportionately based upon their ability to "advance" the Priorities; and requires prospective recipients to "demonstrate ongoing compliance with these priorities" throughout the duration of any award or face termination of funding.

5. The 2027 NOFO's incorporation of the Challenged Conditions harms Plaintiff States. To compete under the 2027 NOFO's terms, Plaintiff States and other direct grantees within their borders must either commit to alter their current Title X programs to conform with the Challenged Conditions, which are inconsistent with Title X's core statutory and regulatory requirements, or submit applications based on their existing, compliant programming and risk rejection for failing to satisfy the Agency Priorities. Under either option, Plaintiff States are harmed.

6. Title X funding to state agencies, nonstate grantees, and subgrantees in Plaintiff States is crucial to the States' public health infrastructure. Title X services, delivered by trusted and highly qualified health care providers, provide essential care and access to cost-effective preventative, screening, and early-stage interventions that safeguard patients' health and the economic stability of state safety nets. With federal Title X funds in jeopardy due to the NOFO's radical and abrupt shift, Plaintiff States will be forced to scramble to fill the funding gap from their own coffers to preserve these critical services; many will not be able to continue funding these programs at the same level using state-only dollars. And the result—curtailing services and even shuttering clinics—will deprive many low-income residents of crucial services. Plaintiff States will bear the substantial costs of increased health care needs caused by worsened immediate and long-term health outcomes. Plaintiff States will also shoulder increased demands on their safety-net programs.

7. The incorporation of the new Challenged Conditions into the 2027 NOFO is unlawful several times over. First, to the extent HHS is attempting to graft new substantive requirements onto the Title X program, it has violated the Administrative Procedure Act ("APA"). 5 U.S.C. § 706(2)(D). The Agency Priorities were announced through publication of a NOFO

without any indication of whether and how the priorities had been assessed for consistency with the governing statutory and regulatory frameworks, and without providing notice or an opportunity for public comment that is required for an amendment to the applicable regulations governing providers.

8. Second, the incorporation of the Challenged Conditions into the NOFO is contrary to law and exceeds the agency's authority. The Challenged Conditions are not authorized by Congress; appear to directly conflict with the statutory requirement that "all pregnancy counseling shall be nondirective," Consolidated Appropriations Act, 2026, Pub. L. No. 119-75, 140 Stat. 173, 262 (2026); and undermine Title X's core purpose of providing low-income individuals with access to a "broad range" of family planning methods, *see* 42 U.S.C. § 300(a). The Challenged Conditions also clash with Title X regulations requiring services be provided in an "inclusive" and "equitable" manner, 42 C.F.R. § 59.5(a)(3); prohibiting discrimination based on gender identity or marital status, *id.* § 59.5(a)(4); encouraging participation from "diverse persons," *id.* § 59.5(a)(3), (b)(3)(iii); *see id.* § 59.2; requiring applicants to demonstrate an "ability . . . to advance health equity," *id.* § 59.7(a)(3); and requiring the provision of non-directive options counseling, *id.* § 59.5(a)(5). And the Challenged Conditions are in tension with the Department's own guidance regarding national standards of care for family planning services providers, which recommends specific, concrete strategies providers should adopt to operationalize health equity and gender-inclusivity in the scope of family planning services and to facilitate access to contraception and nondirective counseling. *See id.* § 59.5(a)(3).

9. Third, the incorporation of the Challenged Conditions is arbitrary and capricious because the Conditions (a) are vague, ambiguous, and contradictory; (b) depart from prior policies without explanation; and (c) lack reasoned consideration by HHS of important aspects of the

problem. Many of the Challenged Conditions are so vague as to be meaningless in practical application: for instance, it is wholly unclear what "ending support for gender ideology," or "contributing to [] efforts to safeguard life affirming" program delivery mean in the context of Title X *family planning services* programs. And the Conditions' few Title X-specific applications often seem to conflict so strongly with statutory and regulatory requirements that applicants cannot discern how the NOFO's inconsistent generic savings clauses might reconcile these apparent conflicts or what standard OPA intends to apply. Next, by requiring alignment with the Challenged Conditions, HHS silently departed from its prior Title X policies without acknowledgement, explanation, or consideration of reliance interests or relevant evidence. Last, HHS failed to consider important aspects of the problem, including reliance interests by Plaintiff States that have structured their states' family planning programs to comply with existing regulations and evidence-based, peer-reviewed guidance promulgated by OPA in previous grant cycles.

10. Fourth, the incorporation of the Challenged Conditions violates the Spending Clause of the U.S. Constitution and therefore is contrary constitutional right, power, privilege, or immunity under the APA, 5 U.S.C. § 706(2)(B), because the Challenged Conditions to receive and maintain Title X funds are vague and ambiguous, and because the Challenged Conditions are wholly unrelated to and even undermine Title X's purpose of providing family planning services to low-income individuals.

11. Plaintiff States accordingly seek a court order vacating Defendants' incorporation in the 2027 NOFO of the Challenged Conditions (a) ending DEI policies and practices; (b) ending support for "gender ideology" and "sex-rejecting procedures"; (c) deprioritizing access to contraceptives (to the extent required by the "overmedicalization" priority); (d) requiring directive counseling that pushes patients towards parenthood and marriage; (e) "safeguarding life-

affirming" program delivery in the name of enforcing the Hyde Amendment; and (f) the HHS priorities that are irrelevant to Title X's purpose. Plaintiff States also seek an injunction prohibiting Defendants from imposing the Challenged Conditions.

JURISDICTION AND VENUE

12. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331.

13. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b)(2) and (e)(1). Defendants are United States agencies or officers sued in their official capacities. Plaintiff State of Maryland is a resident of this district, and a substantial part of the events or omissions giving rise to this Complaint occurred and continues to occur within the District of Maryland.

PARTIES

A. Plaintiffs

14. Plaintiff the State of New York is a sovereign State of the United States of America. New York is represented by Attorney General Letitia James, who is the chief law enforcement officer of New York.

15. Plaintiff the State of Maryland is a sovereign State of the United States of America. Maryland is represented by and through its chief legal officer, Attorney General Anthony G. Brown.

16. Plaintiff the Commonwealth of Massachusetts is a sovereign State of the United States of America. Massachusetts is represented by Andrea Joy Campbell, the Commonwealth's chief legal officer.

17. Plaintiff the State of California, represented by and through their Attorney General, Rob Bonta, brings this action on behalf of the sovereignty of the State of California. As the State's chief legal officer, the Attorney General is authorized to act on behalf of the People in this matter.

18. Plaintiff the State of Colorado is a sovereign state of the United States of America. Colorado is represented by Philip J. Weiser, the Attorney General of Colorado. The Attorney General acts as the chief legal representative of the state and is authorized by Colorado Revised Statute § 24-31-101 to pursue this action.

19. Plaintiff the State of Connecticut is a sovereign State of the United States of America. Connecticut is represented by and through its chief legal officer, Attorney General William Tong, who is authorized under Conn. Gen. Stat. § 3-125 to pursue this action on behalf of the State of Connecticut.

20. Plaintiff the State of Delaware is a sovereign state of the United States of America. This action is brought on behalf of the State of Delaware by Attorney General Kathleen Jennings, the "chief law officer of the State." *Darling Apartment Co. v. Springer*, 22 A.2d 397, 403 (Del. 1941). Attorney General Jennings also brings this action on behalf of the State of Delaware pursuant to her statutory authority. Del. Code Ann. tit. 29, § 2504.

21. Plaintiff the State of Hawai‘i, represented by and through its Attorney General Anne E. Lopez, is a sovereign state of the United States of America. The Attorney General is Hawaii's chief legal officer and chief law enforcement officer and is authorized by Haw. Rev. Stat. § 28-1 to pursue this action.

22. The State of Illinois is a sovereign State of the United States. Illinois is represented by Attorney General Kwame Raoul, who is the State's Chief Law Officer.

23. Plaintiff the Office of the Governor, ex rel. Andy Beshear, brings this suit in his official capacity as Governor of the Commonwealth of Kentucky. The Kentucky Constitution makes the Governor the Chief Magistrate with the "supreme executive power of the Commonwealth," KY. CONST. § 69, and gives the Governor, and only the Governor, the duty to

"take care that the laws be faithfully executed," KY. CONST. § 81. In taking office, Governor Beshear swears an oath that he will support the Constitution of the United States and the Kentucky Constitution. KY. CONST. § 228.

24. Plaintiff the State of Maine is a sovereign state of the United States of America. Maine is represented by Aaron M. Frey, the Attorney General of Maine. The Attorney General is authorized to pursue this action pursuant to 5 Me. Rev. Stat. Ann. § 191.

25. Plaintiff the State of Michigan is a sovereign state of the United States of America. Michigan is represented by Attorney General Dana Nessel, who is the chief law enforcement officer of Michigan and authorized to pursue this action on the State's behalf.

26. Plaintiff the State of Minnesota is a sovereign state in the United States of America. Minnesota is represented by Keith Ellison, the Attorney General of the State of Minnesota. The Attorney General's powers and duties include acting in federal court in matters of State concern. Minn. Stat. § 8.01.

27. Plaintiff the State of Nevada, represented by and through Attorney General Aaron D. Ford, is a sovereign State within the United States of America. The Attorney General is the chief law enforcement officer of the State of Nevada and is authorized to pursue this action under Nev. Rev. Stat. § 228.110 and Nev. Rev. Stat. § 228.170.

28. Plaintiff the State of New Jersey is a sovereign State of the United States of America, and by and through Attorney General Jennifer Davenport, brings this action. The Attorney General of New Jersey is the New Jersey's chief legal adviser and is authorized to act in federal court on behalf of the State on matters of public concern. N.J. Stat. Ann. § 52:17A-4.

29. Plaintiff the State of New Mexico, represented by and through its Attorney General, is a sovereign state of the United States of America. Attorney General Raúl Torrez is the chief legal

officer of the State of New Mexico. He is authorized to prosecute all actions and proceedings on behalf of New Mexico when, in his judgment, the interest of the State requires such action. N.M. Stat. Ann. § 8-5-2(B). Likewise, he shall appear before federal courts to represent New Mexico when, in his judgment, the public interest of the state requires such action. N.M. Stat. Ann. § 8-5-2(J). This challenge is brought pursuant to Attorney General Torrez's statutory authority.

30. Plaintiff the State of Oregon is a sovereign state of the United States. Oregon is represented by Attorney General Dan Rayfield. The Attorney General is the chief legal officer of Oregon and is authorized to institute this action.

31. Plaintiff Josh Shapiro brings this suit in his official capacity as Governor of the Commonwealth of Pennsylvania. The Pennsylvania Constitution vests "[t]he supreme executive power" in the Governor, who "shall take care that the laws be faithfully executed." Pa. Const. art. IV, § 2. The Governor oversees all executive agencies in Pennsylvania and is authorized to bring suit on their behalf. 71 P.S. §§ 732-204(c), 732-301(6).

32. Plaintiff the State of Rhode Island is a sovereign State in the United States of America. Rhode Island is represented by Attorney General Peter F. Neronha, who is the chief law enforcement officer of Rhode Island.

33. Plaintiff the State of Vermont is a sovereign state of the United States of America. Vermont is represented by its Attorney General, Charity R. Clark, who is the chief legal officer of Vermont and has authority to represent the State in this matter.

34. Plaintiff the Commonwealth of Virginia is a sovereign State of the United States of America. Virginia is represented by Attorney General Jay Jones, the chief executive officer of the Department of Law. Va. Code § 2.2-500. Attorney General Jones is authorized to represent the Commonwealth and its interests in controversies with the federal government. *Id.* § 2.2-513.

35. Plaintiff the State of Washington, represented by and through its Attorney General, is a sovereign state of the United States of America. Attorney General Nick Brown is Washington's chief law enforcement officer and is authorized under Wash. Rev. Code § 43.10.030(1) to pursue this action.

36. Plaintiff the State of Wisconsin is a sovereign State in the United States of America. Wisconsin is represented by Josh Kaul, the Attorney General of Wisconsin. Attorney General Kaul is authorized to sue on behalf of the State.

B. Defendants

37. Defendant U.S. Department of Health and Human Services ("HHS") is a cabinet agency within the executive branch of the United States government and an agency under the definition provided in the Administrative Procedure Act. 5 U.S.C. § 551(1). HHS is the agency responsible for implementing Title X.

38. Defendant Robert F. Kennedy, Jr., is the Secretary of HHS and is named in his official capacity.

39. Defendant Office of the Assistant Secretary for Health ("OASH") is an office within HHS that administers the competitive review of applications for Title X funding.

40. Defendant Brian Christine is the Assistant Secretary for Health within HHS. He heads OASH and is named in his official capacity.

41. Defendant Office of Population Affairs ("OPA") is the office within OASH that administers the Title X program. OPA is the entity that announced the release of the NOFO and administers the Title X application process.

42. Amy L. Margolis is the Deputy Director of OPA and is charged with administering the Title X NOFO that is the subject of this lawsuit. Defendant Margolis is named in her official capacity.

FACTUAL ALLEGATIONS

A. Title X Provides Federal Funding for Family Planning and Related Preventive Health Services.

i. Title X Statutory Structure

43. Congress enacted Title X of the Public Health Service Act over 50 years ago as part of the "Family Planning Services and Population Research Act of 1970." 42 U.S.C. §§ 300-300a-6; Pub. L. No. 91-572, 84 Stat. 1504 (1970). It is the nation's only federal grant program dedicated to providing comprehensive family planning and related preventive health services.

44. Title X's first stated purpose was "mak[ing] comprehensive voluntary family planning services readily available to all persons desiring such services." Pub. L. No. 91-572 § 2(1). Through Title X, Congress directed HHS to make grants to and enter into contracts with public or nonprofit private entities to establish and operate voluntary family planning projects which offer a broad range of effective family planning methods and services. 42 U.S.C. § 300(a).

45. Since its enactment, Title X has been critical in Congress's goal of helping low-income people around the country meet their family planning and preventive health care needs. Title X programs have proven highly effective at helping prevent unintended pregnancies, obtain early detection and treatment for cervical and breast cancer, diagnose and treat sexually transmitted infections, and control the spread of HIV and AIDS. These services have helped millions of people, especially low-income women, control their own reproductive decision making and improve their social and economic futures.

46. Over the last five decades, Title X-funded entities, including Plaintiff States' health agencies as direct grantees and non-governmental nonprofit grantees within Plaintiff States, have used Title X funds to provide family planning services directly or through subgrantees. This network of Title X-funded programs forms the backbone of the public health infrastructure for

family planning services and related preventative health care in Plaintiff States. Principal among these services is the provision of contraception, including contraceptive devices and oral contraception (i.e., "the pill"), testing for STIs, and community education.

47. The program has been funded continuously and enjoys bipartisan support. In 2026, Congress appropriated $286,479,000 for the Title X program. *See* Consolidated Appropriations Act, 2026, Pub. L. 119-75, tit. II, 140 Stat. 173, 262 (2026).

48. The Title X program has 77 current grantees administering 84 grants.

ii. Agency Regulations and Guidance Governing the Title X Program

49. HHS issues grants to public and nonprofit private entities that provide voluntary family planning and related health services. 42 U.S.C. § 300(a). The purpose of the Title X program is "the establishment and operation of voluntary family planning projects" which "shall consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children." 42 C.F.R. § 59.1.

50. When issuing grants to Title X applicants, the Secretary of HHS (the "Secretary") "shall" consider "the number of patients to be served, the extent to which family planning services are needed locally, the relative need of the applicant, and its capacity to make rapid and effective use of such assistance." 42 U.S.C. § 300(b). The statute authorizes HHS to issue regulations accordingly and requires that "[g]rants and contracts made under this subchapter shall be made in accordance with such regulations as the Secretary may promulgate." *Id.* § 300a-4(a). Grant recipients must also abide by the Title X implementing regulations which, consistent with the statute, make clear that the purpose of the Title X program is "the establishment and operation of voluntary family planning projects" which "shall consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children." 42 C.F.R. § 59.1. The regulations restate and elaborate on the statutory

factors for evaluating applicants and add consideration of "the ability of the applicant to advance health equity," *id.* § 59.7(a)(3), and define "health equity" as ensuring that "all persons have the opportunity to attain their full health potential and no one is disadvantaged from achieving this potential because of social position or other socially determined circumstances," *id.* § 59.2.

51. Congress mandated that Title X funds may not be used for abortion and that "all pregnancy counseling [supported by Title X funds] shall be nondirective." 42 U.S.C. § 300a-6; Pub. L. 119-75, 140 Stat. at 262. Regulations therefore require providers to offer neutral counseling to pregnant clients regarding their options and provide referrals to abortion services upon request. 42 C.F.R. § 59.5(a)(5)(i)-(ii).

52. Family planning services supported by Title X funds must "include a broad range of medically approved services, which includes . . . (FDA)-approved contraceptive products and natural family planning methods, for clients who want to prevent pregnancy and space births, pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, sexually transmitted infection (STI) services, and other preconception health services." *Id.* § 59.2. The "broad range" of medically approved services explicitly includes the provision of contraceptive practices, devices and supplies. *Id.* § 59.5(a)(1), (b)(1).

53. A service site that is "unable to provide clients with access to a broad range of acceptable and effective medically approved family planning methods and services" must provide prescriptions and referrals for those services to be obtained by a different provider, *id.* § 59.1, and give priority in the provision of services "to clients from low-income families," *id.* § 59.5(a)(6).

54. Title X projects must be "inclusive," *id.* § 59.5(a)(3), which is defined as "when all people are fully included and can actively participate in and benefit from family planning, including, but not limited to, . . . Black, Latino, and Indigenous and Native American persons,

Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons." *Id.* § 59.2.

55. To that end, Title X projects must provide services in a manner "that does not discriminate against any client based on religion, race, color, national origin, disability, age, sex, sexual orientation, gender identity, sex characteristics, number of pregnancies, or marital status." *Id.* § 59.5(a)(4).

56. Title X funding recipients must provide care in a manner that is "client-centered, culturally and linguistically appropriate, inclusive, and trauma-informed; protects the dignity of the individual; and ensures equitable and quality service delivery consistent with nationally recognized standards of care." *Id.* § 59.5(a)(3); *see also id.* § 59.2 (defining "quality healthcare" as healthcare that is safe, effective, and "equitable."). The regulations also require recipients to "[p]rovide services in a manner that does not discriminate against any client based on" protected characteristics including "sex, sexual orientation, gender identity, sex characteristics, number of pregnancies, or marital status." *Id.* § 59.5(a)(4).

57. Title X projects must provide family planning services "consistent with nationally recognized standards of care." *Id.* § 59.5(a)(3).

58. OPA's most recent PPN guidance (attached as Exhibit B),[1] and the Title X Program Handbook (attached as Exhibit C),[2] designate the OPA and CDC publication *Providing Quality Family Planning Services in the United States: Recommendations of the U.S. Office of Populations*

[1] Off. of Population Affs., *OPA Program Policy Notice 2024-02—Implementing Quality Family Planning Services Recommendations within Title X Projects*, U.S. Dep't Health & Hum. Servs. (Nov. 19, 2024), https://opa.hhs.gov/node/4173.
[2] Off. Of Population Affs., *Title X Program Handbook*, U.S. Dep't Heath & Hum. Servs., at 10 (Dec. 2024), https://opa.hhs.gov/sites/default/files/2025-03/title-x-program-handbook-dec-2024.pdf.

Affairs ("2024 QFP") (attached as Exhibit D),[3] as a set of guidelines that fulfill grantees' regulatory obligation to adhere to "a nationally recognized standard of care when implementing Title X requirements," Ex. C, 10. Issued and developed by OPA, the 2024 QFP supplies practitioners with "specific recommendations for how to provide high-quality [sexual and reproductive health] care and connects users to relevant guidelines, primary research, and other resources to inform best practices." Ex. D, S41. OPA has required adherence to the QFP's first edition, published in 2014. The agency has offered "training and technical assistance . . . to facilitate adoption of the QFP recommendations," Ex. C, 10, and has embedded QFP recommendations directly into the rubrics the agency uses to assess grantee compliance with quality requirements, which it also encourages recipients to use both "as a self-assessment" and "for monitoring their subrecipients and service sites," *see, e.g.*, Off. of Population Affairs, Title X Program Review Tool (Dec. 2019), https://www.hhs.nd.gov/sites/www/files/documents/DHS%20Legacy/OPA_Program_Review_Tool_FINAL_1.16.20_corrected.pdf.

59. The 2024 QFP was developed using an extensive process including literature reviews, environmental scans, technical expert panel consultations, and consultation with federal agencies and relevant professional organizations. Ex. D, S45.

60. The 2024 QFP emphasizes health equity and inclusivity, including for LGBTQ people, *see id.*, S42, S46–S48, and S72, and recognizes contraception as a crucial family planning method. It directs providers to meet the family planning needs of transgender clients through practices such as integrating fertility planning into medical transition and accurately documenting patients' names and pronouns in their medical records. *Id.* at S72. It instructs providers to make

[3] Sarah E. Romer et al., *Providing Quality Family Planning Services in the United States: Recommendations of the U.S. Office of Population Affairs (Revised 2024)*, 67 Am. J. Prev. Med. S41 (2024).

available "a full range" of contraceptive methods and to support patients interested in using contraceptives for reasons other than preventing pregnancy (e.g., STI prevention, gender-affirming care, management of chronic conditions). *Id.* at S55. The 2024 QFP further states that "the decision about which method to use should be made by the patient," *id.* at S57, and centers empowering patients "to *self-determine* and achieve *their reproductive goals*," *id.* at S44 (emphasis added).

iii. Title X Program Grant Process

61. Title X grants are awarded through a competitive process administered by OPA.

62. At the beginning of each grantmaking cycle, OPA solicits applications by issuing a NOFO. A NOFO announces the availability of funding and sets forth the program's requirements, priorities, and scope in a given cycle. A NOFO describes the criteria by which applications will be evaluated and specifies the terms that will govern awards, including their duration, awardees' opportunities to apply for noncompeting continuation grants in future years, and grounds for grant termination. A NOFO establishes the core parameters of the funding opportunity, defines the substantive scope of permissible programming services, and imposes requirements as a condition of funding and continued funding that apply across the entire grantmaking cycle.

63. Each application must include a Project Narrative that describes how the grantee or subgrantees will deliver Title X services and provide supporting documentation, a Work Plan, and a Budget Narrative.

64. Formulating an application is time-consuming and labor-intensive, requiring months of time from numerous staff. Applicants must tailor their applications to the requirements of the statute, regulations, and guidance governing the Title X program and the requirements in the NOFO.

65. State agency applicants face special burdens due to their size, the complexity of coordination with different divisions and agencies within state government, their role in coordinating networks of subrecipients, and regulatory obligations as government entities.

66. Applicants are bound to the representations made in their applications and must certify the veracity of their statements on pain of criminal, civil, or administrative penalties, and must, at the time of application, swear to the program's operational capacity to complete the proposed project. *See* Ex. A, 31, 42-3, and 62 (explaining that the "approved project or activity [for any grant funding] is the project described in your application"; and requiring applicants submit Standard Form 424 and a list of additional certifications).

67. For the last several years, Title X applications were due the first week of January, with an annual award period from April 1 through March 31 the following year. The Department typically makes award decisions and issues grants by April 1.

68. Title X grant funds have historically been awarded for a period of performance of up to five years, to be funded in annual increments. To obtain funding each year, grantees must submit noncompeting continuation grant applications that meet certain requirements.

69. Applications are evaluated using criteria established by the NOFO and based in statute and regulations. HHS has historically relied on a "three-stage" review process: first, submissions are reviewed for basic compliance with application formalities (e.g., inclusion of required forms); second, an independent "merit review panel" of external experts scores each application under a points system dictated by the NOFO; and finally, agency staff review those scores and make final funding recommendations. *Id*. at 36–37.

B. The Title X Program in Plaintiff States

70. Many Plaintiff States have received funding since the inception of the Title X program half a century ago, making them longstanding partners in the delivery of family planning

services. Other Plaintiff States that do not receive direct Title X funds rely on nongovernmental or local government grantees as critical components of the States' public health infrastructure.

71. Plaintiff States that receive direct Title X funds are integral to the administration of family planning services and may operate public health clinics themselves and/or administer funding to subrecipient nonprofit organizations operating health centers that deliver services.

i. New York

72. Title X funds play a critical role in covering the costs of family planning services in New York. New York has two Title X grantees: the New York State Department of Health ("NYS DOH") and Public Health Solutions ("PHS"), a nonprofit Title X recipient since the early 1980s. NYS DOH received $11,154,003 in Title X funding in 2024 and delivers services to approximately 250,000 individuals statewide through a mix of subrecipient agencies, including county health departments, hospitals, stand-alone family planning clinics, and federally qualified health centers ("FQHCs"), which are federally funded, community-based clinics that provide primary care services to medically underserved populations. As of the last grant cycle, PHS serves approximately 21,000 clients in four of New York City's five boroughs through five subrecipient agencies with ten clinical service sites that include FQHCs.

73. In 2025, the New York State Family Planning Program provided essential preventative and reproductive health services to 253,975 clients through a total of 379,120 visits. More than 176,200 clients (approximately 70 percent) had household incomes below the federal poverty level.

74. NYS DOH uses Title X funds to support the New York State Family Planning Program, which ensures access to a wide range of reproductive health services, including contraception, pregnancy testing, and non-directive options counseling, education, and preventative care, including breast and cervical cancer screenings and STI testing and treatment.

Providers prioritize populations most in need, including low-income, uninsured or underinsured individuals; racial and ethnic minorities; and adolescents, with a strong emphasis on equitable, client-centered care. To ensure cost is never a barrier, all family planning clinics offer sliding fee scales for patients with incomes at or below 250 percent of the federal poverty level. By offering services that are free or low-cost, the Program serves as the foundation for New York's reproductive healthcare safety net and aligns with the State's health agenda priorities on health equity, reproductive rights, maternal health, and affordability.

75. The majority of New York's Title X funds go to support contracts with 35 clinical providers to deliver reproductive health care at 165 clinics across the State. Subrecipients include county health departments, hospitals, FQHCs, and standalone family planning clinics. Funding to these subrecipients largely supports staffing, operating expenses (contraceptive methods, direct medical supplies, laboratory supplies, and educational materials), rent, utilities, and subcontracts. Title X funds also support ten full-time agency staff to oversee the program; three contracts needed for training, monitoring, and data management; and administrative and related costs.

76. NYS DOH is currently determining whether it would be possible to craft an application under the 2027 NOFO. However, the directive to align with the Agency Priorities, including the Challenged Conditions, directly conflicts with the goals of the New York State Family Planning Program and with the mission, vision, and values of NYS DOH. Full compliance with the Challenged Conditions is incompatible with the current New York State Family Planning Program and with the mission of many of the current subgrantees.

77. The loss of federal Title X dollars will adversely impact New York if NYS DOH continues operating its program as it currently exists. The loss of federal Title X dollars could

result in staff and contract reductions starting April 1, 2027, directly affecting the workforce capacity available to provide family planning services.

ii. Maryland

78. The Maryland Department of Health ("MDH") has participated in the Title X program for more than 50 years and has never been denied a Title X grant. MDH currently administers the Maryland Family Planning Program ("MFPP") through 23 subrecipients—19 local health departments and four private nonprofits. MFPP is supported by both federal Title X and State funds, which are braided to support subrecipients' projects. In other words, State and federal funds together support the operations and services of each subrecipient, rather than funding distinct sets of providers or services. Accordingly, any change in either the federal or State allocation would affect the State of Maryland's entire Title X network, rather than any one subrecipient.

79. MFPP typically operates with an annual baseline of approximately $6.3 million in State funding alongside a federal Title X allocation of about $4 million. Currently, MFPP operates with slightly less funding, having received $3,778,151 in federal Title X funding in Fiscal Year 2026 along with the State's $6,319,404 cost-sharing contribution for State Fiscal Year ("SFY") 2027. As of August 2026, 64 health centers provide funded family planning services. The MFPP program employs 3.6 full-time equivalent staff, and other MDH staff assist as needed. Additionally, program funding supports 37.38 full-time equivalent roles across 78 positions with various local health departments.

80. In SFY 2025, covering July 1, 2024 through June 30, 2025, MDH's Title X subrecipients served 51,561 individuals. Approximately 61.4 percent (31,657 individuals) received services at no cost, and nearly 30 percent were uninsured. Rural health is a significant portion of MFPP's client base, as 18 of 24 Maryland jurisdictions are classified as rural and 27 percent of individuals received services in rural counties in SFY 2025. A reduction in family planning funds

would disproportionately limit access to essential screenings and care for rural Marylanders. MFPP addresses significant public health needs, including the prevention and treatment of sexually transmitted infections. MDH records reflect 30,744 chlamydia infections; 9,678 gonorrhea infections; and 1,607 primary and secondary syphilis infections in 2024. If MDH does not have access to Title X funding, MFPP expects to provide 1,447 fewer Pap smears each year, resulting in an anticipated 25 high-grade cervical pre-cancers going undetected annually.

81. The experience of individual subrecipients illustrates the scope and importance of Maryland's Title X network. For example, the Baltimore City Health Department ("BCHD"), which has participated in the Title X program since the early 1970s, currently receives $1,341,143 in funding through MFPP. Its Title X subrecipients include, among others, school-based health centers; Baltimore Systems, Inc.; and the University of Maryland Adolescent and Young Adult Clinic. During SFY 2025, BCHD served 3,095 individuals, 96.8 percent of whom received services at no cost. The Calvert County Health Department provides another, longstanding example. It currently receives a $334,046 award from MDH. During SFY 2025, the Calvert County Health Department served 659 individuals through two health centers; 99.8 percent (all but one individual) received services at no cost. These providers are representative examples of the longstanding network of Maryland providers that rely on Title X funding to provide essential family planning services to Maryland residents.

82. Maryland law reflects a commitment to providing comprehensive family planning services. Maryland law prohibits MDH from accepting restrictive federal Title X rules that exclude comprehensive family planning providers or mandate abortion-related censorship, requiring the State to backfill any federal funding declined on this basis with State funding. *See* Md. Code, Health-Gen. §§ 13-3401 to -3402. Accordingly, whenever MDH must decline federal funding

because the conditions attached to that funding are inconsistent with the State's statutory requirements, the State of Maryland is manifestly harmed by the loss of federal resources that would otherwise support MFPP.

83. To apply under the 2027 NOFO, MDH must choose between substantially restructuring its existing application and usual programming to conform to the NOFO's new priorities—which appear to be inconsistent with the existing Title X statute and regulations—or risk being denied federal funding for MDH's longstanding approach and programming. Maryland's Title X network and Maryland residents would be best served by continued access to the comprehensive services that they have historically received. If, because of this inconsistency and substantial burden, MDH cannot pursue or does not receive Title X funding, the loss of funding would represent a 38.5 percent reduction in MFPP's total operating revenue. MDH's standard allocation of State-only family planning funding could sustain only a limited portion of the program's existing activities.

iii. Massachusetts

84. Title X plays a critical role in family planning services in Massachusetts. In Fiscal Year 2026, the Commonwealth's two direct grantees received $6,506,688 in Title X family planning services grants: $5,538,547 to the Massachusetts Department of Public Health ("MA DPH") and $968,141 to Action for Boston Community Development ("ABCD"). MA DPH, which began participating in Title X in 2014, delivers services to approximately 104,000 clients a year through a network that includes 73 service sites and subrecipients statewide. ABCD, a nonprofit that has been a Title X recipient since 1973, delivers services to approximately 27,000 clients a year and supports a network that includes 28 service sites and subrecipients concentrated in Boston.

85. MA DPH administers its Title X grant through its Sexual and Reproductive Health Program. The Program breaks down barriers to care in the Commonwealth by providing voluntary, confidential, high-quality services regardless of patients' ability to pay, without judgment, and with respect for each patient's unique needs. It offers a comprehensive range of care that includes preconception health services and counseling; basic infertility services; pregnancy testing and counseling; FDA-approved long-acting and short-acting contraceptives; natural family planning methods; comprehensive STI and HIV-related services (including education, counseling, screening, treatment, PrEP, PEP, and expedited partner therapy); breast and cervical cancer screening; HPV vaccination; screening for intimate partner violence, mental health, obesity, and substance use; and adolescent-friendly health services. In 2025, MA DPH facilitated 152,875 family planning visits for 103,709 individuals; conducted 33,398 gonorrhea tests, 23,576 syphilis tests, and 49,674 HIV tests; and administered 27,102 chlamydia tests and 14,748 Pap tests to female users. The Program serves as the foundation of the Commonwealth's reproductive health care safety net by supporting inclusive and accessible sexual and reproductive health services for all people and communities.

86. The complexity of managing a statewide network requires MA DPH to begin its application process early. MA DPH must initiate conversations with its partners as soon as this fall to continue to support a high-quality network of hospitals, family planning clinics, FQHCs, and school-based health centers, while also fulfilling its legal obligations as a governmental agency subject to both state and federal regulation. *See, e.g.*, Mass Gen. Laws ch. 29, § 6B; 815 Mass. Code Regs. 2.00.

87. In 2025, Title X-funded sites in the Commonwealth served 103,709 family planning clients. 50,303 (48 percent) clients received care at no cost at all, as their incomes were

at or below 100 percent of the federal poverty line; the remainder received care on a sliding fee scale. With respect to insurance, 49,818 (48 percent) had public coverage and 10,440 (10 percent) were uninsured.

88. Title X participation provides invaluable health and significant economic benefits to the Commonwealth. In 2014, research documented that Title X-funded providers' dispensing of contraceptive and related services in the Commonwealth averted 16,200 unintended pregnancies; prevented the spread of 490 cases of chlamydia and 40 cases of gonorrhea among partners; and averted 23 cervical cancer cases, 11 precancer cases, and 49 cases of pelvic inflammatory disease in a single year alone. Absent those critical screening, contraceptive, and early-stage interventions, public sector healthcare costs for necessary downstream procedures such as maternity and birth-related services to 60 months, miscarriage and ectopic pregnancy management, and downstream STI testing would have totaled $155,220,000. Jennifer J. Frost et al., *Return on Investment: A Fuller Assessment of the Benefits and Cost Savings of the US Publicly Funded Family Planning Program*, 92 Milbank Q. 667, online app. tbls. 3–4 (2014), https://doi.org/10.1111/1468-0009.12080.

89. The Massachusetts legislature already reaches deep into the Commonwealth's coffers to provide millions of dollars in additional funding to "enhanc[e] comprehensive family planning services currently funded or previously funded by Title X." *See, e.g.*, FY2027 General Appropriations Act, 2026 Mass. Acts ch. 137, § 2, item 4513-1005. MA DPH has also invested in developing durable infrastructure to support its program, such as the Massachusetts Sexual and Reproductive Health Training Center, which provides training, technical assistance, and resources to program clinicians, administrators, support staff, and other family planning service professionals.

iv. California

90. Title X funds play a critical role in covering the costs of family planning services in California. California's sole Title X grantee, Essential Access Health, Inc. ("Essential Access"), is a nonprofit that has been a Title X recipient since the program's inception in the 1970s.

91. In 2024, Essential Access received $13,084,368 in Title X funding, which it then issued to 52 subgrantees. These subgrantees include comprehensive family planning providers, STI prevention partners, and community-based outreach and education partners. Essential Access also provides training and technical assistance to its subgrantees to enhance the capacity of Title X-funded providers to meet the individual family planning needs of all Title X patients.

92. Last year, approximately 461,218 individuals received Title X services in California. And 67 percent of the Title X-funded care was provided at no cost.

93. California's network of Title X providers ensures that California residents have access to a wide range of reproductive and preventive health services, including contraceptive care; STI and HIV prevention education, counseling, testing and treatment; adolescent services; infertility services; and pregnancy testing and options counseling. Compared with other publicly funded family planning providers, Title X-funded providers are more likely to offer certain specialized services on-site, including vasectomies and long-acting reversible contraception, which can have higher up-front costs. Access to effective family planning services has also been demonstrated to be a cost-effective use of public funds, generating significant savings in health care expenditures. Title X-funded providers also demonstrate greater adherence to evidence-based protocols, such as chlamydia screening guidelines; are more likely to incorporate advanced technologies in their clinics; and are more likely to participate in clinical training opportunities.

94. California's Title X-funded providers also play an important role in serving populations that face barriers to accessing care. They have greater proportions of bilingual staff

and are more likely to serve individuals who have low incomes, are uninsured, are under age 25, or identify as a person of color. Title X-funded providers are also more likely than other publicly funded family planning providers to offer extended clinic hours and provide sexual and reproductive health education.

95. Essential Access intends to submit an application in response to the 2027 NOFO and is currently assessing how its Title X program could be restructured to respond to the NOFO's Agency Priorities, including the Challenged Conditions, while continuing to comply with existing Title X program requirements. Several of these new priorities create significant tension with the current program model and with the goals, mission, and values of Essential Access and some current subrecipients. For example, it is unclear how to appropriately deemphasize hormonal birth control while continuing to ensure access to hormonal contraception consistent with Title X program requirements, or how the priority of reducing crime should be operationalized within a family planning program. These tensions create significant uncertainty regarding how Essential Access can structure its program to respond to the 2027 NOFO while maintaining compliance with existing Title X requirements and supporting its current work.

v. Other Plaintiff States' Title X Programs

96. In Fiscal Year 2026 (FY2026), $3,966,199 in Title X family planning services grant funding flowed into Colorado to the state's only direct grantee, the Colorado Department of Public Health and Environment.

97. In FY2026, $2,365,504 in Title X family planning services grant funding flowed into Connecticut.

98. In FY2026, $1,070,842 in Title X family planning services grant funding flowed into Delaware to the state's only direct grantee, Delaware Health and Social Services.

99. In FY2026, $1,942,880 in Title X family planning services grant funding flowed into Hawai‘i.

100. In FY2026, $8,014,106 in Title X family planning services grant funding flowed into Illinois, including a direct grant of $5,055,829 to the Illinois Department of Public Health.

101. In FY2026, $4,693,969 in Title X family planning services grant funding flowed into Kentucky, to the state's only direct grantee, the Kentucky Cabinet for Health and Family Services. The Department for Public Health, an agency of the Cabinet for Health and Family Services, receives and administers Title X funds. See KRS 11.065. The Governor of Kentucky appoints the Cabinet Secretary and approves the Cabinet Secretary's appointment of the Commissioner of the Department for Public Health. KRS 12.050; KRS 12.255; KRS 194A.030.

102. In Maine, the Family Planning Association of Maine, Inc. ("Maine Family Planning") has received Title X funding since the 1970s. The funding supports Maine Family Planning's network of approximately 63 sites throughout Maine, which include health centers directly operated by Maine Family Planning and its subgrantee partners. Maine Family Planning was awarded $1,780,971 in Title X family planning services funds for FY2026.

103. Under Maine law, the Department of Health and Human Services must provide funding to offset any reduction in Title X funds received by a Title X grantee, as compared to the Title X funding it received in fiscal year 2024–2025, if the reduction is due to an action by the Federal government or a decision by the grantee to withdraw from receiving Title X funds due to conditions attached to them. 22 M.R.S.A. § 1912 (2026).

104. In FY2026, $7,178,497 in Title X family planning services grant funding flowed into Michigan, to the state's only direct grantee, the Michigan Department of Health and Human Services.

105. In FY2026, $3,313,063 in Title X family planning services grant funding flowed into Minnesota.

106. In FY2026, $3,985,318 in Title X family planning services grant funding flowed into Nevada, including a direct grant of $174,750 to the Nevada Department of Human Services.

107. In FY2026, $8,075,812 in Title X family planning services grant funding flowed into New Jersey.

108. In FY2026, $2,993,324 in Title X family planning services grant funding flowed into New Mexico, to the state's only direct grantee, the New Mexico Department of Health.

109. In FY2026, $2,961,906 in Title X family planning services grant funding flowed into Oregon, to the state's only direct grantee, the Oregon Health Authority Public Health Division.

110. In FY2026, $12,729,659 in Title X family planning services grant funding flowed into Pennsylvania.

111. In FY2026, $1,083,848 in Title X family planning services grant funding flowed into Rhode Island to the Rhode Island Department of Health.

112. In FY2026, $790,719 in Title X family planning services grant funding flowed into Vermont, to the state's only direct grantee, the Vermont Agency of Human Services.

113. In FY2026, $5,608,656 in Title X family planning services grant funding flowed into Virginia, including a direct grant of $3,258,656 to the Virginia Department of Health.

114. In FY2026, $4,297,649 in Title X family planning services grant funding flowed into Washington, to the state's only direct grantee, the Washington State Department of Health.

115. In FY2026, $2,864,620 in Title X family planning services grant funding flowed into Wisconsin, to the state's only direct grantee, the Wisconsin Department of Health Services.

C. The 2027 NOFO

116. On July 9, 2026, the Department published the 2027 NOFO soliciting applications for a five-year term with an anticipated grant award date of April 1, 2027. The July 9 NOFO replaced an earlier version issued on April 3, 2026. The deadline to apply for funding under the 2027 NOFO is January 11, 2027. Ex. A, 1.

117. The 2027 NOFO marks a drastic change in Title X policy, requiring Title X programs to "align" with Agency Priorities established by multiple agencies, specifically HHS, OASH, and OPA. The 2027 NOFO directs applicants' proposals to address the Agency Priorities, incorporates assessments of each proposal's conformity with the priorities at several stages of the evaluation process, and conditions funding on ongoing alignment with the priorities in both "program design and activities" after grants have been awarded. *Id.* at 7. The Agency Priorities contain novel conditions that depart from the Department's past practices, are vague and undefined, and are in tension with the statutory and regulatory requirements of Title X.

118. Specifically, Section B of the 2027 NOFO, entitled "Required Alignment with OASH Mission and Agency Priorities," announces that "recipients" must align "program design and activities" with OASH priorities (attached as Exhibit E). Ex. A, 7. The OASH Priorities, included by reference in the NOFO, are:

- Addressing the chronic disease epidemic;
- Ending diversity, equity, and inclusion (DEI) policies and practices across OASH's programs;
- Reducing overmedicalization in health care and increasing focus on optimal health and addressing underlying root causes;
- Providing medically accurate and reliable information necessary for informed consent;
- Ending support for gender ideology, including sex-rejecting procedures for children, and ensuring evidence-based care;

- Enforcing the Hyde Amendment;
- Ensuring gold standard science, curtailing corporate capture and preventing conflicts of interest;
- Ensuring OASH funds benefit eligible individuals and not illegal aliens;
- Ensuring adolescent program materials are age appropriate;
- Protecting parental rights to direct the religious upbringing of their children.

Ex. E, 1–3 ("OASH Priorities").

119. Section B also requires Title X projects to "demonstrate ongoing compliance" with three additional OPA-specific "objectives," including advancement of "reproductive goals counseling." Ex. A, 7.

120. Section C.a.4.i. provides that proposals should align with priorities from OPA, which are "informed" by the OASH priorities and include the three additional OPA-specific objectives:

- Addressing the chronic disease epidemic through the delivery of Title X services;
- Reducing overmedicalization in health care and increasing focus on optimal health through the delivery of Title X services;
- Promoting body and health literacy through the delivery of Title X services;
- Advancing reproductive goals counseling through the delivery of Title X services;
- Promoting evidence-based care through the delivery of Title X services;
- Enforcing the Hyde Amendment through the delivery of Title X services;
- Ensuring OASH funds benefit eligible individuals and not illegal aliens through the delivery of Title X services;
- Implement[ing] a Quality Improvement and Quality Assurance (QI/QA) Plan.

Ex. A, 10–14 ("OPA Priorities").

121. The 2027 NOFO further states that the OPA program office will consider "[a]lignment with HHS [] priorities" when making its recommendations for funding. Ex. A, 41. The 2027 NOFO does not list, cite, or link to these priorities, nor does it qualify or explain their application in the Title X context. HHS's official agencywide priorities, published on its website, list "combat[ing] gender ideology" and "prohibit[ing] funding recipients from conducting DEI programs," as well as other priorities apparently unrelated to either the provision of family planning services or the NOFO, such as "[e]nd[ing] crime and disorder on America's streets." *See HHS Priorities*, U.S. Dep't Health & Hum. Servs. (rev. Sept. 30, 2025), https://www.hhs.gov/about/priorities/index.html ("HHS Priorities") (attached as Exhibit F).

122. The incorporation of these Agency Priorities in the 2027 NOFO defines and constrains the scope of the entire Title X grantmaking process from the pre-submission application stage all the way to the post-award grant stage.

123. Overall, the NOFO requires that projects "must align program design and activities with agency priorities . . . [and] demonstrate ongoing compliance with [them]" to avoid termination and binds applicants to the "activities" described in the application. Ex. A, 7.

124. As early as the application stage, the NOFO imposes its priorities to constrain prospective recipients' proposals. The NOFO requires applicants to provide a Project Narrative, which is "the primary basis to determine whether [a] project merits an award," and makes clear that to be successful, the "proposal should include . . . plans and strategies for providing family planning services that address OPA program priorities." *Id.* at 19–21.

125. The NOFO also embeds the Agency Priorities in the process for evaluating applications at both the merit review stage and the federal staff review stage that follows it. For the merit review, the NOFO establishes a 100-point scoring rubric based on various review criteria

according to which "[f]ederal staff and an independent merit review panel will assess all qualified eligible applications." *Id.* at 39. The most significant single criterion in the merit review rubric—valued at 35 potential points out of a total of 100—is the "extent to which the applicant proposes strategies that meaningfully advance OPA's program priorities . . . and HHS priorities." *Id.* at 40.

126. Meanwhile, factors drawn directly from the Title X statute are awarded significantly fewer points. For example, "the degree to which [applications] adequately provide[] for the requirements set forth in the Title X statute, regulations . . . and legislative mandates" is worth only 15 points. *Id.*

127. The NOFO also incorporates consideration of alignment with HHS and OASH Priorities at the final stage of federal staff review. After receiving the merit scores, OPA "coordinate[s] with a senior appointee to provide recommendations for funding to the Grants Management Officer." *Id.* at 41. When providing these recommendations, "the program office will take into consideration . . . [a]lignment with HHS and OASH priorities." *Id.*

128. Last, the NOFO establishes that applicants' proposed project designs will become grounds for subsequent termination of awards if later deemed not aligned with the Agency Priorities: "[R]ecipients must demonstrate ongoing compliance with these priorities, in all programs that are authorized to advance them, through program design, implementation, reporting, and evaluation. Failure to meaningfully align . . . may result in corrective action . . . including termination pursuant to 2 C.F.R. 200.340(a)(4) for no longer effectuating program goals or agency priorities." *Id.* at 7. Applicants' behavior is necessarily shaped by this threat of funding termination for failure to align a program's design with the Agency Priorities.

129. The NOFO occasionally and inconsistently appends vague savings clauses to the priorities incorporated across these stages of the grant cycle. For instance, when embedding the

priorities into application preparation requirements, it states that "to the extent authorized by law and within the scope of the program, OPA expects recipients to develop and implement plans to address the program priorities and provide evidence of the project's capacity to address program priorities." *Id*. at 10. However, when embedding the priorities into the merit review rubric, the NOFO includes no such limiting clause. *Id*. at 40. The NOFO never explains what limits these clauses functionally impose.

130. Plaintiff States, Title X grantees, and the public at large were not given notice and an opportunity to comment on any of the terms contained in the 2027 NOFO.

D. Plaintiff States' Challenge to the 2027 NOFO

i. The Challenged Conditions

The Anti-DEI Priority

131. The 2027 NOFO conditions funding upon a prospective recipient's alignment with both HHS's and OSHA's Anti-DEI Priority. Ex. A, 7, 11. Collectively, these HHS and OASH anti-DEI priorities constitute the Department's "Anti-DEI Priority."

132. Where the HHS Anti-DEI Priority specifically calls for the end of DEI programs *by funding recipients*, the OASH Anti-DEI Priority states that "[e]nding diversity, equity, and inclusion (DEI) policies and practices *across OASH's programs*" is a priority. Ex. E, 1 (emphasis added). The Priority explains that OASH seeks to "prioritize efforts that go beyond the use of ideologically laden concepts," like "health equity," which it defines as a focus "on identifying and documenting worse health outcomes for minority populations." *Id*. at 2.

133. To the extent the Anti-DEI Priority deprioritizes programs that advance inclusivity and equity, then it contradicts Title X regulations in two ways. *First*, Title X regulations require grantees to provide services in an "inclusive" and "equitable" manner and encourage participation from "diverse persons." 42 C.F.R. §§ 59.5(a)(3), (b)(3)(iii); *see also id.* § 59.2 (defining "inclusive"

as "when all people are fully included and can actively participate in and benefit from family planning, including, but not limited to, individuals who belong to underserved communities," specifically identifying racial and ethnic minorities and "lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons").

134. Additionally, the 2027 NOFO gives no explanation of how applicants are expected to align with the Anti-DEI Priority, nor does it ever acknowledge or explain Defendants' decision to reverse Title X policies upon which grantees have long relied. Rather, Defendants imposed the Anti-DEI Priority without providing any guidance on how prospective grantees are expected to reconcile the apparent conflicts with Title X regulations in their applications. That confusion is heightened by the NOFO's generic and sporadic disclaimers that Agency Priorities apply only "to the extent authorized by law." For example, the NOFO does not clarify to what "extent" OPA expects applicants can reject health equity while simultaneously still advancing it.

135. The NOFO never directly addresses, acknowledges, or offers a reasoned explanation for the agency's apparent about-face on the role of diversity, health equity, and inclusiveness in Title X programs.

136. Moreover, the NOFO does not explain what the Anti-DEI Priority means in the context of Title X family planning services grants and how applicants, including those in Plaintiff States, can craft grant proposals that will align with it. Nor does it offer a reasoned explanation of its decision to depart from past practices that have engendered serious reliance interests among Plaintiff States, which now depend on longstanding Title X programs and networks that have been designed to comply with Title X statutes and regulations.

The Anti-Gender Ideology Priority

137. The 2027 NOFO conditions Title X funding on applicants' compliance with a number of priorities targeting transgender individuals and transgender healthcare in contravention of the law of Title X.

138. Under the 2027 NOFO, the Department will "prioritize funding for grantees who maintain a science-driven approach to healthcare, including by protecting children, [and] respecting biological reality." Ex. A, 13. Applicants are expected "to demonstrate how their Title X projects promote physical and reproductive health priorities established by HHS," *id.*, including the HHS Priority to "[c]ombat gender ideology and protect children," which the Department describes as ensuring programs "accurately reflect science, including the biological reality that a person's sex as either male or female is unchangeable and determined by objective biology," Ex. F, 6.

139. Similarly, the 2027 NOFO adopts the OASH priority of "[e]nding support for gender ideology, including sex-rejecting procedures for children, and ensuring evidence-based care." Ex. E, 2. The OASH Priority states that it will "deprioritize programs" that engage in medical interventions, such as "puberty blockers, cross-sex hormones, and surgeries, that attempt to reject a child's sex," and prioritize programs "that accurately reflect the scientific biological reality of sex." *Id*.

140. Collectively, these priorities targeting transgender individuals and transgender health care form the "Anti-Gender Ideology Priority."

141. To the extent the Anti-Gender Ideology Priority deprioritizes programs that provide reproductive healthcare for LGBTQ+ individuals, it appears to conflict with Title X regulations that explicitly require family planning projects to ensure they are conducted in an "inclusive" and "equitable" manner and encourage participation from "diverse persons." 42 C.F.R. §§ 59.5(a)(3),

(b)(3)(iii); *see id.* § 59.2 (defining "inclusive" as "all people . . . including . . . lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons").

142. Title X regulations also require that transgender persons be "fully included and can actively participate in and benefit from family planning," *id.* § 59.2, and prohibit the provision of services in a manner that discriminates on the basis of "gender identity" and "sex characteristics," *id.* § 59.5(a)(4).

143. The Anti-Gender Ideology Priority's expectation that applicants "ensure" that programs "reflect . . . the biological reality that a person's sex as either male or female is unchangeable" is in tension with these regulatory commands. Ex. F, 6. Fully including transgender individuals in Title X family planning, and providing care in an equitable and nondiscriminatory manner, necessarily involves recognizing the needs and interests of transgender individuals—realities that Title X applicants must now reject to receive funding.

144. The Anti-Gender Ideology Priority is contrary to (i) the prevailing views of most major medical organizations, including multiple nationally recognized standards of family planning care recognized by OPA in agency materials and the agency's own such standard, *see* Ex. C, 10–11; Ex. D, S72–73, (ii) the prevailing standard of care in Plaintiff States, and (iii) laws in many Plaintiff States that protect transgender individuals against discrimination and guarantee access to gender affirming medical care.

145. The NOFO never directly addresses, acknowledges, or explains OPA's apparent departure from its past position on transgender nondiscrimination and inclusion within Title X programs.

146. Moreover, Defendants have not explained what the Anti-Gender Ideology Priority means in the context of Title X programs and how applicants, including those in Plaintiff States,

can craft proposals that will demonstrate alignment with it while still complying with existing Title X regulations.

The Overmedicalization Priority

147. The NOFO conditions Title X funding on applicants' and recipients' alignment with OPA's priority to "[r]educe overmedicalization in health care and increas[e] focus on optimal health through the delivery of Title X services . . . ." Ex. A, 11 (hereinafter the "Overmedicalization Priority"). The NOFO refers to contraception only once—within the context of the Overmedicalization Priority. To the extent it requires applicants and grantees to deemphasize contraception, the Overmedicalization Priority is contrary to law and is arbitrary and capricious.

148. According to the 2027 NOFO, OPA "recognizes the overreliance on pharmaceutical and surgical treatments" and expects applicants "to demonstrate how their Title X projects will integrate noninvasive, evidence-based practices that promote health literacy, fertility awareness, and reproductive health without unnecessary medicalization or symptom suppression." *Id*. at 11–12. The 2027 NOFO further states that "[k]ey strategies for advancing optimal health through Title X services include, but are not limited to, expanding access to fertility-awareness-based methods (often referred to as natural family planning) . . . ." *Id.* at 12.

149. The NOFO does not explain what it means to "integrate noninvasive, evidence-based practices that promote health literacy, fertility awareness, and reproductive health without unnecessary medicalization or symptom suppression." *Id.* Rather, the NOFO appears to equate any form of contraception other than "fertility-awareness-based methods" with "unnecessary medicalization or symptom suppression." *Id.*

150. Despite Title X's historical focus on offering a broad range of contraceptive services to program clients, the 2027 NOFO strongly suggests that applicants that provide access

to a broad range of methods of family planning would not be considered to be sufficiently "aligned" with the Overmedicalization Priority.

151. And if the Overmedicalization Priority does require grantees to deemphasize medical contraception in favor of natural family planning, that would be contrary to nationally recognized standards, depart from OPA's own evidence-based best practices, and contravene Title X's core mandate to "offer a broad range of acceptable and effective family planning methods and services." 42 U.S.C. § 300(a).

152. By definition, "family planning services include a broad range of *medically* approved services, which includes [FDA]-approved contraceptive products." 42 C.F.R. § 59.2 (emphasis added). The Title X regulations further explain that Title X projects "shall" consist of the "comprehensive medical . . . services necessary to aid individuals to determine freely the number and spacing of their children." *Id.* § 59.1.

153. Moreover, the regulations require that if any organization "offers only a single method of family planning, it may participate as part of a project as long as the entire project offers a broad range of acceptable and effective medically approved family planning methods and services." *Id.* § 59.5(a)(1); *see also id.* (a service site that cannot provide a range of acceptable and effective medically approved family planning methods and services "must be able to provide a prescription to the client for their method of choice or referrals to another provider.").

154. The shift away from contraception as a method of family planning also contradicts OPA guidance defining its own 2024 QFP as "a nationally recognized standard of care" for providers to follow "when implementing the Title X requirements." Ex. B, 2. The 2024 QFP instructs providers to keep "a broad range of Food and Drug Administration (FDA)-approved or FDA-cleared contraceptive products . . . available on-site," recognizes the variety of indications

for use of contraception "other than pregnancy prevention" (such as menstrual regulation, STI prevention, and endometriosis), and adopts a patient-centered approach. Ex. D, S54–57.

155. The NOFO never directly addresses, acknowledges, or offers a reasoned explanation supported by relevant evidence for its apparent departure from OPA's past position on contraception within Title X programs.

156. Defendants have not explained what the Overmedicalization Priority means in the context of Title X programs and how applicants, including those in Plaintiff States, can craft proposals that will demonstrate alignment with it while still complying with existing Title X regulations and fulfilling Title X's core mandate established by statute.

The Hyde Amendment Priority

157. The 2027 NOFO directs applicants and grantees to align with OPA's priority entitled "Enforcing the Hyde Amendment" (hereinafter the "Hyde Amendment Priority"). Ex. A, 13–14.

158. Despite the name, this priority is not connected with enforcing the Hyde Amendment; rather, it seeks to impose additional restrictions beyond the Hyde Amendment. The Department states that it "will prioritize programs and funding that uphold Hyde protections and do not use taxpayer resources to promote or support elective abortion," and that recipients are expected to "demonstrate how their Title X projects maintain strict separation from prohibited activities and contribute to broader HHS efforts to safeguard life-affirming, lawful, and ethical program delivery." *Id.* at 14.

159. The Hyde Amendment does not apply to Title X. Rather, by statute, Title X funds may not be used in programs where abortion is a method of family planning. *See* 42 U.S.C. § 300a-6.

160. Since 1996, Congress has included in every appropriations bill for Title X the mandate that "all pregnancy counseling [in the Title X program] shall be nondirective." *See* Pub. L. 119-75, 140 Stat. at 262. Title X regulations also require that funded programs provide "neutral, factual information and nondirective counseling" when asked about pregnancy options, including "[p]regnancy termination," and that Title X programs provide referrals to abortion services upon request. 42 C.F.R. § 59.5(a)(5)(i)–(ii).

161. The 2027 NOFO does not explain what it means to "enforce the Hyde Amendment through the delivery of Title X services" or to "contribute to broader HHS efforts to safeguard life-affirming, lawful, and ethical program delivery." Ex. A, 14. Applicants are left in an untenable position of committing themselves to aligning with the indefinite and unclear Hyde Amendment Priority for the duration of the grant.

162. It is also not clear what the applicant must do "to safeguard life-affirming, lawful, and ethical program delivery" or "maintain strict separation from prohibited activities." The inclusion of these terms under the heading "Enforcing the Hyde Amendment" appears to indicate that they reflect opposition to abortion and extend to matters beyond what the Hyde Amendment requires. Absent any effort by Defendants to explain the priority's concrete meaning in the current Title X regulatory context, its language raises the prospect that any grantee or subgrantee that provides abortion outside of the Title X program would not be considered sufficiently "aligned" with this Agency Priority to receive funding.

163. To the extent that the Hyde Amendment Priority's requirements of "life-affirming" program delivery and "maintain[ing] strict separation" differ from existing regulations, such as by prohibiting non-directive options counseling or referrals to abortion care upon request, they conflict with Title X's statutory and regulatory requirements.

164. To the extent the Hyde Amendment Priority represents a change in agency position relating to abortion counseling or compliance with separation requirements, the NOFO never directly addresses, acknowledges, or offers a reasoned explanation supported by relevant evidence for its departure from OPA's past positions.

165. Defendants have not explained what the Hyde Amendment Priority means for Title X and how applicants, including those in Plaintiff States, can craft proposals that will demonstrate alignment with it while still complying with existing Title X regulations.

166. In addition, Plaintiff States, and Title X recipients within them, have built and rely on systems to ensure compliance with the prohibition of using federal Title X funds for abortion. Those systems are not designed to enforce the significant changes from existing Title X requirements that the Hyde Amendment Priority appears to represent.

The Directive Counseling Priority

167. The 2027 NOFO states that OPA is interested in "innovative strategies to . . . advance reproductive goals counseling for all clients," referred to herein as the "Directive Counseling Priority." Ex. A, 3. "Advanc[ing] reproductive goals counseling" is one of the three OPA-specific priorities singled out as special "objectives in Title X." *Id.* at 7; *see also id.* at 12–13. The Directive Counseling Priority is embedded at all stages of the grant process: applicants must address it, submissions are judged on it, and grantees face termination if they fail to align with it.

168. Based on this priority, Title X clinics will be "expected to offer reproductive goals counseling that presents evidence-informed pathways associated with improved economic stability and family stability, including . . . marriage prior to childbearing . . . . Program counseling should affirm marriage and parenthood as meaningful and valued components of adult life." *Id.* at 13.

169. The 2027 NOFO informs applicants that "[s]uccessful proposals" will include a Project Narrative addressing OPA program priorities including "[a]dvancing reproductive goals counseling." *Id.* at 19, 21. Further, applicants' Work Plan *must* indicate, "[f]or each direct service site," the specific "services (including . . . reproductive goals counseling . . .) that will be provided directly at the site" and offer "a justification for any . . . services that will not be available at the site along with a description of how you will ensure client access for" those services. *Id.* at 23–24.

170. The Directive Counseling Priority is contrary to congressional and regulatory requirements for Title X.

171. The 2027 NOFO's prioritization of projects that "advance reproductive goals counseling *for all clients*," *id*. at 3 (emphasis added), by advising them on the "meaningful and valued" nature of parenthood, *id.* at 13, conflicts with Congress's mandate that "all pregnancy counseling shall be nondirective" in Title X projects, Pub. L. 119-75, 140 Stat. at 262. And regulations that require programs offer pregnant clients the opportunity to receive "neutral, factual information and nondirective counseling" about any of a slate of options, of which parenthood is only one, cannot coexist with the Directive Counseling Priority. *See* 42 C.F.R. 59.5(a)(5).

172. It is not clear how Title X grantees can, on the one hand, promote "marriage prior to childbearing" and "affirm marriage and parenthood as meaningful and valued," Ex. A, 13, while, on the other hand, provide "client-centered" care "in a manner that does not discriminate against any client based on . . . number of pregnancies, or marital status," 42 C.F.R. § 59.5(a)(3)–(4).

173. It is similarly unclear how grantees can comply with the Directive Counseling Priority while also meeting the obligation to offer "quality service delivery consistent with nationally recognized standards of care." *Id.* at § 59.5(a)(3). OPA's own recommended standard,

the QFP, reflects consensus in directing providers to facilitate patients' "ability to self-determine . . . their reproductive goals" and to "avoid attempts to redirect their goals." Ex. D, S44, S50.

174. The NOFO never directly addresses, acknowledges, or offers a reasoned explanation supported by relevant evidence of any apparent departure from OPA's past position on nondirective counseling within Title X programs.

175. Defendants have not explained what the Directive Counseling Priority for Title X means in the context of Title X programs, or how applicants, including those in Plaintiff States, can craft proposals that will demonstrate alignment with it while still complying with statutory and regulatory requirements to provide nondirective, nondiscriminatory, client-centered counseling.

The Irrelevant HHS Priorities

176. The 2027 NOFO incorporates a directive to align with several HHS priorities that have nothing to do with Title X or the provision of family planning services. The largest portion of a Title X applicant's score (35 points out of a possible 100 points) will be based on the "extent to which the applicant proposes strategies that meaningfully advance" OPA and HHS priorities. Ex, A, 39–40. The HHS priorities include "[f]urther[ing] our understanding of autism," "[i]nvestigat[ing] and car[ing] for those with Long COVID," "[a]dvanc[ing] the scientific understanding of the agency process," "[e]nd[ing] crime and disorder on America's streets," and "[i]mprov[ing] oversight of foreign funded institutions." Ex. F, 3–7. Collectively, these five priorities together constitute the "Irrelevant HHS Priorities."

177. Defendants do not explain how alignment with these seemingly irrelevant HHS priorities is "within the scope" of the Title X Program, or what they mean in the context of Title X programs. Ex. A, 41. None of these priorities advance the goals or purposes of the Title X program. Nor have Defendants explained how applicants, including those in Plaintiff States, can craft proposals that will demonstrate alignment with them.

ii. The 2027 NOFO Harms Plaintiff States and Their Citizens

178. Without intervention, the 2027 NOFO will harm Title X applicants, including Plaintiff States, and their citizens.

179. For decades, Plaintiff States have effectively managed Title X programs in their States directly, indirectly through subgrantees and grant recipients, or in both ways. These Title X programs, as Congress intended, provide high-quality family planning services to millions of citizens, many of whom live in rural and underserved communities and are among marginalized populations.

180. Now, Plaintiff States face imminent fiscal injuries in the potential loss of grant funds, increased administrative costs to reformulate applications and modify programs to remain competitive, increased state budget costs to fill the gap of any Title X funding shortfall and/or increased downstream healthcare costs if additional state funding isn't available to continue offering covered services. All such fiscal injuries are directly traceable to Defendants' conduct.

181. Plaintiff States have relied on Title X funding to establish and maintain their family planning programs, and their citizens have relied on their programs to obtain critical—and sometimes even lifesaving—services. Plaintiff States' participation in the Title X program has strengthened not just the health of their citizens but also the financial health of their public health infrastructure. Every dollar of Title X funding saves over $7 of downstream public expenditures, in large part because it invests in critical early-stage screening and preventive care. Jennifer J. Frost et al., *Return on Investment: A Fuller Assessment of the Benefits and Cost Savings of the US Publicly Funded Family Planning Program*, 92 Milbank Q. 667, 696 (2014), https://doi.org/10.1111/1468-0009.12080. For example, birth control access reduces rates of unintended pregnancies; STI testing means fewer untreated and transmitted STIs; and Pap smears allow earlier-stage cervical cancer diagnoses. And, in reliance on consistent Title X funding to

other grantees in Plaintiff States, Plaintiff States have built up state-funded counterparts and state-specific infrastructure to bolster the federal Title X program and ensure their citizens receive these critical reproductive health services.

182. Plaintiff States have established long-term relationships with trusted community partners that provide Title X services, and many of those partners will be unable to continue to provide these essential services should Title X funding be denied to Plaintiff States or to longstanding qualified grantees within Plaintiff States.

183. Plaintiff States reasonably fear that their existing programs will not satisfy the 2027 NOFO's requirement of alignment with the Agency Priorities, including the Challenged Conditions, should they seek to maintain current Title X programs that are structured to comply with Title X's existing statutory and regulatory mandates.

184. Because the NOFO gives disproportionate weight to an application's alignment with the Agency Priorities—35 points of 100, representing more than one third of the total, including the remaining statutory and regulatory factors—it is highly likely that Defendants will deny grants to existing grantees that it views as not aligned with those priorities. The NOFO thus places existing grantees, including Plaintiff States and other grantees within their borders, at a significant disadvantage. Plaintiff States have built their existing Title X programs in light of the program's statutory and regulatory framework and core purpose. Applicants must either craft a grant application based on their existing, well-established programming that meets Title X's statutory and regulatory mandates and risk rejection for lack of alignment with the Agency Priorities or attempt to craft an application based on an entirely new program to increase their chances of being considered aligned and therefore meaningfully competitive under the NOFO.

185. Applicants that take the latter path will be forced to expend hundreds of hours of additional staff time and effort to creating entirely new programs, over and above what would be required to apply based on their established programs. To do so would also likely require finding new subgrantees to provide services. And it would leave many well-established, qualified grantees and subgrantees that serve critical populations to languish and even close, to the detriment of Plaintiff States and their citizenry.

186. Plaintiff States that apply for new programs also face increased administrative costs and increased healthcare costs. Realigning state programs away from family planning programs that meet Title X's statutory and regulatory factors and guidance—including the Department's own guidance regarding nationally-recognized standards of care—and towards the new Agency Priorities, including the Challenged Conditions, will increase States' downstream healthcare costs by redirecting state spending away from cost-effective, evidence-based services.

187. Plaintiff States applying for new programs will also be forced to expend significant administrative costs to reorganize longstanding subrecipient networks and existing Title X infrastructure to ensure subgrantee alignment.

188. Plaintiff States attempting to comport with the Challenged Conditions will struggle to conform their applications to the Agency Priorities on the one hand, and with inconsistent Title X regulations and guidance and their own state laws on the other.

189. For example, some state laws mandate the provision of a comprehensive family planning program; prohibit discrimination in provision of health care including on the basis of gender identity; and protect access to gender-affirming care. States with such requirements, including many Plaintiff States, face grave difficulty in crafting a program that will satisfy the

Agency Priorities, including the Challenged Conditions, and still comply with their state laws, even if they can determine what the new priority terms mean or require.

190. In States that lose Title X funding, many Title X providers will face risk of closure. Losing access to critical Title X resources would reduce the healthcare workforce, increase wait times for patient appointments, eliminate or severely cut back community outreach and education and quality improvement activities, and reduce capacity to meet the family planning needs of patients. States will be forced to cover the long- and short-term cost of the resulting worsened health outcomes for their residents, including higher rates of unintended pregnancy, STIs, cancer, and HIV and AIDS.

191. Plaintiff States also suffer here-and-now competitive injury because Defendants have changed the rules to tilt the process against Plaintiff States' Title X programs. The 2027 NOFO renders Plaintiff States and other Title X grantees within their borders unable to fairly compete for Title X funds despite their programs' long history of providing Title X services, both denying them their one-time chance to participate in a fair competition and favoring their competitors.

192. To the extent the Challenged Conditions conflict with or purport to alter existing legislative Title X regulations, the Department was required to provide notice and comment, and its failure to do so harmed Plaintiff States by depriving them of the opportunity to comment on a regulatory issue critical to Plaintiffs States and their citizens.

CAUSES OF ACTION

COUNT I
(Violation of the APA – Contrary to Law, 5 U.S.C. § 706(2)(A), (C))

193. Plaintiff States incorporate by reference the allegations contained in the preceding paragraphs.

194. The Department is an "agency" under the APA. 5 U.S.C. § 551(1).

195. The APA requires that a court "hold unlawful and set aside agency action, findings, and conclusions found to be . . . not in accordance with law," 5 U.S.C. § 706(2)(A), or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," *id.* § 706(2)(C). This includes action that is contrary to or violative of the agency's own "existing valid regulations." *United States ex rel. Accardi v. Shaughnessy*, 347 U.S. 260, 268 (1954).

196. The Title X statute requires that "[g]rants and contracts made under this subchapter shall be made in accordance with such regulations as the Secretary may promulgate." 42 U.S.C. § 300a-4(a).

197. The 2027 NOFO constitutes final agency action and marks the consummation of the agency's decision-making process as to its policy priorities and criteria for evaluating Title X grant applications and issuing awards for fiscal year 2027. Because the NOFO establishes criteria and mandates for Title X applications and grant awards, rights and obligations are therefore determined by, and legal consequences flow from, the NOFO.

198. The Challenged Anti-DEI Priority, Anti-Gender Ideology Priority, Overmedicalization Priority, Hyde Amendment Priority, and Directive Counseling Priority either undermine or directly conflict with numerous Title X regulations and law.

199. For example, the Anti-DEI Priority conflicts with Title X regulations that require grantees to provide services in an "inclusive" and "equitable" manner and encourage participation from "diverse persons." 42 C.F.R. §§ 59.5(a)(3), (b)(3)(iii); *see also id.* § 59.2.

200. The Anti-Gender Ideology Priority, to the extent it requires applicants to mistreat, treat differently, or refuse to provide transgender individuals services in an inclusive manner, conflicts with Title X regulations which require Title X projects to provide services in a manner

that is "inclusive" and "equitable," encourage participation from "diverse persons," and prohibit discrimination on the basis of gender identity and sex characteristics. *Id.* §§ 59.5(a)(3), (b)(3)(iii); *id.* § 59.5(4); *see also id.* § 59.2.

201. The Overmedicalization Priority, to the extent it requires an emphasis on the promotion of fertility and natural family planning and deemphasis on contraception (including hormonal contraception), contravenes Title X's central purpose to support the establishment and operation of voluntary family planning projects which shall offer "a broad range of acceptable and effective family planning methods and services." 42 U.S.C. § 300(a); *see* 42 C.F.R. § 59.2 (defining "family planning services" to include "[FDA]-approved contraceptive products and natural family planning methods"). Moreover, the Overmedicalization Priority contradicts the mandate that Title X projects consist of "comprehensive medical [] services necessary to aid individuals to determine freely the number and spacing of their children," 42 C.F.R. § 59.1.

202. The Directive Counseling Priority, to the extent it requires counseling "all clients" towards marriage and parenthood, conflicts with the congressional mandate that "all pregnancy counseling be nondirective" under Title X, Pub. L. No. 119-75, 140 Stat. at 262, and regulations that require grantees to offer "pregnant clients" "neutral, factual information and nondirective counseling" on any pregnancy option (of which parenthood is only one), 42 C.F.R. § 59.5(a)(5). The Directive Counseling Priority also conflicts with regulations that require grantees to provide client-centered, quality services that do not discriminate based on marital status. *Id.* § 59.5(a)(3).

203. The Hyde Amendment Priority, to the extent it forbids grantees from providing nondirective counseling to pregnant clients about their pregnancy options, including termination, conflicts with federal regulations and the congressional appropriations rider requiring them to do just that. 42 C.F.R. § 59.5(a)(5); Pub. L. No. 119-75, 140 Stat. at 262.

204. The 2027 NOFO thus exceeds the Agency's authority and is contrary to the Title X statute and regulations.

COUNT II
(Violation of the APA – Arbitrary, Capricious, and Abuse of Discretion, 5 U.S.C. § 706(2)(A))

205. Plaintiff States incorporate by reference the allegations contained in the preceding paragraphs.

206. The APA requires that a court "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary [or] capricious." 5 U.S.C. § 706(2)(A).

207. The 2027 NOFO is arbitrary and capricious because, among other things, the Challenged Conditions are vague; reverse course within Title X without acknowledgement, reasoned explanation, or consideration of reliance interests; and are unreasoned, fail to consider important aspects of the problem, and are counter to the evidence before the agency.

208. The Challenged Conditions are arbitrary and capricious because their ambiguous language and unresolved conflicts with other Title X requirements preclude prospective grantees from ascertaining what standard the OPA and the Department expects them to follow, and denies them fair notice.

209. The Anti-DEI, Anti-Gender Ideology, Overmedicalization, Hyde Amendment and Directive Counseling Priorities are also arbitrary and capricious because they depart from prior Department positions on DEI, health equity, nondiscrimination, contraception, and nondirective counseling, without any acknowledgment, explanation, or fair notice of these changes to Title X—much less any consideration of Plaintiff States' reliance interests in existing Title X programs. Further, OPA has not justified its apparent abandonment of former research-backed positions by

making claims that either implicitly misstate or actively run counter to the evidence before the agency.

210. Finally, the Irrelevant HHS Priorities are arbitrary and capricious because they demand applicants and grantees align themselves with mandates that do not appear to relate to Title X, provide no reasoned explanation for their application to Title X grant awards, and are ambiguous as to how applicants and recipients can comply with these provisions within the context of Title X.

COUNT III
(Violation of the APA – Without Observance of Procedure Required by Law, 5 U.S.C. § 706(2)(D))

211. Plaintiff States incorporate by reference the allegations contained in the preceding paragraphs.

212. The APA provides that courts "shall . . . hold unlawful and set aside" final agency action that is "without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

213. An agency may only reverse or amend a legislative rule issued through notice and comment rulemaking through notice and comment rulemaking.

214. The Title X regulations were a product of notice and comment rulemaking. *See* 42 C.F.R. §§ 59.1-59.11; 86 Fed. Reg. 56177 (Oct. 7, 2021).

215. Neither the 2027 NOFO nor the Agency Priorities, including the Challenged Conditions, were promulgated through notice-and-comment rulemaking.

216. To the extent the Challenged Conditions constitute an amendment or reversal of any legislative Title X regulations, *see supra* Count I, the Department failed to observe the notice and comment rulemaking procedure required by law. 5 U.S.C. § 706(2)(D).

COUNT IV
(Violation of the Spending Clause, U.S. CONST. ART. I, § 8, CL. 1; Violation of APA § 706 (2)(B), Contrary to Constitutional Right)

217. Plaintiff States incorporate by reference the allegations contained in the preceding paragraphs.

218. Art. I, § 8, cl.1 of the U.S. Constitution provides that "Congress shall have Power To lay and collect Taxes, Duties, Imposts and Excises, to pay the Debts and provide for the common Defence and general Welfare of the United States."

219. The APA provides that courts "shall . . . hold unlawful and set aside" final agency action that is "contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B).

220. While Congress may attach conditions on the receipt of federal funds, it must do so unambiguously such that the recipient can make an informed choice. *See Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17, 25 (1981).

221. The Challenged Conditions are unconstitutionally vague and ambiguous under the Spending Clause because they do not give applicants fair notice of the conditions for receiving or maintaining Title X funding.

222. The Spending Clause also requires that conditions imposed on funding be reasonably related to the federal interest in the program at issue. *See Massachusetts v. United States,* 435 U.S. 444, 461 (1978) (plurality opinion).

223. The Challenged Conditions are not reasonably related to Title X's purpose of providing family planning services to individuals with low income and as such unconstitutionally violate the relatedness requirement of the Spending Clause.

224. The Challenged Conditions accordingly also violate the APA, 5 U.S.C. § 706(2)(B), as being contrary to a constitutional right, power, privilege, or immunity.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff States pray that this Court:

i. Issue a judicial declaration that the Challenged Conditions of the 2027 NOFO, and specifically the requirements that Title X applicants or grantees demonstrate alignment with:

   a. The Anti-DEI Priority;

   b. The Anti-Gender Ideology Priority;

   c. The Overmedicalization Priority;

   d. The Hyde Amendment Priority;

   e. The Directive Counseling Priority; and

   f. The Irrelevant HHS Priorities

   are unlawful because they violate the Administrative Procedure Act and the Spending Clause of the U.S. Constitution;

ii. Pursuant to 5 U.S.C. § 706, vacate the incorporation of the Anti-DEI Priority, Anti-Gender Ideology Priority, Overmedicalization Priority, Hyde Amendment Priority, Directive Counseling Priority, and Irrelevant HHS Priorities in the 2027 NOFO;

iii. Enjoin Defendants from applying or imposing the Challenged Conditions of the 2027 NOFO to or upon any applicant or grantee in evaluating applications submitted under the NOFO, or in evaluating grantee compliance with award terms and conditions;

iv. Award the Plaintiff States their reasonable fees, costs, and expenses, including attorneys' fees, pursuant to 28 U.S.C. § 2412; and

v. Grant such other relief as this Court may deem proper.

Dated: August 27, 2026

Respectfully submitted,

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* *pro hac vice application forthcoming*

EXHIBIT A

U.S. Department of Health and Human Services

Office of Population Affairs

Notice of Funding Opportunity
Title X Family Planning Services Grants

Opportunity Number
PA-FPH-27-001

Application Due Date
January 11, 2027

Technical Assistance Webinar Date
November 9, 2026

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BASIC INFORMATION	
Opportunity Title Title X Family Planning Services	
Program Office Office of Population Affairs	**Application Submission and Format** Electronic application submitted via Grants.gov ONLY.
Opportunity Number PA-FPH-27-001	
Award Type Grant	**Application Deadline** January 11, 2027
Announcement Type Initial	**Technical Assistance Webinar Date** November 9, 2026
Assistance Listing 93.217 (Family Planning)	**Technical Assistance Webinar Details** visit the OPA website at https://opa.hhs.gov/grant-programs/funding-opportunities for details
Eligible Applicants (see Section A.1 for full details) _____	
Executive Order 12372 does apply to this NOFO (see section F.3.D)	
Estimated Total Funding Available Up to $ 257,000,000	**Estimated Period of Performance (months)** 60
Estimated Number of Awards up to 90	**Anticipated Award Date** April 1, 2027
Anticipated Award Funding Range $200,000 - $22M	**Anticipated Project Start Date** April 1, 2027
QUESTIONS? **Additional contact information in Section J**	

SUMMARY

The Office of Population Affairs (OPA) announces the anticipated availability of funds for Fiscal Year (FY) 2027 grants under the authority of Title X of the Public Health Service Act, Section 1001 (42 U.S.C. §300).

This notice solicits applications for projects to provide Title X services throughout the 50 United States, District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, American Samoa, the U.S. Outlaying Islands (Midway, Wake, et al.), the Republic of the Marshall Islands, the Federated State of Micronesia, and the Republic of Palau (hereafter, States). OPA intends to make available approximately up to $257 million for up to 90 grant awards for a period of up to five (5) years. The actual amount available will not be determined until enactment of the FY 2027 federal budget.

OPA's Title X Family Planning Program funds "voluntary family planning projects [that] offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents)." (Title X of the Public Health Service Act, 42 U.S.C. 300 et seq., available at https://opa.hhs.gov/sites/default/files/2020-07/title-x-statute-attachment-a_0.pdf). The Title X Program is implemented through competitively awarded grants to a diverse network of public and private nonprofit entities. The program helps millions of low-income and uninsured Americans develop health literacy and access family planning and related health services, empowering individuals and families to make informed decisions and navigate chronic health conditions and pregnancy with confidence. By offering counseling and education to improve individuals' optimal health outcomes, Title X promotes the level of health literacy necessary to support informed consent across the reproductive lifespan. For example, endometriosis often goes undiagnosed for years because symptoms such as severe menstrual pain or irregular bleeding are frequently normalized or minimized. Body literacy counseling helps patients recognize that these experiences are not "normal" features of womanhood, but potential indicators of an underlying condition, prompting earlier discussion with providers, timely diagnosis, appropriate treatment, and improved long-term reproductive and overall health outcomes.

Likewise, foundational knowledge of reproductive physiology enables patients and couples to recognize early signs of dysfunction, seek timely evaluation, and participate meaningfully in care decisions. Persistent gaps in reproductive knowledge highlight the need for such education. For example, a survey conducted for OPA in 2020 found that only 50% of women and 38% of men know that a woman's ovaries do not keep producing new eggs until menopause (https://opa.hhs.gov/sites/default/files/2021-01/fertility-knowledge-survey-findings-exec-summary-2020.pdf). By supporting body

literacy education alongside evidence-based evaluation and treatment of chronic disease, Title X services can help patients move beyond symptom-focused care toward informed, preventive, and restorative approaches to reproductive health.

These efforts align with HHS's focus on addressing the root causes of chronic illnesses by targeting conditions that affect reproductive health and fertility. By promoting strategies that support education and counseling on reproductive health goals, reduce chronic disease, and assist individuals seeking to achieve healthy pregnancies, the Title X Program strengthens American families, individuals, and communities.

This notice solicits applications from public and private nonprofit entities to establish and operate voluntary Title X projects. These projects include a broad range of effective and acceptable services, including pregnancy testing and counseling, basic infertility services, sexually transmitted infection (STI) services (such as HIV prevention education, counseling, testing, and referral), health literacy, reproductive goals counseling to increase optimal health outcomes, and other preconception health services. Title X services also help address and provide referrals for health conditions that affect fertility, including endometriosis, polycystic ovary syndrome (PCOS), and uterine fibroids in women, as well as low sperm count, low sperm motility, low testosterone, and erectile dysfunction in men. OPA seeks a broad competition for Title X grant awards and are interested in innovative strategies to address chronic disease; reduce overmedicalization by strengthening approaches focused on underlying behavioral and lifestyle factors of health and evidence-based practices such as fertility-awareness based methods; promote health and body literacy; advance reproductive goals counseling for all clients; and support family formation.

All activities funded under this announcement must be in compliance with the requirements of the Title X statute, legislative mandates, and regulations. Copies of the Title X statute, regulations, and legislative mandates may be downloaded from the OPA website at https://opa.hhs.gov/grant-programs/title- x-service-grants/title-x-statutes-regulations-and-legislative-mandates.

While there is not a fixed cost-sharing percentage or amount, projects must include financial support from sources other than Title X. The proposed project budget must reflect non-federal financial support in addition to Title X funds on both the Standard Form (SF) 424A, Budget Information for Non-Construction Programs, and in the budget narrative. Recipients will provide family planning services that are in compliance with the Title X statute, regulations, and legislative mandates and that are guided by OPA's key priorities.

OPA encourages applicants to review all program requirements, eligibility information, application format and submission information, evaluation criteria, and other information in this funding announcement to ensure that their application complies with all requirements and instructions.

The Office of the Assistant Secretary for Health (OASH) Grants and Acquisitions Management Division (GAM) will administer this competition.

We encourage you to review all program requirements, eligibility information, application format and submission instructions, and other content of this notice to ensure your application complies with all requirements.

A. ELIGIBILITY INFORMATION

1. Eligible Applicants

Any public or private nonprofit entity is eligible to apply.

You must meet all of the eligibility requirements in order for us to review your application.

Eligible Entities

Additional examples of eligible organizations include:

Any public or private nonprofit entity located in a State (which includes one of the 50 United States, District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, American Samoa, the U.S. Outlaying Islands (Midway, Wake, et al.), the Republic of the Marshall Islands, the Federated State of Micronesia, and the Republic of Palau (hereafter, States) is eligible to apply for a grant under this announcement. Faith-based organizations and American Indian/Alaska Native/Native American (AI/AN/NA) organizations are eligible to apply for Title X family planning services grants. Examples of eligible Organizations include:

- State Governments
- U.S. territories
- County Governments
- City or township governments
- Special district governments
- Independent school districts
- Public and State controlled institutions of higher education
- Native American tribal governments (Federally recognized)
- Public Housing authorities/Indian housing authorities
- Native American tribal organizations (other than federally recognized tribal governments)
- Nonprofits having 501(c)(3) status with the IRS, other than institutions of higher education
- Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education

- Non-profit private institutions of higher education

PDPI Eligibility
There is no restriction on an individual's eligibility to be Project Director (PD)/Principal Investigator (PI) on an application. However, we will not make an award with a PD/PI who has an active government-wide exclusion, suspension, or debarment recorded in SAM.gov.

We expect that throughout the period of performance the PD/PI will be involved in, and have substantial knowledge about, all aspects of the project. Although your organization may recognize co-PD/PIs on team-managed projects, we recognize only a single PD/PI who will be responsible for the programmatic aspects of the project.

Other Considerations

Submitting Multiple Applications

You may submit more than one application, but each application must be for a distinctly different project.

If you submit multiple applications for the same project, we will accept only the last application submitted a Grants.gov timestamp that is before the due date and time. We will disqualify all other versions of the application. See Section G.1.b for all disqualification factors.

Submitting an Application as a Group or Consortium

For any given project, we will only make an award to a single eligible entity. More than one entity may choose to work together on a project under this opportunity, but only one entity may submit the application. If awarded, that entity will be the award recipient and will be responsible for conducting the project.

The other entities may participate in the project, if awarded, and would be responsible to the recipient for their respective roles, typically as subrecipients.

Groups may form a consortium, partnership, or other legally recognized entity for the purpose of applying for this opportunity and carrying out any awarded project. The resulting entity must exist and be legally recognized when it applies and must have an active registration in SAM.gov. We will conduct a risk assessment on the applying entity (Section F.4) prior to making any award.

Eligibility Documentation

Entity eligibility documentation (e.g., proof of 501(c)(3) status as determined by the Internal Revenue Service or an authorizing Tribal Resolution) must be included in the submitted application. For additional information, see Section 4.a. It is important that your organization is correctly classified in your SAM registration (Section F.2.a).

During our review of your application, we might request additional documentation to support your eligibility. This request means only that your application is under review and not that you will receive an award.

More specific information on the type of documentation that we might request specific to this opportunity appears in Section F.4.b.

Application Disqualification

We will disqualify applications that fail to meet the eligibility, responsiveness, formatting, and submission requirements (Sections G.1.b) prior to conducting merit review. Disqualified applications will not undergo further review.

We will notify disqualified applicants at the end of the competition when we announce the award recipients.

2. Application Responsiveness Criteria

We will review your application to determine whether it meets the responsiveness criteria below. If your application does not meet the responsiveness criteria, we will disqualify it from the competition; we will not review it beyond the initial screening.

The responsiveness criteria are as follows:

- **Family Participation Certification**. Applicants must include a written statement in the appendix of the application certifying that:

  "if funded, this Title X Family Planning Services project will encourage family participation in the decision of minors to seek family planning services and will provide counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities."

3. Cost Sharing or Matching

Program regulations at 42 C.F.R. § 59.7(c) stipulate that ``No grant may be made for an amount equal to 100 percent of the project's estimated costs." Also, 42 C.F.R. § 59.7(b) states that "No grant may be made for less than 90 percent of the project's costs, as so estimated, unless the grant is to be made for a project that was supported, under section 1001, for less than 90 percent of its costs in fiscal year 1975. In that case, the grant shall not be for less than the percentage of costs covered by the grant in fiscal year 1975."

While there is not a fixed cost-sharing percentage or amount, projects must include financial support from sources other than Title X. The proposed project budget should reflect financial support in addition to Title X funds on both the Standard Form (SF) 424A, Budget Information, and in the budget narrative and justification. **The amount and source(s) of these funds must be clearly identified separately from the requested Title X support** as indicated on the SF 424A, as well as on the SF 424, Application for Federal Assistance. The OASH Grants and Acquisition Management (GAM) Division will review applications to ensure that the requested amount of Title X funding is in compliance with this business requirement.

The cost sharing requirements outlined above are waived for any grant made to the U.S. Virgin Islands, Commonwealth of the Northern Mariana Islands, American Samoa, Guam, Republic of Palau, Federated States of Micronesia, and the Republic of the Marshall Islands. Although projects are expected to identify additional sources of funding and not solely rely on Title X funds, there is no specific amount of level of financial match requirement for this program.

B. AGENCY PRIORITIES

Required Alignment with OASH Mission and Agency Priorities

Consistent with OASH's mission, in carrying out any project that is funded under this NOFO, recipients must align program design and activities with agency priorities where consistent with program authority and the scope of the award (Priorities of the Office of the Assistant Secretary for Health," available online at: https://health.gov/priorities), and when authorized by law according to the Title X statute, regulations, legislative mandates, and additional program guidance. Funded activities must advance and support OASH's mission to improve the health and well-being of Americans.

In addition, the recipient is required to administer any project that is awarded under this NOFO in accordance with the following objectives in Title X that are authorized to advance them:

1) Promote body and health literacy
2) Advance reproductive goals counseling
3) Implement a Quality Improvement and Quality Assurance (QI/QA) Plan with the goal to achieve optimal health outcomes

The recipients must demonstrate ongoing compliance with these priorities, in all programs that are authorized to advance them, through program design, implementation, reporting, and evaluation. Failure to meaningfully align funded activities with the applicable requirements may result in corrective action, additional reporting requirements, or other actions consistent with federal grant regulations found at 2 C.F.R. Part 200 and the terms and conditions of this award (including termination pursuant to 2 C.F.R. 200.340(a)(4) for no longer effectuating program goals or agency priorities).

C. PROGRAM DESCRIPTION

The Office of the Assistant Secretary for Health (OASH), Office of Population Affairs (OPA) announces the anticipated availability of funds for Fiscal Year (FY) 2027 grants under the authority of Title X of the Public Health Service Act, Section 1001 (42 U.S.C. §300).

The primary focus of OASH is to lead Americans toward healthier lives by promoting health and well-being across the lifespan. This includes the reproductive lifespan, supported through innovative, evidence-based programs, services, partnerships, and research that strengthen family formation and assist clients in achieving healthy pregnancies. Grants funded through this NOFO will expand access to Title X family services for millions of Americans, helping them build body literacy, address infertility,

plan and space pregnancies, and navigate reproductive health conditions such as endometriosis, polycystic ovary syndrome (PCOS), and uterine fibroids in women, as well as low sperm count, low sperm motility, low testosterone levels, and erectile dysfunction in men.

Background

Title X clinics provide services to clients of both sexes and all ages, including adolescent clients, with priority given to persons from low-income families. Title X services are voluntary, confidential, and provided regardless of one's ability to pay or a client's religion, race, color, national origin, disability, age, sex, number of pregnancies, or marital status. For many clients, Title X clinics are their only ongoing source of health care and health education.

The majority of the clients served by Title X providers are low-income, female, and under 30 years old. In order to ensure that all prospective low-income clients are able to access services, there is no charge for services to people with family incomes below 100% of the most recent federal poverty level (FPL) guidelines, and services are discounted on a sliding scale for people with family incomes between 101-250% of the FPL. In 2023, 60% of clients had family incomes at or below 100% FPL, while 83% had family incomes below 250% of the FPL. Detailed information about current and past clients served by Title X recipients and the broad range of services provided to clients by Title X recipients is available in the Family Planning Annual Report (FPAR) available on the OPA website at https://opa.hhs.gov/research-evaluation/title-x-services- research/family-planning-annual-report.

The Title X statute specifies that local and regional public or private nonprofit entities may apply directly to the Secretary for a Title X family planning services grant under this announcement. For applicants that will not provide all services directly, you must document, in your application, the process and selection criteria you will use to identify qualified subrecipients to fulfill Title X activities. You should also show how your subrecipients will provide the required services and best serve individuals in need throughout the anticipated service area. Applicants must additionally outline how all subrecipients, through their activities and services, will comply with Title X statutory and regulatory requirements and OPA program guidance.

Expectations for Recipients

a. Comply with Title X Statute, Regulations, Legislative Mandates, and Additional Program Guidance

All activities funded under this announcement must be in compliance with the requirements of the Title X statute, legislative mandates, and applicable regulations. We also expect all activities funded under this announcement to be in compliance with additional program guidance issued by OPA.

1. Title X Statute

Requirements regarding the provision of family planning services under Title X are in the statute (Title X of the Public Health Service Act, 42 U.S.C. 300 et seq., available at https://opa.hhs.gov/sites/default/files/2020-07/title-x-statute-attachment-a_0.pdf) and in the implementing regulations which govern project grants for family planning services (42 C.F.R. part 59, subpart A). In addition, sterilization of clients as part of the Title X program must be consistent with 42 C.F.R. part 50, subpart B ("Sterilization of Persons in Federally Assisted Family Planning Projects").

Title X of the Public Health Service Act authorizes the Secretary of HHS to award grants for projects to provide family planning services to any person desiring such services, with priority given to individuals from low-income families. Section 1001 of the Act, as amended, authorizes grants "to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents)."

In addition, Section 1001 of the statute requires that, to the extent practicable, Title X service providers shall encourage family participation in family planning services projects. Finally, Section 1001(b) assures the right of local and regional entities to apply directly to the Secretary for Title X grant funds.

Section 1008 of the Act, as amended, stipulates, "None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning."

2. Title X Regulations

On October 4, 2021, OPA issued a final rule, (42 C.F.R. Part 59), to revise the regulations that govern the Title X family planning program by readopting the 2000 regulations (65 F.R. 41270), with several revisions to ensure access to quality family planning services for clients, especially low-income clients.

The 2021 final rule includes a description of what programs the regulations apply to (§ 59.1), definitions (§ 59.2), who is eligible to apply for a family planning services grant (§ 59.3), how one applies for a family planning services grant (§ 59.4), requirements that must be met by a family planning project (§ 59.5), procedures to assure the suitability of informational and educational material (print and electronic) (§ 59.6), criteria HHS will use to decide which family planning services projects to fund and in what amount (§ 59.7), how grants are awarded (§ 59.8), for what purposes the grant funds may be used (§ 59.9), confidentiality (§ 59.10), and additional conditions (§ 59.11). A copy of the 2021 final rule is available at https://www.govinfo.gov/content/pkg/FR-2021-10-07/pdf/2021-21542.pdf.

3. Legislative Mandates

The following legislative mandates have been part of the Title X appropriations language

for the last several years. This NOFO assumes these provisions will be carried forward in FY 2027, please review all applicable Title X appropriations when completing your application. Title X family planning services projects should include administrative, clinical, counseling, and referral services, as well as training of staff necessary to ensure adherence to these requirements.

"None of the funds appropriated in this Act may be made available to any entity under Title X of the PHS Act unless the applicant for the award certifies to the Secretary of Health and Human Services that it encourages family participation in the decision of minors to seek family planning services and that it provides counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities;" and "Notwithstanding any other provision of law, no provider of services under Title X of the PHS Act shall be exempt from any State law requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape, or incest."

4. Additional Program Guidance

We also expect recipients to follow additional program guidance issued by OPA. Additional program guidance includes, but is not limited to, occasional Program Policy Notices issued by OPA to provide clarity and guidance on policy issues relevant to Title X recipients.

i. Address OPA Program Priorities

In addition to the statute, regulations, legislative mandates, and additional program guidance that apply to Title X, Title X grantees should align their programs with OPA priorities to the extent authorized by law and within the scope of the program, OPA expects recipients to develop and implement plans to address the program priorities and provide evidence of the project's capacity to address program priorities. OPA's program priorities for recipients funded under this NOFO are in part informed by the Office of the Assistant Secretary for Health's Statement of Priorities (available at https://health.gov/priorities), and are as follows:

1. Addressing the chronic disease epidemic through the delivery of Title X services

Chronic disease prevention and management are essential to improving public health and promoting healthy pregnancies and family formation. HHS is leading a science-driven response to the nation's chronic disease epidemic, with a focus on identifying and addressing root causes that contribute to poor health outcomes, including those affecting fertility and reproductive health. OASH's health programs and offices play a central role in developing solutions to reduce the burden of chronic disease through efforts that address nutrition, physical activity, sleep, and exposure to harmful chemical and environmental toxins. Integrating these priorities within the Title X program helps strengthen reproductive health outcomes by addressing conditions that affect women, such as hormonal imbalances, polycystic ovary syndrome (PCOS), endometriosis, and

uterine fibroids, as well as conditions that affect men, including low sperm count, low sperm motility, low testosterone levels, and erectile dysfunction. Title X services may also address lifestyle and behavioral factors—such as sleep quality, nutrition, physical activity, and pornography use—that influence hormonal function and health in males and females.

We expect recipients to demonstrate how their Title X projects will contribute to broader HHS efforts to reduce chronic disease risks across the reproductive lifespan, improve health outcomes, and support individuals seeking to achieve healthy pregnancy. Key strategies for addressing chronic disease through Title X services include, but are not limited to, providing education and counseling on nutrition, sleep, stress, and physical activity; incorporating screening and referral pathways for health conditions linked to chronic disease and infertility in both women and men; collaborating with community health partners to reduce environmental exposures; and integrating health literacy education to help clients better understand and manage their reproductive and overall health. Additional information on HHS priorities and strategies related to addressing chronic disease is available at https://health.gov/priorities, https://www.whitehouse.gov/wp-content/uploads/2025/05/MAHA-Report-The-White-House.pdf, and https://www.whitehouse.gov/wp-content/uploads/2025/09/The-MAHA-Strategy-WH.pdf.

2. Reducing overmedicalization in health care and increasing focus on optimal health through the delivery of Title X services

Promoting better health outcomes requires a balanced approach to care that emphasizes optimal health (defined as physical, mental, and social wellbeing), not just medical intervention. OPA recognizes the overreliance on pharmaceutical and surgical treatments. Over the years, the Center for Disease Control and Prevention's National Survey of Family Growth reports have shown a decrease in females' current use of any contraception (approximately 65% of females of reproductive age in both 2015-2017 and 2017-2019 data, then 54% in the most recent 2022-2023 report).[1] According to the 2023 National Health Statistics Report, the most common reason women reported discontinuing use related to dissatisfaction was side effects.[2] This approach has failed to adequately address the root causes of the nation's chronic disease burden, resulting in

[1] Centers for Disease Control and Prevention. Current Contraceptive Status Among Women Aged 15–49: United States, 2015-2017. December 2018. https://www.cdc.gov/nchs/products/databriefs/db327.htm; Centers for Disease Control and Prevention. Current Contraceptive Status Among Women Aged 15–49: United States, 2017–2019. https://www.cdc.gov/nchs/products/databriefs/db388.htm; Centers for Disease Control and Prevention. Current Contraceptive Status Among Females Ages 15–49: United States, 2022–2023. August 2025. https://www.cdc.gov/nchs/products/databriefs/db539.htm.

[2] Daniels K, Abma JC. Contraceptive methods women have ever used: United States, 2015–2019. National Health Statistics Reports; no 195. Hyattsville, MD: National Center for Health Statistics. 2023. DOI: https://doi.org/10.15620/cdc:134502.

ongoing health challenges that affect fertility, pregnancy outcomes, and long-term health outcomes. Through the delivery of Title X services, OPA seeks to strengthen approaches that focus on the underlying behavioral and lifestyle factors of health—such as nutrition, sleep, physical activity, stress management, and environmental factors—that impact overall health and are shown to be effective in improving optimal health.

We expect applicants to demonstrate how their Title X projects will integrate noninvasive, evidence-based practices that promote health literacy, fertility awareness, and reproductive health without unnecessary medicalization or symptom suppression. Key strategies for advancing optimal health through Title X services include, but are not limited to, expanding access to fertility-awareness–based methods (often referred to as natural family planning); providing education and counseling that encourage lifestyle practices supporting reproductive health and healthy pregnancies; fostering collaboration with community-based programs that address wellness and environmental health; and incorporating approaches that empower individuals to understand and manage their own health.

3. Promoting body and health literacy through the delivery of Title X services

Body literacy is foundational to informed decision-making, reproductive health, and lifelong health. OPA recognizes that gaps in biological understanding contribute to delayed diagnosis of health conditions and to the nation's growing infertility crisis, which now affects approximately one in five married women of reproductive age with no prior births, according to the CDC.[3] As part of this priority, Title X family planning clinics will be required to incorporate foundational body and health literacy into reproductive health counseling. This includes education on menstrual cycle physiology, hormonal health, male and female fertility awareness, and early indicators of reproductive disorders such as endometriosis, polycystic ovary syndrome (PCOS), thyroid dysfunction, metabolic disorders, and other conditions that often first emerge in adolescence. Body literacy counseling should equip individuals to recognize when symptoms such as pain, irregular cycles, hormonal disruption, or changes in sexual health warrant further medical evaluation rather than symptom suppression. By integrating body literacy into Title X services, OPA seeks to ensure that women and men understand the health significance of ovulation, endocrine function, and lifestyle factors that influence fertility, reproductive health, and future family formation, as well as pregnancy planning and risk reduction.

4. Advancing reproductive goals counseling through the delivery of Title X services

Reproductive goals counseling supports individuals in making informed, intentional

[3] Centers for Disease Control and Prevention. National Survey of Family Growth (2015-2019), May 2024. https://www.cdc.gov/nchs/nsfg/key_statistics/i-keystat.htm#infertility

decisions about education, work, relationships, marriage, and childbearing across the lifespan, while advancing optimal health and wellbeing. OPA's Fertility Knowledge Survey, conducted in 2020, found that over 65% of both women and men want or intend to have (more) children, but only 32% of women and 9% of men have discussed their plans to have children with a medical provider. (https://opa.hhs.gov/sites/default/files/2021-01/fertility-knowledge-survey-findings-exec-summary-2020.pdf). OPA recognizes that many individuals lack access to resources that integrate family goals into broader life planning, often due to longstanding omissions in educational and counseling environments. As part of this priority, Title X clinics will be expected to offer reproductive goals counseling that presents evidence-informed pathways associated with improved economic stability and family stability, including completion of education, participation in the workforce, and marriage prior to childbearing. Research demonstrates that individuals who follow this sequence experience substantially lower risks of poverty across socioeconomic groups. Program counseling should affirm marriage and parenthood as meaningful and valued components of adult life, particularly in counseling adolescents on longterm reproductive goals, and support informed decision-making by helping individuals understand how life choices, reproductive health, and fertility intersect to shape long-term stability, health, and wellbeing. As part of these efforts to support family planning, Title X clinics are expected to provide services that support individuals and families seeking to have children.

5. Promoting evidence-based care through the delivery of Title X services

Protecting children and adolescents and ensuring that federally supported programs reflect the best available scientific evidence are central to promoting lifelong physical and reproductive health. HHS will prioritize funding for grantees who maintain a science-driven approach to healthcare, including by protecting children, respecting biological reality, and upholding scientific integrity across its programs. Integrating these priorities within the Title X program ensures that program activities reflect evidence-based practices and biological and reproductive health. To the extent permitted by applicable law, including any applicable court orders, we expect recipients to demonstrate how their Title X projects promote physical and reproductive health priorities established by HHS. Key strategies include, but are not limited to, providing developmentally appropriate counseling rooted in biological science; ensuring referral pathways align with evidence-based care; and collaborating with community partners to promote practices that support healthy adolescent development.

6. Enforcing the Hyde Amendment through the delivery of Title X services

Protecting the integrity of taxpayer funding and advancing programs that respect the dignity of human life are core HHS responsibilities. The Hyde Amendment expressly prohibits the use of federal funds administered by HHS to pay for elective abortion. OASH's programs and offices play an essential role in implementing this statutory

requirement across the Department's activities. Integrating Hyde compliance within the Title X program strengthens its capacity to support women, families, and communities while ensuring adherence to federal law. To the extent permitted by applicable law, OASH will prioritize programs and funding that uphold Hyde protections and do not use taxpayer resources to promote or support elective abortion. As referenced above in the "Expectations for Recipients," Section 1008 of the Public Health Service Act, as amended, stipulates, "None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning." We expect recipients to demonstrate how their Title X projects maintain strict separation from prohibited activities and contribute to broader HHS efforts to safeguard life-affirming, lawful, and ethical program delivery. Key strategies include, but are not limited to, implementing robust financial and programmatic safeguards; providing clear guidance to staff and subrecipients on Hyde requirements; and establishing monitoring processes that ensure ongoing compliance among staff and subrecipients.

7. Ensuring OASH funds benefit eligible individuals and not illegal aliens through the delivery of Title X services

Federal law requires that taxpayer-funded public benefits be administered in a manner that serves eligible individuals and does not encourage or support illegal immigration. To the extent allowed under Federal law and regulations, including the preliminary injunction issued in New York, et al. v. DOJ, et al. (DRI), 1:25-cv-00345, OASH is committed to ensuring that Title X funds are used exclusively to benefit individuals who are lawfully eligible to receive federally funded services. Pursuant to Executive Order 14218 (available at https://www.govinfo.gov/content/pkg/DCPD-202500283/pdf/DCPD-202500283.pdf) and in alignment with OASH's priorities (available at https://health.gov/priorities), OASH will prioritize programs, partnerships, and funding mechanisms that further the agency's priority to ensure that federal resources are not used to facilitate or incentivize illegal immigration.

8. Implement a Quality Improvement and Quality Assurance (QI/QA) Plan

We expect recipients to implement a quality improvement and quality assurance (QI/QA) plan that involves collecting and using data to monitor the delivery of quality family planning services, inform modifications to the provision of services, inform oversight and decision-making regarding the provision of services, and assess patient satisfaction. We expect recipients to address oversight and service provision at the recipient level, the subrecipient level, and the service site level within their QI/QA plan.

As a part of the QI/QA plan, all recipients must collect and report FPAR 2.0 data to OPA on an annual basis and are expected to use their FPAR data to inform their QI/QA activities. Additional information about FPAR 2.0, including the data elements and response options, is available on the OPA website at https://opa.hhs.gov/research-evaluation/title-x-services-research/family-planning-annual-report/fpar2.

3. Federal Involvement in the Project

If you receive an award, we will encourage you to seek the advice and opinion of federal staff

when problems arise. However, you would be responsible for making sound programmatic and administrative judgments. The responsibility for operating decisions will be yours and does not shift to HHS, OASH, or OPA.

Under a grant, the program office's involvement may include routine monitoring and technical assistance such as monthly conference calls, occasional site visits, ongoing review of plans and progress, participation in relevant meetings, provision of training and technical assistance.

4. Eligibility criteria for project participants

You must not restrict participation in the project on the basis of race, color, national origin, religion, sex, disability, age, or another protected characteristic (See Section I.5).

D. AWARD INFORMATION

Budget period(s)

We expect to fund awards in 12-month budget periods for a total period of performance up to 60 month(s). However, we may approve shorter periods of performance. Budget periods may vary from the estimated 12 months because of the timing of award issuance or other administrative factors.

For multi-year projects, recipients must submit a non-competing continuation (NCC) application for each budget period after the first. We will provide guidance generally 3 months prior to the end of the active budget period. Continuation funding is contingent upon the availability of funds, satisfactory progress of the project, appropriate stewardship of federal funds, and the best interests of the government. Funding for all approved budget periods after the first is generally the same as the initial award amount and may be subject to any offset with funds unused in a previous budget period.

E. APPLICATION CONTENTS AND FORMAT

1. Format of the Application

You must prepare your application using the forms and information described in this NOFO. The official online application package on Grants.gov contains all necessary forms and guidance for preparing an application. This package includes but is not limited to:

- Full Text of the NOFO
- Standard forms (required) and their instructions
    - SF-424 Application for Federal Assistance
    - SF-424A Budget Information for Non-Construction Programs
    - SF-LLL Disclosure of Lobbying Activities
    - Project Abstract Summary
- Sample templates, if available.

In addition to the four standard forms in the application package, your application will consist of 3 sections of materials you prepare:

1. Project Narrative
2. Appendices to the Project Narrative

3. Budget Package

We strongly encourage you to read all instructions for the application format and content to avoid disqualification of your application. An application checklist is available in Section J.1.

a. **Project Narrative - Formatting**

Following the formatting instructions below will help ensure that your application is readable for review process. Acceptable electronic file formats are in Section E.3.a.

Names of Individuals

We encourage you to use individuals' full names (first, middle, last) on the standard forms and any other documents such as résumés/curricula vitae/biographical sketches to distinguish them for verification in the SAM exclusion records. Delays may result in award processing if full names are not provided.

You should avoid submitting personally identifiable information such as personal contact information (e.g., home address and telephone number) on résumés/curricula vitae/biographical sketches. Do not submit social security numbers.

If you receive an award, only one Project Director/Principal Investigator (PD/PI) will be named on the award documents. (Section A.1.b) Avoid using a placeholder or honorary PD/PI. If you have not hired an individual to be the PD/PI, you should name an interim PD/PI, and your application should clearly identify that person as such.

We typically expect the PD/PI to be named on the SF-424 in box 8.f. Avoid naming grant writers in box 8.f unless they have the expertise to respond to technical questions about the proposed project in a timely manner.

Identify other personnel who are essential or key to the execution of the proposed project clearly in your project narrative.

If you receive an award, a request for a change in PD/PI or key personnel under any circumstance requires prior approval of the grants management officer before becoming effective. We may disallow any costs incurred as a result of that change prior to our approval. See Section I.1.c.

Page Formatting

If you submit documents that do not conform to the following instructions, GAM will disqualify your application during the review process (SectionF.1.b).

Use an easily readable typeface, such as Times New Roman or Arial.

Use a 12-point font.

Use an 8.5" X 11" page size. Any other size page (e.g., A4, legal) will disqualify your Application.

You must double-space the Project Narrative pages or we will disqualify your application. You may single-space tables or use alternate fonts, but you must ensure the tables are easy to read.

Do not number pages or include a table of contents. Our grants management system will generate page numbers once your application is complete.

You must submit your application in the English language and in terms of U.S. dollars (2 C.F.R. § 200.111(a)).

Page Limits

Your project narrative and appendices must adhere to these page limits.

The page limits do not include the budget package (Section D.2.c)

The page limits do not include the required forms (SF-424, SF-424A, SF-LLL, and the Project Abstract Summary)

If your application exceeds the specified page limits when printed on 8.5" X 11" page, we will not review your application further.

We encourage you to print out your application before submitting it to ensure that it is within the page limits and is easy to read. Do not reduce pages to fit multiple pages on a single sheet to avoid exceeding the page limitation.

Do not hyperlink to documents or sites outside of your application to augment your application. Reviewers will not be permitted to follow links to external content during their assessment of your application. The one exception to this is a link to your internal controls as part of your budget package (Section D.2.c.3).

	Page Limit
Project Narrative	50
Project Narrative plus Appendices	100

Labeling Proprietary Information

Proprietary information includes patentable ideas, trade secrets, privileged or confidential commercial or financial information, the disclosure of which may harm the applicant. You should include proprietary information in your application only to the extent that it is essential to the reviewers' understanding of the project. Proprietary information should not appear in your Project Abstract Summary.

If your application contains proprietary information, you should clearly label the top of the first page of the project narrative. For example,

"Contains proprietary or confidential information that [Your Organization Name] requests not be released to persons outside the government, except for purposes of review and evaluation."

Awarded applications are subject to release under the Freedom of Information Act (FOIA) with redactions as the FOIA statute permits.

b. Appendices to the Project Narrative – Formatting

Your appendices should include any specific items outlined in Section D.2.b. Your documents should be easy to read.

You should use the same formatting specified for the Project Narrative. However, documents such as résumés/curricula vitae/biographical sketches, organizational charts, tables, Memoranda of Agreement (MOAs) or Letters of Commitment (LOCs) may have formatting common to those documents, so long as the pages are easy to read. For example, resumes, MOAs and LOCs may be single-spaced.

You must upload all of your appendices as a single, consolidated file in the Attachments section of your Grants.gov application. You must use an acceptable file format (Section E.3.a). We strongly encourage you to convert your file(s) to PDF format before uploading and review them to ensure accurate conversion.

Your Project Narrative plus the Appendices may not exceed the total number of pages for the application (Section D.1.a).

Budget Package - Formatting

The budget narrative should use the formatting required of the project narrative for the explanatory text. Budget tables may be single-spaced but should be laid out in an easily readable format and within the printable margins of an 8.5" x 11" page. You must use an acceptable file format (Section E.3.a). We do not accept Excel or other similar spreadsheet formats.

The application page limit does not include the SF-424A or the budget narrative (including budget tables).

We recommend you present budget amounts and computations in a columnar format: first column, object class categories; second column, federal funds requested; third column, non-federal resources; and last column, total budget.

Object Class	Federal Funds Requested	Non-Federal Resources	Total Budget
Personnel	$100,000	$25,000	$125,000

2. Content

a. Project Narrative - Content

The Project Narrative is the most important part of your application. We will use it as the primary basis to determine whether your project merits an award. The project narrative should provide a clear and concise description of your project. We recommend that your project narrative include the following components with the requested information. Labeling the sections accordingly will help the reviewers find information quickly.

You must clearly describe the administrative, management, and clinical capability of the applicant organization and plans for delivering family planning services that meet the expectations outlined in the NOFO. You should include all services to be provided by the project as part of the program plan. Proposed projects must adhere to all requirements of the Title X statute; applicable regulations, including regulations regarding sterilization of persons in federally assisted family planning projects; and legislative mandates.

Successful proposals should include the following:

1) Proposed Service Area and Plans to Address the Need for Title X Services

a. Describe the proposed service area, including the service area boundaries, and the need for Title X services in the proposed service area. Describe the current availability of Title X services in the proposed service area and any existing gaps in the availability or accessibility of services.

b. Describe your process for assessing the need for services within the proposed service area and how you have/will continue to use the results of your assessment to inform and improve service delivery.

c. Using and citing current data, describe the clients in need of services in the proposed service area and any factors associated with access and utilization of Title X services (e.g., geography, transportation, occupation, transience, unemployment, income level, educational attainment). Also describe any unique health care needs or characteristics that impact health status and delivery of family planning services (e.g., language barriers, food insecurity, housing insecurity, financial strain, lack of transportation, the physical environment, intimate partner violence, human trafficking). Describe the structure of your Title X network, including your recipient organization, any subrecipients that will assist in carrying out the proposed project, and the proposed services sites where family planning services will be delivered. To the extent that

you will not provide all services directly, describe the process and selection criteria that will be used to select subrecipients and service sites, including a description of eligible entities for funding as subrecipients.

d. For each direct service site, describe the location of the site compared to the identified need; the days/hours of planned operation; the estimated number of clients expected to receive services at the site; the broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, STI services, reproductive health condition services, preconception health services, and adolescent-friendly health services) that will be provided directly at the site; and a justification for any methods and services that will not be available at the site along with a description of how you will ensure client access for the methods and services not available directly at the site.

e. Describe how you will address identified health care access and utilization barriers and other factors that impact health status to ensure the availability and accessibility of Title X services within the proposed service delivery area.

f. Describe how you plan to educate clients and the broader service delivery area about the availability of family planning services.

g. Describe the number of clients in need of services, particularly low-income clients, to be served, the broad range of services and methods that will be provided, and how the proposed project will expand access to Title X services to clients in need of services in the defined service area. Describe the number of unduplicated clients that you project to serve on an annual basis. Include how that determination took into consideration recent or potential changes in the local health care landscape (e.g., potential changes in insurance coverage), organizational structure, and/or workforce.

h. Describe how grant funds will be used to best address the identified needs. Demonstrate that the cost per client and cost per encounter are reasonable. Describe other non-Title X resources available to address the needs for these services within the proposed service area and how grant funds will be used to leverage and expand available resources and not duplicate them.

2) Plan to deliver Title X services in compliance with the statute, regulations, legislative mandates and aligned with OPA program priorities

a. Describe how you will implement Title X family planning services that are in compliance with the Title X statute, regulations, and legislative mandates. Your plan should include a description of how you will ensure compliance with the statute, with each provision of the regulation (42 C.F.R. Part 59, Subpart A §59.1-§59.11), and with each legislative mandate.

b. Describe plans and strategies for providing family planning services that address OPA program priorities and data collection requirements, including:

- Addressing the chronic disease epidemic through the delivery of Title X services
- Reducing overmedicalization and increasing focus on optimal health through the delivery of Title X services
- Promoting body and health literacy through the delivery of Title X services
- Advancing reproductive goals counseling through the delivery of Title X services
- Promoting evidence-based care through delivery of services
- Enforcing the Hyde Amendment
- Implementing a QI/QA plan, including but not limited to, collecting, reporting, and using FPAR 2.0 data.

c. Clearly describe your project plan including goal statements and related outcome objectives that are S.M.A.R.T. (Specific, Measurable, Achievable, Realistic and Time-framed) and designed to provide services that are in compliance with the Title X statute, regulations, and legislative mandates and that address OPA's program priorities. The activities proposed are feasible, are clearly connected to the identified needs, and likely to achieve the stated outcomes.

d. Describe any major anticipated barriers and describe how you propose to overcome such barriers.

3) Project management and capability

a. Describe your project management structure and how it will

enable accountability and rapid and effective use of grant funds.

b. Describe the expertise and experience of your organization and other organizations that will partner with you on the project to deliver Title X services. Provide evidence of your experience working in the proposed service area and with the community(ies) to be served.

c. Describe your experience and expertise providing clinical health services, specifically quality Title X services.

d. Describe the key management team for your project. Describe how the makeup and distribution of functions among key management staff, and their qualifications, support the operation and oversight of the proposed project.

e. Describe the facilities where your project will be administered and where family planning services will be delivered. Describe how the location of project facilities will ensure continued access to Title X for clients in the proposed service area.

f. Provide a staffing plan which is reasonable and adheres to the Title X regulatory requirement that family planning medical services be performed under the direction of a clinical services provider, with services offered within their scope of practice and allowable under state law, and with special training or experience in family planning. Staff providing clinical services should be licensed and function within the applicable professional practice acts for the State in which they practice. Demonstrate that proposed staff have the expertise needed to implement Title X family planning services. Describe how the size, demographics, and health care needs of the service area/client population were considered when determining the number and mix of staff, and how you maintain documentation of licensure and credentialing verification for clinical staff.

g. Describe your plans for providing ongoing training and professional development for staff across your recipient network.

h. Describe how you will monitor and oversee provision of Title X services across your network to ensure compliance and continuous quality improvement, including detailed plans for subrecipient monitoring.

i. Describe how your financial accounting and internal control systems will align with the requirements of 42 C.F.R. § 59.5 and § 59.7.

j. Demonstrate your ability to make use of non-federal resources (i.e., non-Title X funds) within the community to be served and the degree to which those resources are used to enhance the range of family planning services provided through the project.

b. Appendices to the Project Narrative - Content

All items described in this section will count toward the total page limit of your application. You must submit them as **a single electronic file** uploaded to the Attachments section of your Grants.gov application.

Samples and optional forms/templates for some of these items are located under the Related Documents tab for this NOFO on Grants.gov.

Your application should include the following appendices:

1) Work Plan

Your work plan should reflect, and be consistent with, the Project Narrative and Budget Narrative, and must cover all years of the period of performance. However, each year's activities should be fully attainable in one budget year. You may propose multi-year activities, as well as activities that build upon each other, but each phase of the project must be discreet and attainable within a single budget year.

Your work plan should include a statement of the project's overall goal, anticipated outcome(s), key objectives, and the major tasks, action steps, or products that will be pursued or developed to achieve the goal and outcome(s). For each major task of each year, action step, or product, your work plan should identify the timeframes involved (including start and end dates), and the lead person responsible for completing the task.

You must include a detailed list of all the services proposed to be provided by your project. If some or all of the services will be provided by subrecipients, you must include a list of these entities. For each direct service site:

- describe the location of the site compared to the identified need;
- the days/hours of planned operation;
- the estimated number of clients expected to receive services at the site;
- the broad range of acceptable and effective medically approved family planning methods (including fertility awareness-based methods) and services (including pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, STI services, preconception health services, reproductive goals counseling, body literacy counseling, and adolescent- friendly health services) that will be provided directly at the site; and
- a justification for any methods and services that will not be available

at the site along with a description of how you will ensure client access for the methods and services not available directly at the site.

Title X service sites that are unable to provide clients with access to a broad range of acceptable and effective medically approved family planning methods and services must be able to provide a prescription to the client for their method of choice or referrals to another provider, as requested.

2) Schedule of Discounts and Billing

A schedule of discounts, based on ability to pay, is required for those from families with incomes between 101-250% of the Federal Poverty Level. For those from families whose income exceeds 250% of the Federal Poverty Level, charges must be made in accordance with a schedule of fees designed to recover the reasonable cost of providing services. Include a schedule of discounts for your projects and the methodology for how you developed/will develop this schedule. If you propose to have the sub recipient(s) develop their own schedule(s) of discounts, you should include guidance on how the schedule(s) of discounts are developed and how you intend on monitoring subrecipient development and implementation of the schedule of discounts. Also include a description of the processes in place to ensure that persons from low-income families, with incomes that fall at or below 100% of the current FPL, will not be charged except where third parties are authorized or legally obligated to pay; and that all reasonable efforts will be made to obtain third party payment without the application of any discounts. Include evidence that you have the ability to bill third parties, including private and public insurance such as Medicaid, when appropriate, and the ability to facilitate enrollment of clients into Medicaid.

3) Coverage Map

You must include a coverage map of your proposed service area that clearly shows the location of proposed Title X service sites compared to the need for services.

4) Letters of Commitment from Referral Entities

You may include signed Letters of Commitment for the organizations that have been specifically named as referral entities (organizations that provide services that are not paid with Title X funds, but that may contribute to continuum of care for clients) to carry out any aspects of the project not provided by subrecipients. The signed letters of commitment should include the specific role and resources that will be provided (if any), or activities that will be undertaken, in support of the applicant. The entity's expertise, experience, and access to the targeted population(s) should also be described in the letter of commitment.

Letters of commitment are not the same as letters of support. Letters of support are letters that are general in nature that speak to the writer's belief in the capability of an applicant

to accomplish a goal/task. Letters of support also may indicate an intent or interest to work together in the future, but they lack specificity. You should NOT provide letters of support, and letters of support such as this will not be considered during the review.

5) Curriculum Vitae/Resume for Key Project Personnel

You must submit with your application curriculum vitae and/or resumes of all key personnel. Key Personnel includes those individuals who will oversee the technical, professional, and managerial functions and/or assume responsibility for assuring the validity and quality of your organization's program. This includes at a minimum the Project Director, Program Manager/Coordinator, and Medical Director. We encourage individuals to use their full name (first, middle, last) on these documents to distinguish them for verification in the System for Award Management exclusion records.

6) Family Participation Certification

You must include a written statement certifying that, if funded, your Title X Family Planning Services project will encourage family participation in the decision of minors to seek family planning services, and that they will provide counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities. See Section F.1.

c. Budget Package - Content

A complete budget package consists of the following required components:

- SF-424A "Budget Information Non-Construction Programs"
- Budget narrative with detailed justification by cost category/object class, and
- Plan for oversight of federal funds.

You should include supporting documentation for your budget (e.g., a copy of your approved indirect cost rate) as part of the budget package, not as part of your appendices to the project narrative. There is no page limit for the budget package contents. If you are recommended for an award, you may be asked to provide additional information about your budget package.

Throughout your budget package, "Federal resources" refers only to the funds you are requesting from the program office for this project. "Non-federal resources" are all other non-HHS/OASH federal and non-federal resources. Funds from federal grant programs typically are not eligible as cost share for other federal grants. It is your responsibility to confirm with other federal agencies whether funds you receive from them are eligible resources to apply to your proposed project.

1. Standard Form SF-424A

You must enter the project budget according to the directions provided with the standard form.

You must provide costs by object class category for the first 12 months (i.e., first budget period) of the proposed project using Section B, box 6 of SF-424A. If the estimated period of performance is 12 months or less, this will be your total budget request for the entire project.

"Federal resources" refers only to the funds for which you are applying under this NOFO. "Non-federal resources" are all other resources (federal and non-federal).

Do not include costs beyond the first budget period in the object class budget in box 6 of SF-424A or box 18 of SF-424. The amounts entered in these sections should only reflect the first budget period.

If there is a discrepancy between your SF-424A and budget narrative and justification, we will rely on the narrative and justification to determine the final amounts.

2. Budget Narrative with Justification

Your budget narrative must include a detailed line-item budget and must include calculations for all costs and activities by the "object class categories" identified on SF-424A. You must provide a detailed justification for the costs by object class. The object class budget organizes your proposed costs into a set of defined categories.

Use the guidelines in Section J.4 for preparing the detailed object class budget.

Budget Periods

Your budget narrative must describe the first budget period in detail. For each proposed cost for the first budget period, provide a justification that includes explanatory text and line-item detail. You should describe how you derived your categorical costs. Your justification should show the necessity and reasonableness of the proposed costs for the project.

For subsequent budget years in an anticipated multi-year period of performance, provide a summary narrative and line-item budget for each year beyond the first. For categories or items that differ significantly from the first budget period, provide a detailed justification explaining these changes.

Funding levels for all approved budget periods after the first are generally the same as the initial award amount and are subject to an offset with funds unused in the previous budget period. Carryover of unobligated funds from one budget period to the next requires prior approval.

Determining Proposed Costs

Your budget narrative should justify the overall cost of the project as well as the proposed cost per activity, service delivered, and/or product. For example, the budget narrative should define the amount of work you have planned and expect to perform, what it will cost, and an explanation of how the result is cost effective. If you are proposing to provide services to clients, you should describe how many clients you expect to serve, the unit cost of serving each client, and how this is cost effective.

Proposed costs must adhere to the cost principles described in 2 C.F.R. §200.416. We have provided additional information on the most common cost categories for applications for OASH awards in Section J.4.

Budget calculations must include estimation methods, quantities, unit costs, and other similar quantitative detail sufficient to verify the calculations. Carefully review Funding Restrictions (below) for specific information regarding allowable, unallowable, and restricted costs.

Describing Federal and Non-federal Share

Both federal and non-federal resources (if applicable) must be detailed and justified in the budget narrative. "Federal resources" refers only to the HHS/OASH funds for which you are applying under this NOFO. "Non-federal resources" are all other non-HHS/OASH federal and non-federal resources.

If matching or cost sharing is required or offered voluntarily, you must include a detailed listing of any funding sources identified in box 18 of SF-424 (Application for Federal Assistance).

Indirect Costs

Indirect costs for training are limited to a fixed rate of eight percent of the modified total direct costs (MTDC) exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $50,000 (2 C.F.R. § 200.414 (c)(1).

Funding Restrictions

The following restrictions apply to costs you may propose and be awarded.

Pre-Award Costs

Pre-award costs are NOT allowed. Pre-award costs (2 C.F.R. § 200.458) are those incurred prior to the effective date of the Federal award directly pursuant to the negotiation and in anticipation of the Federal award where such costs are necessary for efficient and timely performance of the scope of work.

Salary Rate Limitation

Each year's appropriations act limits the salary rate that you may charge to the grants and cooperative agreements that we award. You must not use award funds to pay the salary of an individual at a rate in excess of Federal Executive Pay Scale Executive Level II.

As of January 2026, the Executive Level II maximum salary is $228,000. This amount reflects an individual's base salary exclusive of fringe benefits and any income that an individual working on the award project may be permitted to earn outside of the duties to the applicant organization. This salary rate limitation also applies to subawards/subcontracts under an HHS/OASH award.

An example of the application of this limitation for an individual devoting 50% of their time to this award is broken down below:

Salary Rate Limitation

Individual's *actual* base full-time salary $350,000 with 50% of time devoted to project, i.e., 0.5 FTE	**Direct salary ($350,000 x 0.5) =** $175,000
	Fringe (25% of salary) = $43,750
	Total = $218,750
Individual's base full-time salary *adjusted* to Executive Level II: $225,700 with 50% of time devoted to the project	**Direct salary ($225,700 x 0.5) =** $112,850
	Fringe (25% of salary) = $28,212.50
	Total amount allowed = $141,062.50

Appropriate salary rate limits will apply as required by law.

Vehicle Purchase

We will not approve a vehicle purchase at the time of award even when included in your application. You must obtain prior approval before the purchase of a mobile health unit or any other vehicle with award funds. A request for prior approval must include a detailed justification of the need for the vehicle that includes an analysis of comparing purchase, lease, and other alternatives. Equipment purchases are subject to transfer to another federal project or sale at the end of the period of performance (2 C.F.R. § 200.313(e)).

Construction Costs

We will not approve construction costs. This includes major improvements to or significant renovations of facilities.

3. Plan for Recipient Oversight of Federal Award Funds

You must include a plan for oversight of federal award funds which describes:

- how your organization will provide oversight of federal funds and how award activities and partner(s) will adhere to applicable federal award and programmatic regulations. Include identification of risks specific to your project as proposed and how your oversight plan addresses these risks.
- the organizational systems that demonstrate effective control over and accountability for federal funds and program income, compare outlays with budget amounts, and provide accounting records supported by source documentation.
- for any program incentives proposed, the specific internal controls that will be used to ensure only qualified participants will receive them and how they will be tracked.

- organizational controls that will ensure timely and accurate submission of Federal Financial Reports to the OASH Grants and Acquisitions Management Division via the Payment Management System as well as timely and appropriate withdrawal of cash from the Payment Management System.

If your internal controls are available online, you may provide a link as part of your plan in the budget narrative. Although merit reviewers are not permitted to access any external materials linked in the application as part of their review, this link would facilitate review of your proposal if recommended for risk assessment (Section F.4).

Section J.5 contains questions you may find useful in preparing your Recipient Plans for Oversight of Federal Funds.

a. Project Abstract Summary Guidance

You must complete the Project Abstract Summary form. The application page limit does not include the Project Abstract Summary Form. Research projects may enter zero for "Estimated number of people to be served as a result of the award of this grant."

The abstract will serve as the application summary going forward. Do not include sensitive or proprietary information in your abstract.

If your project is funded, we will publish the abstract on TAGGS.hhs.gov and USASpending.gov as you submitted it. You may request to edit it later, or we may ask you to edit it later to reflect any negotiated changes to the project. The abstract may also appear on the program office website or other government websites.

Your abstract should contain:

- Specifics about the project purpose
- Activities that you will perform
- Expected deliverables and outcomes
- Intended project beneficiary(ies) or participant(s)

Your description of the project should be brief and use plain language an average reader can understand. You should limit abbreviations, acronyms, or jargon without definitions. The abstract should be unique to your project.

F. SUBMISSION REQUIREMENTS AND DATES

1. Obtaining an Application Package

The official complete application package is available on Grants.gov. Search either the Assistance Listing number or the NOFO number PA-FPH-27-001.

The package consists of several Adobe PDF format documents. This is a standard format widely accessible across multiple platforms including mobile devices. The Acrobat Reader application is available at https://www.adobe.com/acrobat/pdf-reader.html.

All materials will be under the Package tab on the page for this opportunity on Grants.gov. If you have problems locating the application package, contact Grants.gov Helpdesk.

2. Required Registrations

You must have an active registration in SAM.gov and Grants.gov to apply for this opportunity.

It is your responsibility to plan ahead to ensure adequate time to register in both systems before submitting your application. We recommend beginning the registration process immediately, but **no later than** 30 days prior to the application deadline with a goal of your registration being complete at least 15 days prior to the application deadline.

a. Unique Entity Identifier and System for Award Management (SAM)

Grants.gov will not accept an application unless you have an active SAM.gov registration and received a Unique Entity Identifier (UEI). There is no fee for registering in SAM.gov.

In cases where an individual is an eligible applicant (see Section A.1.a), the individual does not need a SAM.gov registration. However, the individual must still create a Grants.gov account. Grants.gov will assign a default UEI value where applicable.

We cannot make an award to your entity unless it has an active SAM registration. In accordance with 2 C.F.R. § 25.205, if you have not complied with this requirement, we may:

- determine that you are not qualified to receive an award; and
- use that determination as a basis for making an award to another applicant.

Should you successfully compete and receive an award, all first-tier subrecipients must have a UEI number at the time you make a subaward to them.

Registering in SAM

Your organization must register online in the System for Award Management (SAM). Grants.gov will reject submissions from applicants with nonexistent or expired SAM Registrations. You will find instructions on the Grants.gov website as part of the organization registration process.

Complete a SAM registration (or renewal) as soon as possible if you do not currently have an active registration that will remain active through the competitive process. Registration will include obtaining a unique entity identifier (UEI). SAM.gov provides an Entity Registration Checklist to help you prepare the necessary documentation.

You may register in SAM as an entity applying for either

- Federal Assistance Awards Only (e.g., grants and cooperative agreements) or

- All Awards (including procurement awards).

  If you chose to register for All Awards, you must answer Yes to the question "Do you wish to apply for a federal financial assistance project or program, or is your entity currently the recipient of funding under any federal financial assistance project or program?" Failure to do so will require us to obtain a separate assurance document from you during our risk assessment (Section E.3) and may delay any award.

  The list of representations and certifications to be certified as part of your registration is reproduced in Section J.6 with the corresponding HHS regulation citations. By submitting your application to this NOFO, your authorized representative certifies to these representations and certifications by signing Box 21 of SF-424A.

  Make sure your SAM registration information is accurate, especially your organization's legal name and physical address including your ZIP+4. Should you successfully compete and receive an award, this is the legal name and address we must use on the NOA.

  During your registration, your organization will need to designate an E-Business Point of Contact (EBiz POC). The EBiz POC will need to be the individual to set up your Grants.gov account.

SAM Registration Renewal

If your organization has previously registered in SAM, confirm your status and determine whether you need to update or renew it. You must renew your SAM registration each year.

If you are successful and receive an award, you must maintain an active SAM registration with current information at all times during an active award or an application or plan under consideration by an HHS agency.

Timing of Registration

It may take up to 2-3 weeks (or longer during periods of high volume) for a registration to become active in SAM. After that, it may take an additional 24-72 hours for SAM to synchronize with Grants.gov. Grants.gov must recognize your SAM registration as active to accept your application. We strongly encourage confirming your registration status well before you are ready to submit your application to Grants.gov.

b. Grants.gov Registration

The Grants.gov Applicant Registration page provides the most up to date guidance on registering. There is no fee for registering to use Grants.gov.

Your EBiz POC may begin creating your account prior to receiving your UEI from SAM.gov. However, your will need to complete the SAM.gov registration prior to complete your Grants.gov registration.

Grants.gov is a platform that allows you to have multiple users with a variety of role-based access to perform actions on application(s). You must register an authorizing official for your organization. We do not determine who your organization's authorizing official is; your organization makes that decision. However, your authorizing official(s) must have the authority to act on behalf of your organization.

You may consider registering a backup authorized organization representative(s) in Grants.gov to ensure someone is available to submit your application. We will not extend due dates because your authorized official is unavailable.

We encourage potential applicants to familiarize themselves with the Workspace Overview and options as soon as possible.

3. Submission Instructions

It is your responsibility to read and understand the instructions to submit a complete and properly formatted application.

a. Electronic Application Submission

We require that all applications be submitted electronically via Grants.gov unless the Grants Management Officer has granted an exemption in writing (See Section E.3).

Grants.gov Information

You may access the application for this opportunity on Grants.gov. Search for the downloadable application page by the NOFO number PA-FPH-27-001 or Assistance Listing number 93.217.

To ensure successful submission of your application, you should carefully follow the step-by-step instructions on the site. These instructions are kept up-to-date and also provide links to Frequently Asked Questions and other troubleshooting information. You are responsible for reviewing all Grants.gov submission requirements on the Grants.gov site.

You should contact Grants.gov with any questions or concerns regarding the technical system questions about the electronic application process (Section I).

See Section F.2 for requirements related to UEI numbers and SAM registration.

Electronic File Submission

Applications, excluding required standard forms, must be submitted as three (3) files. Any additional files submitted as part of the Grants.gov application will not be accepted for processing and will be excluded from the application during the review process. Merit reviewers are not permitted to follow embedded links to materials outside of the application. Your content must fit within the page limits of the application.

File 1	The complete Project Narrative
File 2	All documents that make up the Appendices described in Section D.3.c

File 3	The entire Budget Package including supporting documentation described in the Budget Narrative content section.

Acceptable File Formats

All files uploaded for your application must be in an acceptable file format and must contain a valid file format extension in the filename.

We only accept the file formats identified in the table to ensure compatibility across our other systems although Grants.gov will allow you to attach unacceptable formats.

We strongly encourage you to upload your application in Adobe PDF format. By converting to PDF prior to submission, you may prevent any unintentional changes that might occur with submission of an editable document. Most commonly available applications for document preparation have the ability to "Save As" or "Print To PDF."

We do not recommend submitting scanned copies through Grants.gov unless you have confirmed the clarity of the scan and the readability of the documents.

Any file submitted as part of the Grants.gov application that is not in a file format listed as acceptable will not be imported for processing and will be excluded from the application during the review.

We will not contact you for resubmission of files to the correct the file type.

We will not contact you for passwords or for resubmission of unprotected files. We will forward unprotected information in the application forwarded for consideration, but we will not forward password protected portions.

Acceptable File Formats (extension)
• Adobe PDF (.pdf) • Microsoft Word (.doc or .docx) • Image formats (.jpg, .gif, .tif, or .bmp only)
Unacceptable File Formats (extension)
• Microsoft Excel files (.xls) or other similar spreadsheet files • Any compressed file formats (e.g., .zip, .rar, or Adobe Portfolio) • Any password protected files

Timing Considerations

We strongly encourage you to submit your application a minimum of 4-5 days prior to the application closing date. You are responsible for allowing time for system registrations and where applicable State Single Point of Contact (SPOC) notifications (Section E.3.d).

Do not wait until the last day in case you encounter technical difficulties, either on your end or with Grants.gov. Grants.gov can take up to 48 hours to notify you of a successful or rejected submission. You are better off having a less-than-perfect application successfully submitted and under consideration than no application.

If your submission fails due to a system problem with Grants.gov, we may accept your application if you provide verification from Grants.gov indicating system problems existed at the time of your submission and that time was before the submission deadline. If you have reported a system problem to the Grants.gov helpdesk, obtain a ticket number to provide us so that we can verify the problem.

A "system problem" does not include known issues for which Grants.gov has posted instructions regarding how to submit an application successfully, such as compatible Adobe versions or file naming conventions. Nor does a "system problem" include issues that should have been identified by reviewing and confirming your account status prior to the submission deadline.

Exemption to the Grants.gov Submission Requirement

We will consider an exemption to the Grants.gov submission requirement only under limited circumstances. To obtain an exemption, you must request one via email from GAM point of contact Eric West at eric.west@hhs.gov. Your request **must provide details as to why you are technologically unable to submit** electronically through Grants.gov. You should submit your request at least 4 business days prior to the application deadline to ensure we can review your request at least to 2 business days before the deadline.

In your e-mail requesting an exemption include:

- the NOFO number;
- your organization's UEI number;
- your organization's name, address and telephone number;
- the name and telephone number of your Authorizing Official;
- the Grants.gov Tracking Number (e.g., GRANT####) assigned to your submission; and
- a copy of the "Rejected with Errors" notification from Grants.gov.

We will not grant an exemption to the electronic submission requirement for:

- Failure to have an active System for Account Management (SAM) registration prior to the application due date.
- Failure to follow Grants.gov instructions to ensure software compatibility.
- Failure to have the correct permission levels configured in your Grants.gov workspace.

GAM will only accept applications via alternate methods (i.e., PDF via email or hardcopy paper via U.S. mail or other provider) from applicants with prior written approval. If you receive an exemption, you must still submit your complete application, and we must receive it by the due date.

We will accept only applications submitted through Grants.gov or a pre-approved alternate format.

b. Submission Dates and Times

You must submit your application for this funding opportunity by January 11, 2027.

Your submission time is the date and time stamp provided by Grants.gov when you **complete** your submission. If you do not submit your application by the due date and time, we will not review it, and it will receive no further consideration.

It is your responsibility to review all instructions available on Grants.gov for successfully submitting an application. For information on registering for Grants.gov or to receive assistance on any technical system questions, contact Grants.gov directly (Section J).

c. NOFO Technical Assistance Webinar

We will provide a technical assistance webinar for applicants on November 9, 2026.

You should review the entire announcement prior to attending to have any questions answered well in advance of the application due date. You should also subscribe to this opportunity on Grants.gov to receive any amendments, revisions, question and answer documents, or other updates.

Following the webinar, we will typically post an FAQ addressing common questions including those of general applicability asked during the webinar. We will also post a link to the recorded TA webinar.

Out of fairness to all applicants, we do not provide one-on-one consultation on the specific content development for any applications.

d. Intergovernmental Review

Applications under this opportunity are subject to the requirements of Executive Order 12372, ''Intergovernmental Review of Federal Programs,'' as implemented by 45 C.F.R. part 100, ''Intergovernmental Review of Department of Health and Human Services Programs and Activities.''

As soon as possible, you should discuss the project with the State Single Point of Contact (SPOC) for the State in which your organization is located.

The SPOC should forward any comments to

Department of Health and Human Services

OASH Grants & Acquisitions Management

ATTN: Grants Management Officer

1101 Wootton Parkway, Plaza Level

Rockville, MD 20852.

The SPOC has 60 days from the due date listed in this announcement to submit any comments.

For further information, contact the OASH Grants and Acquisitions Management Division (Section J).

4. Other Submission Requirements
a. Program-Specific Requirements

Non-profit Status

If you are a non-profit organization, please submit documentation of nonprofit status. Any of the following constitutes acceptable proof of such status:

(a) A reference to the Applicant organization's listing in the Internal Revenue Service's (IRS) most recent list of tax-exempt organizations described in the IRS code;

(b) A copy of a currently valid IRS tax exemption certificate;

(c) A statement from a State taxing body, State attorney general, or other appropriate State official certifying that the applicant organization has a nonprofit status and that none of the net earnings accrue to any private shareholders or individuals; or

(d) A certified copy of the organization's certificate of incorporation or similar document that clearly establishes nonprofit status.

b. Follow-up Submission Requirements
We may request additional documentation during the review process. We suggest having these documents readily available. Requests will only come from the OASH GAM staff. If you have any concern about the validity of a request, please contact us through the contact information provided in Section J.

Requested documentation may include a copy of your:

- Approved negotiated indirect cost rate, if not submitted in your budget package
- Internal controls
- Authorizing Tribal Resolution

We may request additional documentation as needed during our risk assessment process in Section G.4.

Failure to provide the requested documentation by the requested deadline may result in our no longer considering your application and moving on to another to make an award.

You should not interpret a request for information as an indication that we will make an award to you. A request only means that we are continuing to review your application.

G. APPLICATION REVIEW INFORMATION

Your application will undergo a series of reviews.

Application Qualification
GAM personnel will conduct a qualification review. There are three components to qualifying an application to proceed to merit review.

- **Eligibility Review** to determine whether you are an eligible applicant as described in Section

A.

- **Responsiveness Review** to determine whether the responsiveness criteria have been met as described in Section G.1.
- **Formatting Review** to determine whether your application meets the formatting requirements described in Section E.1.

The Grants Management Officer will make the final determination on whether an application is eligible and qualified to proceed to merit review. This decision is not appealable.

b. Merit Review

Consistent with the HHS Grants Policy Statement, effective October 1, 2025 (available at available at https://www.hhs.gov/sites/default/files/hhs-grants-policy-statement-oct-2025.pdf), an independent merit review panel will evaluate applications that are qualified and eligible. These reviewers are experts in their fields, and are drawn from academic institutions, non-profit organizations, state and local government, and Federal government agencies.

We do not disclose the identities of our review panelists. Each is vetted during the selection process to identify and manage any real or apparent conflict of interests.

Using the Merit Review Criteria, the reviewers will provide comments and rate the applications. We will provide reviewer comments to applicants after we have made final award decisions and issued notices of award. We do not provide scores.

c. Programmatic Technical Review and Risk Assessment

In addition to the independent merit review panel, federal staff will review each application for technical (programmatic), budgetary, and grants management compliance.

1. Responsiveness Review

The responsiveness review assesses your application at a high level to determine whether the application has addressed the subject matter of the opportunity or met any legal requirements. The criteria, if any, we describe below facilitate a go/no-go determination by the review team. Failure to address the responsiveness criteria clearly and provide the required information will result in disqualification.

a. Responsiveness Criteria

For this opportunity, the responsiveness criteria are:

- **Family Participation Certification**. Applicants must include a written statement in the appendix of the application certifying that:

  > "if funded, this Title X Family Planning Services project will encourage family participation in the decision of minors to seek family planning services and will provide counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities."

b. Disqualifying Criteria

Disqualification means we will not review the application and will give it no further consideration.
We will disqualify applications:

• not submitted electronically via Grants.gov (unless an exemption was granted by the grants management officer in writing 2 business days prior to the deadline)
• not submitted by the due date and time (Section E.3.b)
• not submitted by an eligible applicant (Section A.1.a)
• submitted multiple times for the same project from the same organization, *except* for the last application received by the deadline (Section A.1.c)
• not meeting the Responsiveness Criteria (Section F.1.a), if any
• not including a non-federal sources justification in the budget narrative when including cost-sharing (voluntary or required) (Section A.3)
• requesting total funds (direct plus indirect costs) that are either: o Above the Award Ceiling of $5,000,000; or o Below the Award Floor of $0.

• missing or incomplete required forms in the application package found on Grants.gov including SF-424; SF-424A, SF-LLL, and the Project Abstract Summary (Section D)
• not meeting the formatting requirements (Section D), specifically: o not submitted in the English language and U.S. dollars (2 C.F.R. § 200.111(a)) o not submitted with ▪ an 8 ½ ” x 11” page size ▪ 1” margins on all sides (top, bottom, left and right) ▪ a font size of not less than 12 points ▪ a Project Narrative that is double-spaced o exceeding the 50-page limit for the Project Narrative o exceeding the total 100-page limit for the Project Narrative plus Appendices combined, excluding SF-424, SF-424A, SF-LLL, Project Abstract Summary, and Budget Narrative with budget tables

2. Merit Review Criteria

Federal staff and an independent merit review panel will assess all qualified eligible applications according to the following criteria. Disqualified applications will not be reviewed against these criteria.

a. **Proposed Service Area and Plans to Address Demonstrated Need for Title X Family Planning Services**

- The extent to which the applicant substantiates, using current and relevant data, that Title X family planning services are needed locally within the proposed service area, particularly among low-income families as prioritized in Title X statute (**15 points**)

- The extent to which the applicant clearly identifies the number of clients, and, in particular, the number of low-income clients to be served, and describes the broad range of methods and services that will be provided to address client needs. For applicants that will not provide all services directly, the extent to which the applicant has described a rigorous and transparent process and criteria for selecting, monitoring, and overseeing qualified subrecipients to ensure alignment with Title X activities and agency priorities. (**10 points**)

b. **Plan to Deliver Family Planning Services in Compliance with the Statute, Regulations, Legislative Mandates, and Aligned with OPA Program Priorities**

- The degree to which the project plan adequately provides for the requirements set forth in the Title X statute, regulations (42 C.F.R. part 59, subpart A), and legislative mandates (**15 points**)
- The extent to which the applicant proposes strategies that meaningfully advance OPA's program priorities as discussed in Section C(a)(4)(i), "Address OPA Program Priorities" and HHS priorities. (**35 points**)

c. **Project Management and Capability**

- The relative need of the applicant, including the extent to which the applicant's project management plan shows the applicant's need for funds and the applicant's capability to make effective use of grant funds. (**5 points**)
- The adequacy of the applicant's facilities and staff, including evidence of an infrastructure that is sustainable in ensuring continued access to family planning services for clients in the proposed service area. (**10 points**)
- The capacity of the applicant to make rapid and effective use of the Federal assistance. Applicants must demonstrate/explain how they propose to use the federal assistance to provide quality family planning services that meet the needs of and improve access for clients in the proposed service area. (**5 points**).

d. **Budget**

- The relative availability of non-Federal resources within the community to be served and the degree to which those resources are committed to the project, including the degree to which the budget and budget narrative identify other sources of revenue, including but not limited to the estimated amount of program income and how the applicant proposes to invest it back into the proposed Title X project **(5 points)**

3. Merit Review and Selection Process

Application Status Inquiries

During the review process, we do not release information about individual applications. If you would like to track your application, please see the instructions on Grants.gov.

If you receive communications to negotiate an award or request additional or clarifying information, this does not mean you will receive an award. It only means that your application is still under consideration.

Federal Staff Review

In addition to the independent merit review panel, Federal staff will review each application for technical (programmatic), budgetary, and grants management compliance.

OPA is responsible for facilitating the process of evaluating applications and setting funding levels according to the criteria set forth in Title X regulations at 42 C.F.R. §59.7(a) and described above.

The Office of Population Affairs will coordinate with a senior appointee to provide recommendations for funding to the Grants Management Officer to conduct the required risk analysis consistent with 2 CFR 200 and applicable HHS policy. No award decision is final until a Notice of Award is issued by the Grants Management Officer, in coordination with a senior appointee or appointee's designee, consistent with the Executive Order on "Improving Oversight of Federal Grantmaking."

In providing these recommendations, the program office will take into consideration the following additional factors(s):

- Geographic distribution of projects
- Alignment with HHS and OASH priorities, where authorized by law and within the scope of the program.

4. Review of Risk Posed by Applicant

Before issuing any award, GAM evaluates each recommended application for risks in accordance with 2 C.F.R. § 200.206. This evaluation may incorporate results of the evaluation for eligibility or of the quality of an application.

Risk Factors Considered

We will use a risk-based approach and may consider any items such as the following:

a. Your financial stability;
b. Quality of management systems and ability to meet the management standards prescribed in 2 C.F.R. part 200;
c. History of performance. Your record in managing Federal awards, if you are a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards; however, not being a prior recipient of a Federal award shall not negatively impact a determination of award;
d. Reports and findings from audits performed; and
e. Your ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

Also, prior to making a Federal award with a total Federal share greater than the simplified acquisition threshold (currently $250,000), GAM must review and consider any information about you that is in the designated integrity and performance system accessible through the

System for Award Management (SAM) (formerly the Federal Awardee Performance and Integrity Information System (FAPIIS)).

If you are a prior Federal award recipient, the information in the system must, at a minimum, demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics." 2 C.F.R. § 300; see also 2 C.F.R. §200.206. You have the option to review information in SAM and comment on any information about your organization that a Federal awarding agency previously entered and is currently available through SAM.

During this review, the agency may request more details or action from you, as consistent with the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/hhs-grants-policy-statement-oct-2025.pdf).

GAM will consider any comments by you, other information in the designated system, and input from Federal staff including a senior appointee or that appointee's designee. This review will inform judgments regarding your integrity, business ethics, and record of performance and responsible stewardship of Federal awards.

Risk Review Outcomes

If, after consideration of risk factors, Federal staff including a senior appointee's review, and applicable integrity and performance information, GAM does not make an award to you because we determine that your organization does not meet either or both of the minimum qualification standards as described in 2 C.F.R. § 200.206, we must report that determination to SAM.gov, if certain conditions apply. See 2 C.F.R. § Part 300.

If we determine that a federal award will be made, specific conditions that correspond to the degree of risk assessed will be applied to the Federal award. Such conditions may include additional programmatic or financial reporting or releasing funds on a reimbursable rather than cash advance basis.

H. AWARD NOTICES

Upon completion of risk analysis and concurrence of the GMO, GAM will issue Notices of Award (NOAs). No award decision is final until the GMO issues a NOA. All award decisions, including the level of funding, if an award is made, are final and you may not appeal.

We are not obligated to make any federal award as a result of this NOFO. If we make awards, the awards may be for periods shorter than indicated. Only the GMO can bind the federal government to the expenditure of funds.

Funded Applications

If you are successful, you will receive official notice of your award with a Notice of Award (NOA) via a system notification from our grants management system (Grant Solutions) and/or via e-mail. The NOA includes the amount awarded for the specified budget period, the purpose(s) of the award, the anticipated length of the period of performance, terms and conditions of the award, and the amount of cost share or matching, if applicable.

If you receive an NOA, we strongly encourage you to read the entire document to ensure your organization's information is correct and that you understand all terms and conditions. You should pay specific attention to the terms and conditions, as some may require a time-limited response. The NOA will also identify the Grants Management Specialist (GMS) and Federal Project Officer (FPO) assigned to the award for assistance and monitoring. The GMS and FPO will work as a team. Any questions or concerns during the project should be communicated to both the GMS and FPO.

Pre-award costs are not allowed. If you begin a project prior to receiving a NOA or the project period start date on the NOA, you incur costs at your own risk. We will disallow the costs and will not approve them retroactively.

We intend to award funds as much in advance of the anticipated project start date (See Overview, page 1) as practicable, with a goal of 10-15 days. Note this is an estimated start date and award announcements may be made at a later date and with a later period of performance start date.

Unfunded Applications

If you are unsuccessful or your application was disqualified, OASH will notify you by email and/or letter. If the merit review panel reviewed your application, you may receive summary comments pertaining to the application resulting from the review process. We do not release application scores.

You may receive a letter indicating that your application was "approved, but unfunded" (ABU). This does not mean you will receive an award or funding. Applications designated ABU are kept active for up to 12 months. During that time, a program office may consider an ABU application for award should funds become available. However, an ABU status does not guarantee that we will fund your project.

We will not transfer an ABU application for consideration under a new NOFO. You would have the option to resubmit your application, with any updated material, for consideration under that new NOFO.

I. AWARD REQUIREMENTS AND ADMINISTRATION

The following subsections describe the administrative requirements and the terms and conditions that will apply to any award you might receive under this NOFO. As of October 1, 2025, HHS has adopted 2 CFR Part 200, with some modifications included in 2 CFR Part 300. These regulations replace those in 45 CFR Part 75.

1. Administrative and National Policy Requirements

a. Recipient Responsibilities

You will have the full responsibility for the conduct of the approved project or activity and for adherence to all award terms and conditions, statutory, regulatory, or policy requirements applicable to grants and cooperative agreements. The approved project or activity is the project described in your application subject to any OASH GMO approved amendments. Approval of

the project does not waive or negate any statutory, regulatory, or policy requirements applicable to grants and cooperative agreements.

You will be encouraged to seek the advice and opinion of the federal project officer and grants management specialist on special problems that may arise. Such advice does not diminish your responsibility for making sound programmatic and administrative judgments and does not imply that the responsibility for operating decisions has shifted to HHS, OASH, or the program office.

b. Accepting an Award

You accept an award and its terms and conditions by drawing or otherwise obtaining funds for the award from the grant payment system. By accepting an award, you agree to comply with the applicable federal requirements for grants and cooperative agreements, including those in the SAM registration certifications and representations, and to the prudent management of all expenditures and actions affecting the award, including the monitoring of any subrecipients.

You must comply with all terms, conditions, and requirements outlined in the Notice of Award, including: award policy terms and conditions contained in the HHS Grant Policy Statement (GPS, effective October 1, 2025, available at https://www.hhs.gov/sites/default/files/hhs-grants-policy-statement-oct-2025.pdf), and its subsequent updates, all requirements imposed by program statutes and regulations, Executive Orders, and HHS grant administration regulations; and requirements or limitations in any applicable appropriations acts.

c. Scope of the Award and Prior Approvals

You may only use award funds to support activities in your funded project. HHS GPS Section II and 2 C.F.R. § 200.308 describe the aspects of your funded project that will require prior approval from the OASH GMO for any changes. Some of the award modifications to an approved project that will require prior GMO approval include:

- a change in the scope or the objective(s) of the project (even if there is no associated budget revision, such as reduction in services, closing of service or program site(s)).
- significant budget revisions, including changes in the approved cost-sharing or matching;
- a change in a key person(s) specified in your application;
- reduction in time devoted to the project by the approved PD/PI, either as percentage of full-time equivalent of 25% or more or absence for 3 months or more; or
- the transferring of any work to another entity or individual through contract, subaward, or other means that differs from described in the awarded proposal.

d. Applicable Termination Provisions

If you receive an award, HHS may terminate it if any of the conditions in 2 C.F.R. §§ 200.340(a)(1)-(4) are met.

2. Program Specific Terms and Conditions

We may include on any awards made under this opportunity the following as special terms and requirements.

a. Paperwork Reduction Act Clearance Packages

Any collection of information you conduct as defined in 5 C.F.R. § 1320.3(c) may require OMB clearance under the Paperwork Reduction Act (PRA) if it is a requirement of your award to collect that information. You would be responsible for preparing the clearance package necessary to obtain PRA clearance and submitting it to the project officer. The project officer will assist in the submission of the package to OMB and notify you when the approval has been received or request additional information.

3. Award Closeout

When the award expires, you must submit within 120 days all necessary documentation to closeout your award. If we do not receive acceptable final performance, financial, and property reports in a timely fashion and we determine that closeout cannot be completed with your cooperation, we must complete a unilateral closeout with the information available to us (2 C.F.R. § 200.344). See Section I.3 for specific detail.

If you do not submit all reports within one year of the period of performance end date, we must report your material failure to comply with the terms and conditions of the award with the OMB-designated integrity and performance system. As a result, we may also determine that enforcement actions are necessary, including actions such as withholding support or a high-risk designation on an existing or future award.

4. Lobbying Prohibitions

In general, any funds from an award made under this NOFO must not be used for other than normal and recognized executive legislative relationships. See 2 C.F.R. § 200.450.

You must not use funds for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat:

- the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any State or local legislature itself, or
- any proposed or pending regulation, administrative action, or order issued by the executive branch of any State or local government, except in presentation to the executive branch of any State or local government itself.

You must not use any funds awarded to pay the salary or expenses of any employee or subrecipient, or agent acting for you, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive Order proposed or pending.

5. Non-Discrimination Requirements

If you receive an award, you must follow all applicable nondiscrimination laws. You agree to

this when you register in SAM.gov. You must also submit an Assurance of Compliance (HHS-690). To learn more, see the HHS Office for Civil Rights website.

6. Smoke- and Tobacco-free Workplace

We strongly encourage all award recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. This is consistent with the HHS mission to protect and advance the physical and mental health of the American people.

7. Acknowledgement of Funding

Each year's annual appropriation requires that when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money, all organizations receiving Federal funds, including but not limited to State and local governments and recipients of Federal research grants, shall clearly state— (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) percentage and dollar amount of the total costs of the project or program that will be financed by non-governmental sources.

You must also acknowledge Federal support in any publication you develop using funds awarded under this program, with language such as:

> This [project/publication/program/website, etc.] was supported by [Award Number] issued by the Office of the Assistant Secretary for Health of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling $XX with 100 percent funded by Organization Name.

You must also include a disclaimer stating the following:

> The contents are solely the responsibility of the author(s) and do not necessarily represent the official views of, nor an endorsement by, Organization Name, OASH, HHS, or the U.S. Government. For more information, please visit [Organization Name website, if available].

8. HHS Rights to Materials and Data

All publications you develop or purchase with funds awarded under this announcement must adhere to the requirements of the program. You own the copyright for materials that you develop under an award, and pursuant to 2 C.F.R. § 200.448 the HHS awarding agency reserves a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use those materials for federal purposes, and to authorize others to do so.

In addition, pursuant to 2 C.F.R. § 200.448, the federal government has the right to obtain, reproduce, publish, or otherwise use data produced under this award and has the right to authorize others to receive, reproduce, publish, or otherwise use such data for federal purposes.

9. Trafficking in Persons

Awards are subject to the requirements of Section 106(g) of the Trafficking Victims Protection Act of 2000, as amended (22 U.S.C. § 7104).

10. Efficient Spending

Awards will be subject to the HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items, and Printing and Publications.

11. Whistleblower Protection

Awards will include a term and condition that applies the terms of 2 C.F.R. § 200.217 to the award, and requires that you inform your employees in writing of employee whistleblower rights and protections under 41 U.S.C. § 4712 in the predominant native language of the workforce.

12. Health Information Technology (IT) Interoperability

Health information technology is defined in Section 3000 of the Public Health Service Act (42 U.S.C. § 300jj). HHS has substantially adopted and codified that definition at 45 C.F.R. § 170.102. The regulation defines health information technology as hardware, software, integrated technologies or related licenses, IP, upgrades, or packaged solutions sold as services that are designed for or support the use by health care entities or patients for the electronic creation, maintenance, access, or exchange of health information.

If you receive an award that involves:

a. implementing, acquiring, or upgrading health IT for activities, you are required to utilize health IT that meets standards and implementation specifications adopted in 45 C.F.R. part 170, Subpart B, if such standards and implementation specifications can support the activity.
b. implementing, acquiring, or upgrading health IT for activities by eligible clinicians in ambulatory settings, or hospitals, eligible under Section 4101, 4102, and 4201 of the HITECH Act, you are required to utilize health IT certified under the Office of the HHS Office of the National Coordinator for Health Information technology (ONC) Health IT Certification Program, if certified technology can support the activity. See https://www.healthit.gov/topic/certification-ehrs/certification-health-it.

If standards and implementation specifications adopted in 45 CFR Part 170, Subpart B cannot support the activity, recipients and subrecipients are encouraged to utilize health IT that meets non-proprietary standards and implementation specifications developed by consensus-based standards development organizations. This may include standards identified in the ONC Interoperability Standards Advisory, available at https://www.healthit.gov/isa/.

13. Certain telecommunications and video surveillance services or equipment

As described in 2 C.F.R. 200.216, recipients and subrecipients are prohibited from obligating or spending grant funds (to include direct and indirect expenditures as well as cost share and

program) to:

a. Procure or obtain;
b. Extend or renew a contract to procure or obtain; or
c. Enter into a contract (or extend or renew a contract) to procure or obtain equipment, services, or systems that use covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. As described in Pub. L. 115-232, section 889, covered telecommunications equipment is telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities).
    1. For the purpose of public safety, security of government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities).
    2. Telecommunications or video surveillance services provided by such entities or using such equipment.
    3. Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of the National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise, connected to the government of a covered foreign country.

14. Human Subjects Protection

Federal regulations (45 C.F.R part 46) require that applications and proposals involving human subjects be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. If research involving human subjects is anticipated, you must meet the requirements of the HHS regulations to protect human subjects from research risks as specified in 45 C.F.R. part 46. Additional information is available on the Office of Human Research Protections website. This includes a series of decision charts to help assess whether an activity is human subjects research covered by the regulation and when an exemption may apply.

OASH requires, as part of any award involving human subjects, that recipients submit copies of all IRB approvals (not full protocols), or documentation of exemption determinations, within 5 days of the IRB approving the research or documentation of the specific exemption applied. Recipients must receive IRB approval or determine an exemption is applicable before any human subjects research begins.

15. Research Integrity

Federal regulations require that an applicant for or recipient of Public Health Service support for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training must comply with the Public Health Service Policies on Research Misconduct in 42 C.F.R. part 93. Compliance includes having written policies and

procedures for addressing allegations of research misconduct that meet the requirements of part 93, unless exempt; responding to each allegation of research misconduct for which the applicant or recipient is responsible under part 93 in a thorough, competent, objective, and fair manner; fostering a research environment that promotes the responsible conduct of research and discourages research misconduct; and maintaining an active assurance. More information about assurances is available in 42 CFR Part 93 Subpart C and on the Office of Research Integrity assurance program website.

16. Reporting

Recipients must report on project progress 2 C.F.R. § 200.329 and financial status 2 C.F.R. § 200.328 during the course of the project. At the end of the project, acceptable final progress and financial reports are a requirement of the award closeout process. Failure to provide final progress or financial reports on any HHS award may affect decisions on future new or continuation funding.

a. ***Performance Project Reports (PPR)***

You must submit periodic performance project reports on an annual basis via the Performance Project Report (PPR) module in GrantSolutions. We must receive the PPR by the due date included in the terms and conditions on the NOA. PPRs must address the content required by 2 C.F.R. § 200.329. The program office may provide additional guidance on the content of the progress report.

At the end of the project, you must submit a final performance report covering the entire period of performance no later than 120 days after the end of the period of performance. The program office may provide additional guidance on the content of the final report, which you must submit in the PPR module.

Project Performance and Continuation Awards

For projects with multiple budget periods anticipated, you will be required each year of the approved period of performance to submit in addition to your PPRs, a noncompeting continuation application. This application will include a summary of progress the last PPR, an updated work plan, and a budget package (SF-424A, narrative, and justification) for the upcoming budget period. Specific guidance will be provided via Grant Solutions well in advance of the application due date.

For the optional competitive additional year of funding intended to transition successful projects to sustainability, application guidance and review criteria will be provided during the final year of the period of performance.

We will award continuation funding based on availability of funds, satisfactory progress of the project, grants management compliance, including timely reporting, and continued best interests of the government. Progress is assessed relative to meeting the goals, objectives, and outcomes in the approved, funded project as described in the approved application and other supporting documents.

Performance Measures

Each year of the project period, the recipient is required to submit a Family Planning Annual Report (FPAR). The information collection (reporting requirements) and format for this report have been approved by the Office of Management and Budget (OMB) and assigned OMB No. 0990-0479 (Expires 9/30/2028). The FPAR 2.0 data elements, instrument and instructions can be found on the OPA Web site at http://hhs.gov/opa.

b. Financial Reports

You must submit quarterly Federal Financial Reports (FFR) (SF-425). Your specific reporting schedule will be issued as a condition of award. Typically, we align the FFR reporting periods with the quarters of the federal fiscal year. FFRs are cumulative and due 30 days after the end of each reporting period or more specifically for the:

Quarter ending September 30, your FFR is due October 30
Quarter ending December 31, your FFR is due January 30
Quarter ending March 30, your FFR is due April 30
Quarter ending June 30, your FFR is due July 30.

In lieu of the last quarterly FFR, you will also be required to submit a final FFR covering the entire award 120 days after the end of the period of performance. You must submit FFRs via HHS Payment Management System (PMS) (https://pms.psc.gov).

Once submitted and accepted, your financial report data will be available in GrantSolutions, which is our grant management system.

c. Audits

If your organization expends $1,000,000 or greater in federal funds, it must undergo an independent audit in accordance with 2 C.F.R. § 200.501, often referred to as the Single Audit requirement.

d. Reporting of Matters Relating to Recipient Integrity and Performance

If the total value of your currently active grants, cooperative agreements, and procurement contracts from all Federal awarding agencies exceeds $10,000,000 for any period of time during the period of performance of this Federal award, then you must maintain the currency of information reported to SAM.gov that is made available in the designated integrity and performance system (currently FAPIIS) about civil, criminal, or administrative proceedings described in 2 C.F.R. part 200. This is a statutory requirement (41 U.S.C. § 2313).

All information posted in the designated integrity and performance system will be publicly

available. For more information about this reporting requirement related to recipient integrity and performance matters, see Appendix XII to 2 C.F.R. part 200.

e. Other Required Notifications

Before you enter into a covered transaction at the primary tier, in accordance with 2 C.F.R. § 180.335, you as the participant must notify OASH, if you know that you or any of the principals for that covered transaction:

- Are presently excluded or disqualified;
- Have been convicted within the preceding three years of any of the offenses listed in 2 C.F.R. § 180.800(a) or had a civil judgment rendered against you for one of those offenses within that time period;
- Are presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State or local) with commission of any of the offenses listed in 2 C.F.R. § 180.800(a); or
- Have had one or more public transactions (Federal, State, or local) terminated within the preceding three years for cause or default.

At any time after you enter into a covered transaction, in accordance with 2 C.F.R. § 180.350, you must give immediate written notice to OASH if you learn either that—

- You failed to disclose information earlier, as required by 2 C.F.R. § 180.335; or
- Due to changed circumstances, you or any of the principals for the transaction now meet any of the criteria in 2 C.F.R. § 180.335.

J. CONTACTS

Administrative and Budgetary Requirements

For information related to administrative and budgetary requirements, contact the HHS/OASH grants management specialist listed below.

Eric West
OASH Grants and Acquisitions Management
Email: eric.west@hhs.gov

Program Requirements

For information on program requirements, please contact the program office representative listed below.

Elizabeth Nash
Office of Population Affairs
Email: Elizabeth.nash@hhs.gov

Grants.gov Support

For information or assistance on submitting your application electronically via Grants.gov, contact Grants.gov directly. Assistance is available 24 hours a day, 7 days per week.

GRANTS.GOV Applicant Support

Website: https://www.grants.gov

Phone: 1-800-518-4726

Email: support@grants.gov

SAM.gov Registration Support
For information or assistance on registering with SAM.gov, contact the General Services Administration (GSA) Federal Service Desk (FSD) Monday through Friday 8:00 AM to 8:00 PM Eastern at:

Website: https://www.fsd.gov/gsafsd_sp (Live Chat option available)

U.S. Phone: 866-606-8220

International Phone: +1 334-206-7828

K. OTHER INFORMATION

1. Application Checklist

The below is a summary listing of all the application elements required for this funding opportunity.

Application Checklist	
	SAM.gov Registration/Renewal – start as soon as possible (recommended minimum of 6-8 weeks prior to submission deadline
	Grants.gov Registration (recommended minimum of 6-8 weeks prior to submission deadline)
	Application for Federal Assistance (SF-424)
	Budget Information for Non-construction Programs (SF-424A)
	Disclosure of Lobbying Activities (SF-LLL)
	Project Abstract Summary, including any responsiveness criteria (Section F.1.a)
	Project Narrative – Submit all Project Narrative content (Section D.2.a) as a single acceptable file (Section E.3.a).
	Project Narrative Appendices – Submit all Appendix content (Section D.2.b) as a single acceptable file (Section E.3.a).

	Budget Package – Submit all Budget Package content (Section D.2.c) as a single acceptable file (Section E.3.a). Note SF-424A is not included in the package and should be uploaded with the standard forms. Must include documentation of any cost-share or matching proposed regardless of whether it is voluntary or mandatory. (Section A.3)
	Other Submission Requirements (Section E.4).

2. Acronyms

ABU	Approved, but Unfunded
FAPIIS	Federal Awardee Performance and Integrity Information System
FFATA	Federal Financial Accountability and Transparency Act
FFR	Federal Financial Report (SF-425)
FSD	Federal Service Desk (GSA)
FSRS	FFATA Subaward Reporting System
GAM	Grants and Acquisitions Management Division
GMO	Grants Management Officer
GMS	Grants Management Specialist
GPS	Grants Policy Statement
GSA	General Services Administration
HHS	Department of Health and Human Services
MTDC	Modified Total Direct Costs
NCC	Non-competing Continuation
NOA	Notice of Award
NOFO	Notice of Funding Opportunity
OASH	Office of the Assistant Secretary for Health
OMB	Office of Management and Budget
PD/PI	Project Director/Principal Investigator
PHS	Public Health Service
PPR	Performance Project Report
SF	Standard Form
SPOC	State Single Point of Contact

3. Glossary

4. Object Class Descriptions and Required Justifications

Personnel

Description

Includes costs of employee salaries and wages, excluding benefits.

Does NOT include consultants, subrecipient personnel costs, personnel costs outside of your organization. 2 C.F.R. § 200.459.

Justification

Clearly identify the PD/PI, if known. Provide a separate table for personnel costs detailing for each proposed staff person: the title; full name (if known at time of application), time commitment to the project as a percentage or full-time equivalent: annual salary and/or annual wage rate; federally funded award salary; non-federal award salary, if applicable; and total salary.

No salary rate may exceed the statutory limitation in effect at the time you submit your application (see E.2.c.2).

Sample Personnel Table					
Position Title and Full Name	Percent Time	Annual Salary	Federally-Funded Salary	Non-Federal Salary	Total Project Salary
Project Director, John K. Doe	50%	$100,000	$50,000	$0	$50,000
Data Assistant, Susan R. Smith	10%	$30,000		$3,000	$3,000

Fringe Benefits

Description

Includes costs of personnel fringe benefits, unless treated as part of an approved indirect cost rate.

Justification

Provide a breakdown of the amounts and percentages that comprise fringe benefit costs such as health insurance, Federal Insurance Contributions Act (FICA) taxes, retirement insurance, and taxes.

Travel

Description

Includes costs of travel by staff of the applicant organization only.

Does NOT include travel costs for subrecipients or contractors under this object class.

Justification

For each trip proposed for your organization employees only, show the date of the proposed travel, total number of traveler(s); travel destination; duration of trip; per diem; mileage allowances, if privately owned vehicles will be used; and other transportation costs and subsistence allowances.

Equipment

Description

Includes tangible personal property (including information technology systems) having a useful life of more than one year and a per-unit acquisition cost that equals or exceeds the lesser of the capitalization level established by the recipient or subrecipient for financial statement purposes, or $10,000 ((2 C.F.R. § 200.1 and § 200.313(e)).

Acquisition cost means the cost of the asset including the cost to ready the asset for its intended use. Acquisition cost for equipment, for example, means the net invoice price of the equipment, including the cost of any modifications, attachments, accessories, or auxiliary apparatus necessary to make it usable for the purpose for which it is acquired. Acquisition costs for software includes those development costs capitalized in accordance with generally accepted accounting principles (GAAP). Ancillary charges, such as taxes, duty, protective in transit insurance, freight, and installation may be included in or excluded from the acquisition cost in accordance with the non- Federal entity's regular accounting practices.

Justification

For each type of equipment requested you must provide a description of the equipment; the cost per unit; the number of units; the total cost; and a plan for use of the equipment in the project; AND a plan for the use, and/or disposal of, the equipment after the project ends.

If your organization uses its own definition for equipment you should include in the budget narrative a copy of the policy, or section of your policy, that includes the equipment definition. Reference the policy in your justification. Do not include this policy in your appendices.

Supplies

Description

Includes costs of all tangible personal property other than those included under the Equipment category. This includes office and other consumable supplies with a per-unit cost of less than $10,000 (2 C.F.R. § 200.1).

Justification

Specify general categories of supplies and their costs. Show computations and provide other information that supports the amount requested.

Contractual

Description

Includes costs of all contracts or subawards for services and goods except for those that belong under other categories such as equipment, supplies, construction, etc.

Include third-party evaluation contracts, if applicable, and contracts or subawards with subrecipient organizations (with budget detail), including delegate agencies and specific project(s) and/or businesses to be financed by the applicant.

This line item is not for individual consultants.

Justification

Demonstrate that all procurement transactions will be conducted in a manner to provide, to the maximum extent practical, open, and free competition. Recipients and subrecipients are required to use 2 C.F.R. § 200.320 procedures and must justify any anticipated procurement action that is expected to be awarded without competition and exceeds the simplified acquisition threshold fixed by FAR 2.101 and currently set at $250,000. In some cases, OASH may require recipients make pre-award review and procurement documents, such as requests for proposals or invitations for bids, independent cost estimates, etc., available. Any proposal for awarding fixed amount subawards is subject to 2 C.F.R. § 200.333 and will require detailed justification to support the fixed award amount.

Transferring a substantive part of the project effort to another entity (including non-employee individuals) through contract or other mechanism requires a detailed budget and budget narrative for each subrecipient, by title or name, along with the same supporting information referred to in these instructions. If you plan to select the subrecipients post-award and a detailed budget is not available at the time of application, you must provide information on the nature of the work to be transferred, the estimated costs, and the process for selecting the subrecipient.

Other

Description

Includes such costs as, where applicable and appropriate,

- consultants;
- insurance;
- professional services (including audit charges);
- space and equipment rent;
- printing and publication;
- training, such as tuition and stipends;
- participant support costs including incentives,
- staff development costs; and
- any other costs not addressed elsewhere in the budget.

Do not include costs covered by your negotiated indirect cost rate.

Justification

Provide computations, a narrative description, and a justification for each cost under this category.

Indirect Costs

Description

Calculate your indirect costs based on a percentage of your modified total direct costs (MTDC)(2 C.F.R. § 200.1).

There are two methods. You must clearly identify the rate you used in your submitted budget.

Negotiated Indirect Cost Rate

If you have an approved negotiated indirect cost rate from the Department of Health and Human Services (HHS) or another cognizant federal agency, you should apply that negotiated rate. You should enclose a copy of the current approved rate agreement in your Budget package file.

If you request a rate that is less than allowed, your authorized representative must submit a signed acknowledgement that you are accepting a lower rate than allowed. This should be an explicit statement that you are accepting a lower rate than is allowed and specify what the lower rate is.

De minimis Rate (2 C.F.R. § 200.414(f))

If you do not have a current Federal negotiated indirect cost rate (including provisional rate) you "may elect to charge a de minimis rate of up to 15 percent of modified total direct costs (MTDC)." (2 C.F.R. § 200.414(f).) You may "determine the appropriate rate up to this limit. . . When applying the de minimis rate, costs must be consistently charged as either direct or indirect costs and may not be double charged or inconsistently charged as both." (2 C.F.R. § 200.414(f).) If you elect to use the de minimis rate, you must use the de minimis rate for all Federal awards until you choose to receive a negotiated rate.

Indirect costs for training are limited to a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $50,000 (45 C.F.R. § 75.414 (c)(1)(i)).

Modified Total Direct Cost (MTDC) means all direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel, and up to the first $50,000 of each subaward (regardless of the period of performance of the subawards under the award). MTDC excludes equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs, and the portion of each subaward in excess of $50,000. Other items may only be excluded when necessary to avoid a serious inequity in the distribution of indirect costs, and with the approval of the cognizant agency for indirect costs (2 C.F.R. § 200.1).

Justification

Provide the calculation for your indirect costs total, i.e., show each line item included in the base, the total of these lines, and the application of the indirect rate. If you have multiple approved rates, indicate which rate as described in your approved agreement is being applied and why that rate is being used. For example, if you have both on-campus and off-campus rates, identify which is being used and why.

Program Income

Description

Program income means gross income earned by your organization that is directly generated by an awarded project except as provided in 2 C.F.R. § 200.307. Program income includes but is not limited to income from fees for services performed or the use or rental of real or personal property acquired under the award.

Interest earned on advances of Federal funds is not program income. Except as otherwise provided in Federal statutes, regulations, or the terms and conditions of the Federal award, program income does not include rebates, credits, discounts, and interest earned on any of them. See also 2 C.F.R. § 200.307 and 35 U.S.C. § 200-212 (applies to inventions made under Federal awards).

Justification

Describe and estimate the sources and amounts of program income that this project may generate. All program income generated as a result of awarded funds must be used within the scope of the approved project-related activities.

Any program income earned must be used under the addition or additive method unless otherwise specified in Section C.2. These funds should not be added to your budget, unless you are using the funds as cost sharing or matching, if applicable. This amount should be reflected in box 7 of the SF-424A.

Non-Federal Resources (Cost Share or Match)

Description

Amounts of non-federal resources that will be used to support the project as identified in box 18 of the SF-424. For all federal awards, any shared costs or matching funds and all contributions, including cash and third-party in-kind contributions, must be accepted as part of the recipient's cost sharing or matching when such contributions meet all of the criteria listed in 2 C.F.R. § 200.306.

For awards that require matching by statute, you will be held accountable for projected commitments of non-federal resources in your application budgets and budget justifications by budget period even if the justification exceeds the amount required.

For awards resulting from an application where you voluntarily propose cost sharing, we will include this voluntary cost sharing in the approved project budget, and you will be held accountable for it as shown in the Notice of Award (NOA).

Failure to meet a cost sharing or matching obligation that is part of the approved project budget on the NOA may result in the disallowance of federal funds.

If you are funded, you must report cost sharing or matching funds on your quarterly Federal Financial Reports.

Justification

You must provide detailed budget information in your budget narrative (not your appendices) for every funding source identified in box 18. "Estimated Funding ($)" on the SF-424.

You must fully identify and document the specific costs or contributions you propose as part of your required or voluntary cost sharing requirement. You must provide documentation in your application on the sources of funding or contribution(s).

For in-kind contributions, you must include how the stated valuation was determined. Matching or cost sharing must be documented by budget period.

Unrecovered indirect costs may be included as part of your cost sharing or matching only with prior approval of the grants management officer. Your budget narrative must clearly state that it is your intent to include unrecovered indirect costs as part of your cost sharing or matching. You should include in your budget narrative a copy of your negotiated cost rate to support the justification. Unrecovered indirect cost means the difference between the amount charged to the Federal award and the amount which could have been charged to the Federal award under your approved negotiated indirect cost rate. (See 2 C.F.R. § 200.306(c)).

If your application does not include the required supporting documentation for required or voluntary cost-sharing or matching, it will be disqualified from competitive review (Section C.4).

5. Considerations in Recipient Plans for Oversight of Federal Funds

(See also Section E.3.b.3)

To the maximum extent possible, a recipient organization should segregate responsibilities for receipt and custody of cash and other assets; maintaining accounting records on the assets; and authorizing transactions. In the case of payroll activities, the organization, where possible, should segregate the timekeeping, payroll preparation, payroll approval, and payment functions.

Questions for consideration in developing your plan may include:

- Do the written internal controls provide for the segregation of responsibilities to provide an adequate system of checks and balances?
- Are specific officials designated to approve payrolls and other major transactions
- Does the time and accounting system track effort by cost objective?
- Are time distribution records maintained for all employees when his/her effort cannot be specifically identified to a particular program cost objective?
- Do the procedures for cash receipts and disbursements include:
- Receipts are promptly logged in, restrictively endorsed, and deposited in an insured bank account?
- Bank statements are promptly reconciled to the accounting records, and are reconciled by someone other than the individuals handling cash, disbursements and maintaining accounting records?
- All disbursements (except petty cash or EFT disbursements) are made by pre-numbered checks?
- Supporting documents (e.g., purchase orders, Invoices, etc.) accompany checks submitted for signature and are marked "paid" or otherwise prominently noted after payments are made?

6. Financial Assistance General Certifications and Representations

When you register your organization in SAM.gov, you must complete the certifications and representations applicable to grants (i.e., federal assistance). We have provided for your reference the list of items that you are certifying when you complete this during your registration.

When your organization completes its registration (new or renewal) in SAM.gov, your organization attests that your organization:

1. Has the legal authority to apply for federal assistance and the institutional, managerial and financial capability to ensure proper planning, management, and completion of any financial assistance project covered by this Certifications and Representations document (See 2 C.F.R. § 200.113 Mandatory disclosures, 2 C.F.R. § 200.214 Suspension and debarment, OMB Guidance A- 129, "Policies for Federal Credit Programs and Non-Tax Receivables");
2. Will give the awarding agency, the Comptroller General of the United States and, if appropriate, the State, through any authorized representative, access to and the right to examine all records, books, papers, or documents related to the award; and will establish a proper accounting system in accordance with generally accepted accounting standards or agency directives (See 2 C.F.R. § 200.302 Financial Management 2 C.F.R. § 200.303 Internal controls;
3. Will disclose in writing any potential conflict of interest to the federal awarding agency or pass through entity in accordance with applicable federal awarding agency policy (See 2 C.F.R. § 300.112 Conflict of interest;
4. Will comply with all limitations imposed by annual appropriation acts;
5. Will comply with the U.S. Constitution, all federal laws, and relevant Executive guidance in promoting the freedom of speech and religious liberty in the administration of federally-funded programs (See 2 C.F.R. § 200.300 Statutory and national policy requirements [2 C.F.R. § 300.112] and 2 C.F.R. § 200.303 Internal controls [2 C.F.R. § 300);
6. Will comply with all applicable requirements of all other federal laws, executive orders, regulations, and public policies governing financial assistance awards and any federal financial assistance project covered by this certification document, including but not limited to:
    1. Trafficking Victims Protection Act (TVPA) of 2000, as amended, 22 U.S.C. § 7104(g);
    2. Drug Free Workplace, 41 U.S.C. § 8103;
    3. Protection from Reprisal of Disclosure of Certain Information, 41 U.S.C. § 4712;
    4. National Environmental Policy Act of 1969, as amended, 42 U.S.C. § 4321 et seq;
    5. Universal Identifier and System for Award Management, 2 C.F.R. part 25;
    6. Reporting Subaward and Executive Compensation Information, 2 C.F.R. part 170;
    7. OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (Non-procurement), 2 C.F.R. part 180;
    8. Civil Actions for False Claims Act, 31 U.S.C. § 3730;
    9. False Claims Act, 31 U.S.C. §3729, 18 U.S.C. §§ 287 and 1001;
    10. Program Fraud and Civil Remedies Act, 31 U.S.C. § 3801 et seq;

11. Lobbying Disclosure Act of 1995, 2 U.S.C. § 1601 et seq;
12. Title VI of the Civil Rights Act of 1964, 42 U.S.C. § 2000d et seq;
13. Title VIII of the Civil Rights Act of 1968, 42 U.S.C. § 3601 et seq;
14. Title IX of the Education Amendments of 1972, as amended; 20 U.S.C. § 1681 et seq
15. Section 504 of the Rehabilitation Act of 1973, as amended; 29 U.S.C. § 794; and
16. Age Discrimination Act of 1975, as amended, 42 U. S.C. § 6101 et seq.

7. Protections for Healthcare Entities under Weldon and Other Conscience Protection Statutes

Under this program, HHS will not require grantees, individuals and institutions, who are covered by the Weldon Amendment to counsel or refer for abortions, notwithstanding the program's current regulations, *see* 42 C.F.R. 59.5(a)(5); See 86 FR 56144, 56153 (10/7/2021) ("[O]bjecting individuals and grantees will not be required to counsel or refer for abortions in the Title X program in accordance with applicable federal law. OPA has long worked with grantees and providers to ensure appropriate compliance with conscience laws".). The Weldon Amendment provides that Federal or State agencies or programs cannot subject institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions. *See* Consolidated Appropriations Act, 2026, H.R. 7148, Div. B., Tit. V, Section 507(d). Under Weldon, a health care entity includes an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan.

For more information about whether an entity is covered by the Weldon Amendment, applicants/grantees may consult resources provided by the Office for Civil Rights, https://www.hhs.gov/conscience/your-protections-against-discrimination-based-on-conscience-and-religion/index.html. And if an entity believes it has been subject to discrimination under Weldon, it may file a complaint with OCR here: https://ocrportal.hhs.gov/ocr/smartscreen/main.jsf

EXHIBIT B

OASH | Office of Population Affairs

OPA Program Policy Notice 2024-02—Implementing Quality Family Planning Services Recommendations within Title X Projects

Release Date: November 19, 2024
OPA Program Policy Notice: 2024 – 02

Purpose

The purpose of this Program Policy Notice (PPN) is to clarify OPA expectations for Title X grant recipients implementing *Providing Quality Family Planning Services in the United States: Recommendations of the U.S. Office of Population Affairs (Revised 2024)* (QFP) within their Title X projects and to outline where specific QFP recommendations are outside of the scope of the Title X project. This PPN applies to Title X grant recipients, subrecipients, and service sites.

Background

Title X projects must comply with requirements set out in the Title X statute (42 U.S.C. §300 et seq.), any legislative mandates included in annual HHS appropriations (e.g., Further Consolidated Appropriations Act, 2024 (Pub. L. No. 118-47)), Title X implementing regulations at 42 CFR Part 59, Subpart A, and any applicable court orders.

The Title X regulations specify that Title X projects must provide services in a manner that "ensures equitable and quality service delivery consistent with nationally recognized standards of care" (42 CFR § 59.5(a)(3)). *Providing Quality Family Planning Services in the United States: Recommendations of the U.S. Office of Populations Affairs (Revised 2024)* is an update to the QFP recommendations originally published by OPA and the Centers for Disease Control and Prevention (CDC) in 2014, and it is a nationally recognized standard of care for providing quality sexual and reproductive health (SRH) services for people of reproductive age.

Although the audience for both the 2014 and 2024 QFPs include, but are not limited to, providers funded by the Title X program, a key difference between the 2014 QFP and the 2024 QFP is the scope. The 2014 QFP recommendations were more focused on the type of family planning services provided in Title X projects. The 2024 QFP recommendations, in contrast, are broader than the provision of Title X family planning services, and also include recommendations for providing additional quality sexual and reproductive health services. With respect to Title X-funded providers, where the scope of the 2024 QFP recommendations is broader than Title X family planning services and may conflict with the Title X statute, legislative mandates, regulations, or court orders, the Title X requirements control.

The Title X regulations can be found in their entirety at: **eCFR :: 42 CFR Part 59 Subpart A -- Project Grants for Family Planning Services**. Many requirements from the Title X regulations are directly relevant to the recommendations provided in the QFP. The QFP is a nationally recognized standard of care when implementing the Title X requirements.

QFP and Title X

Because the 2024 QFP recommendations are broader than Title X requirements, it is important to distinguish which QFP recommendations are beyond the scope of the Title X project and cannot be provided using Title X funding. A non-exclusive list of QFP recommendations which are beyond the scope of Title X, with corollary requirements that are within the scope of Title X, is set out below.

- The provision of abortion and certain abortion-related activities are beyond the scope of Title X. Title X funds cannot be expended for abortions (Further Consolidated Appropriations Act, 2024 (Pub. L. No. 118-47, 138 Stat. 460, 652)); *see also* Section 1008, Public Health Service Act (42 U.S.C. §300a-6) (prohibiting Title X grant recipients from providing abortion as a method of family planning as part of the Title X project); 42 CFR § 59.5(a)(5). This prohibition applies not only to the performance of abortion by a Title X project, but also to the conduct of certain abortion-related activities by the project. For interpretations and policies relating to the Title X statutory abortion prohibition, including on abortion counseling and referral, advocacy activities, and separation, see **https://opa.hhs.gov/sites/default/files/2022-02/provision-abortion-related-services-family-planning-july-3-2000.pdf**. However, Title X projects are required to provide non-directive options counseling and referral, including on pregnancy termination (Further Consolidated Appropriations Act, 2024 (Pub. L. No. 118-47, 138 Stat. 460, 652); 42 CFR § 59.5(a)(5)).
- Medically assisted reproduction services are beyond the scope of Title X. However, Title X grant recipients are required to provide basic infertility services (Section 1001(a), Public Health Service Act (42 U.S.C. §300(a)); 42 CFR § 59.5(a)(1)) and should

establish referrals to providers for medically assisted reproduction services for people who need them.

- Prenatal care is beyond the scope of Title X. However, Title X projects are required to provide non-directive options counseling and referral, including on prenatal care and delivery (42 CFR §59.5(a)(5)), and should offer STI testing and treatment at the time of pregnancy diagnosis. Title X projects are expected to follow the QFP recommendations on prenatal counseling for people who indicate that they want to continue a pregnancy as a nationally recognized standard of care.
- Therapeutic options for perimenopausal care are beyond the scope of Title X. Title X providers should offer basic guidance and counseling related to perimenopausal symptoms and management and should establish referrals for therapeutic options for people who need them.
- Treatment for hypertension, diabetes, mental health, and alcohol and other substance abuse is beyond the scope of Title X. However, Title X providers are expected to follow the QFP recommendations for screening and counseling for hypertension, diabetes, mental health, and alcohol and other substance abuse, and should establish referrals for people who need treatment.

As noted above, with respect to Title X projects, where recommendations in QFP may conflict with the Title X statute, legislative mandates, regulations, or court orders, the Title X requirements control.

Guidance

Title X projects must provide services in a manner that "ensures equitable and quality service delivery consistent with nationally recognized standards of care" (42 CFR § 59.5(a)(3)). *Providing Quality Family Planning Services in the United States: Recommendations of the U.S. Office of Populations Affairs (Revised 2024)* is a nationally recognized standard of care for services within the scope of the Title X program and for providing quality sexual and reproductive health (SRH) services for people of reproductive age.

The audience for QFP is broader than Title X-funded providers and there are several QFP recommendations, including, but not limited to, those outlined above that are beyond the scope of the Title X program. Title X grant recipients may not use their Title X funding to provide services that are beyond the scope of the Title X program. To facilitate access to those services, Title X grant recipients may provide those services through other sources of funding. Title X grant recipients can also support clients with referrals to another provider to ensure access to care.

EXHIBIT C

OASH | Office of Population Affairs

Title X Program Handbook

December 2024
(Replaces version published July 2022)

HHS Office of Population Affairs
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LinkedIn: hhs-office-of-population-affairs-opa
YouTube: HHSOfficeofPopulationAffairs

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Table of Acronyms

Acronyms/Abbreviation	Definition
ACOG	American College of Obstetricians and Gynecologists
ACIP	Advisory Committee on Immunization Practices
ACS	American Cancer Society
AO	Authorized Organizational Representative or Authorized Official
ASCCP	American Society for Colposcopy and Cervical Pathology
ASRM	American Society for Reproductive Medicine
CDC	Centers for Disease Control and Prevention
CFDA	Catalog of Federal Domestic Assistance
CFR	Code of Federal Regulations
CSP	Clinical Services Provider
CTC-SRH (formerly NCTCFP)	Clinical Training Center for Sexual and Reproductive Health (formerly National Clinical Training Center for Family Planning)
EAA	Embryo Adoption Awareness and Services
EIN	Employer Identification Number
FAIN	Federal Award Identification Number
FDA	Food and Drug Administration
FFATA	Federal Funding Accountability and Transparency Act
FFR	Federal Financial Report
FPAR	Family Planning Annual Report
FPL	Federal Poverty Level
FQHC	Federally Qualified Health Center
FY	Fiscal Year
GAM	Grants and Acquisition Management
GMO	Grants Management Officer
GMS	Grants Management Specialist
GPS	Grants Policy Statement

HHS	Department of Health and Human Services
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome
HRSA	Health Resources & Services Administration
I&E	Information and Education
IFR	Interim Final Rule
IRB	Institutional Review Board
JSI	John Snow Inc.
LARC	Long-Acting Reversible Contraceptive
LGBTQI+	Lesbian, gay, bisexual, transgender, queer, intersex, nonbinary or otherwise gender non-conforming
MEC	Medical Eligibility Criteria for Contraceptive Use
NCC	Non-Competing Continuation
NOA	Notice of Award
NOFO	Notice of Funding Opportunity
OASH	Office of the Assistant Secretary for Health
OMB	Office of Management and Budget
ONC	Office of the National Coordinator for Health Information Technology
OPA	Office of Population Affairs
OPDIV	Operating Division
OSHA	Occupational Safety and Health Administration
PD	Program or Project Director
PHS	Public Health Service
PI	Principal Investigator
PMS	Payment Management Services
PO	Project Officer
PPN	Program Policy Notice
PSC	Program Support Center
QA	Quality Assurance

QFP	Providing Quality Family Planning Services in the United States: Recommendations of the U.S. Office of Population Affairs (Revised 2024)
QI	Quality Improvement
R&D	Research and Development
RHNTC	Reproductive Health National Training Center
SF	Standard Form
SFDS	Sliding Fee Discount Schedule
SPR	Selected Practice Recommendations for Contraceptive Use
SRH	Sexual and Reproductive Health
STI	Sexually Transmitted Infection
TPP	Teen Pregnancy Prevention
UDS	Uniform Data System
U.S.C	United States Code
USPSTF	United States Preventive Services Taskforce

Chapter 1: Introduction

Background

The Title X Family Planning Program (Title X) was established in 1970 when Congress enacted Title X of the Public Health Service (PHS) Act and is the only domestic federal program dedicated solely to family planning and related preventive health services. It is administered by the Office of Population Affairs (OPA) within the Office of the Assistant Secretary for Health (OASH) in the United States Department of Health and Human Services (HHS) and implemented through competitively awarded grants to a diverse network of public and private nonprofit health and community-based clinics.

The Title X family planning program is a critical part of America's public health safety net, serving as a point-of-entry into care for millions and the gold standard for providing high-quality, affordable, and confidential voluntary family planning and related preventive health services, with priority given to low-income clients. Family planning services delivered by Title X recipients include a broad range of medically approved services, which includes all Food and Drug Administration (FDA)-approved contraceptive products and natural family planning methods for clients who want to prevent pregnancy and space births; pregnancy testing and counseling; assistance to achieve pregnancy; basic infertility services; sexually transmitted infection (STI) services; and other preconception health services.

Purpose

The Title X Program Handbook provides information critical to managing a Title X project in one place and serves as a one-stop reference document for new and existing Title X recipients. It provides key information and resources that will help recipients and subrecipients be successful as they implement their Title X projects. This document does not provide guidance on expectations in areas beyond Title X or outside OPA's oversight authority, and does not supersede statute, regulations, legislative mandates, the Notice of Award, or HHS policy.

Applicability

The information included in this Title X Program Handbook applies to all entities that receive federal award funds under section 1001 of the PHS Act (42 U.S.C. § 300), including Title X recipients, subrecipients and service sites operating under the Title X recipient project, to assist in the establishment and operation of voluntary family planning projects. The Title X Program Handbook includes information and references current as of the date of publication and may be updated as needed in the future.

Chapter 2: Sources for the Title X Program Expectations

This chapter describes the sources for the expectations that apply to Title X family planning services projects. For purposes of this Handbook, the term "expectation" is used broadly to include both sources that are legal authorities (e.g., statutes and regulations) and sources that are program guidance.

All recipients must comply with the expectations regarding the provision of family planning services that can be found in the statute (Title X of the Public Health Service Act, 42 U.S.C. § 300 *et seq.*), the implementing regulations (42 CFR Part 59, Subpart A), and any applicable legislative mandates, and are expected to comply with additional program guidance. In addition, sterilization of clients as part of the Title X program must be consistent with 42 CFR Part 50, Subpart B ("Sterilization of Persons in Federally Assisted Family Planning Projects").

In addition to the statute, regulations, legislative mandates, and additional program guidance that apply to Title X, OPA establishes program priorities that represent overarching goals for the Title X program. Program priorities are derived from Healthy People Objectives and from HHS priorities and are published in Title X Notices of Funding Opportunity (NOFOs). The Notice of Award (NOA), signed by the Grants Management Officer (GMO), is the official document for a Title X grant award and contains the terms and conditions recipients accept by drawing funds. Included in the NOA terms and conditions is the expectation that recipients develop and implement plans to address OPA program priorities.

Title X Statute

Expectations regarding the provision of family planning services under Title X are in the statute, Title X of the Public Health Service Act, 42 U.S.C. 300 *et seq.*, which authorizes the Secretary of HHS to award grants for projects to provide family planning services to any person desiring such services, with priority given to individuals from low-income families. A copy of the entire Title X statute can be found in the Appendices. Included below is a summary of the sections of the statute that apply to Title X service delivery grants funded under the authority of Section 1001.

Section 1001 of the PHS Act authorizes grants "to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents)." In addition, section 1001 of the statute requires that, to the extent practicable, Title X service providers shall encourage family participation in family planning services projects. Finally, section 1001 assures the right of local and regional entities to apply directly to the Secretary for Title X grant funds.

Section 1006 of the PHS Act stipulates that priority will be given to the furnishing of Title X services to persons from low-income families and no charge will be made in a Title X project for services provided to any person from a low-income family except to the extent that payment will be made by a third party (including a government agency) which is authorized or is under legal obligation to pay such charge. This ensures that economic status shall not be a deterrent to participation in Title X programs. In addition, section 1006 requires that informational or educational materials developed or made available under a Title X grant will be suitable for the purposes of Title X and for the population or community to which they are to be made available, taking into account the educational and cultural background of the individuals to whom such materials are addressed and the standards of such population or community with respect to such materials. It also requires that Title X recipients shall provide for the review and approval of the suitability of such materials, prior to their distribution, by an advisory committee established by the recipient; such a committee shall include individuals broadly representative of the population or community to which the materials are to be made available.

Section 1007 of the PHS Act stipulates that Title X services and/or information "shall be voluntary and shall not be a prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, any other program of the entity or individual that provided such service or information."

Section 1008 of the PHS Act stipulates that "[n]one of the funds appropriated under this title shall be used in programs where abortion is a method of family planning."

The sections listed above are relevant to Title X recipients funded under section 1001. Other sections that are included in the Title X Statute relate to formula grants to State health authorities (section 1002), training for family planning services personnel (section 1003), family planning research (section 1004), and information grants (section 1005).

Regulations

Expectations regarding the provision of family planning services under Title X are set out in the implementing regulations which govern project grants for family planning services (42 CFR Part 59, Subpart A). In addition, sterilization of clients as part of the Title X project must be consistent with PHS sterilization regulations (42 CFR Part 50, Subpart B). Grants administration regulations at 45 CFR Part 75 ("Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards") and other relevant regulations also apply to Title X awards.

2021 Title X Final Rule: 42 CFR Part 59, Subpart A - "Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services"

On October 7, 2021, OPA published a final rule (86 Fed. Reg. 56144) to revise the regulations that govern the Title X family planning program by readopting the 2000 final rule with several revisions to ensure access to equitable, affordable, client-centered, quality family planning services for clients, especially low-income clients. The 2021 Final Rule went into effect on November 8, 2021.

The 2021 final rule includes a description of: to what programs the regulations apply (§ 59.1), definitions (§ 59.2), who is eligible to apply for a family planning services grant (§ 59.3), how one applies for a family planning services grant (§ 59.4), requirements that must be met by a family planning project (§ 59.5), procedures to assure the suitability of informational and educational material (print and electronic) (§ 59.6), criteria HHS will use to decide which family planning services projects to fund and in what amount (§ 59.7), how grants are awarded (§ 59.8), for what purposes the grant funds may be used (§ 59.9), confidentiality (§ 59.10), and additional conditions (§ 59.11).

42 CFR Part 50, Subpart B - "Sterilization of Persons in Federally Assisted Family Planning Projects"

Title X recipients and subrecipients that provide sterilization services must be in compliance with 42 CFR Part 50, Subpart B. This rule includes a description of applicability (§50.201), definitions (§50.202), sterilization of a mentally competent individual aged 21 or older (§50.203), informed consent requirement (§50.204), consent form requirements (§50.205), sterilization of a mentally incompetent individual or of an institutionalized individual (§50.206), sterilization by hysterectomy (§50.207), program or project requirements (§50.208), use of federal financial assistance (§50.209), and review of regulation (§50.210). The required consent form is set out as an appendix to the regulation.

Included in Appendix A (Resources) of this Handbook are links to the sterilization consent forms (English and Spanish versions) that Title X projects must use to obtain consent from their sterilization clients.

Legislative Mandates

Expectations regarding the provision of family planning services also come from legislative mandates that apply to Title X recipients whose awards are funded by the annual HHS appropriations act. (Consolidated Appropriations Act, 2024, Pub. L. No. 118-47, 138 Stat. 652, 673 (2024)).
The following legislative mandates have been part of the Title X appropriations language for the last several years:

- "None of the funds appropriated in this Act may be made available to any entity under title X of the PHS Act unless the applicant for the award certifies to the Secretary [of Health and Human Services] that it encourages family participation in the decision of minors to seek family planning services and that it provides counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities;"
- "Notwithstanding any other provision of law, no provider of services under title X of the PHS Act shall be exempt from any State law requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape, or incest."
- "That amounts provided to said projects under such title shall not be expended for abortions, that all pregnancy counseling shall be nondirective, and that such amounts shall not be expended for any activity (including the publication or distribution of literature) that in any way tends to promote public support or opposition to any legislative proposal or candidate for public office."

Additional Program Guidance

Title X recipients and subrecipients are expected to follow and provide clinical services consistent with additional program guidance issued by OPA. Additional program guidance includes, but is not limited to, occasional Program Policy Notices (PPNs) and other program-related notices issued by OPA to provide clarity and guidance on policy issues relevant to Title X recipients.

Program Policy Notices (PPN)

Program Policy Notice 2024-02: Implementing Quality Family Planning Services Recommendations within Title X Projects. The purpose of this PPN is to clarify OPA expectations for Title X grant recipients implementing *Providing Quality Family Planning Services in the United States: Recommendations of the U.S. Office of Population Affairs (Revised 2024)* (QFP) within their Title X projects and to outline where specific QFP recommendations are outside of the scope of the Title X project. It applies to Title X grant recipients, subrecipients, and service sites. The audience for QFP is broader than Title X-funded providers and there are several QFP recommendations that are beyond the scope of the Title X program. Title X grant recipients, subrecipients, and service sites may not use their Title X funding to provide services that are beyond the scope of the Title X program. To facilitate access to those services, Title X grant recipients may provide those services through other sources of funding. Title X grant recipients can also support clients with referrals to another provider to ensure access to care. With respect to Title X projects, where recommendations in QFP may conflict with the Title X statute, legislative mandates, regulations, or court orders, the Title X requirements control.

Program Policy Notice 2024-01: Clarification Regarding Confidential Services to Adolescents under the Title X Program. The purpose of this PPN is to update Title X recipients regarding adolescent confidentiality requirements in response to the recent U.S. Court of Appeals for the Fifth Circuit ruling in *Deanda v. Becerra*. Pursuant to the court's declaratory judgment, Title X projects may not provide Mr. Deanda's minor daughter with Title X family planning services without parental consent. In light of the Fifth Circuit's decision, the Title X confidentiality regulation at 42 C.F.R. § 59.10(b) will remain in effect. OPA will not be enforcing 42 C.F.R. § 59.10(b) in the State of Texas, nor will it enforce that regulation elsewhere in the Fifth Circuit to the extent it conflicts with state law. OPA will continue to enforce § 59.10(b) throughout the rest of the country. Title X projects in states in the Fifth Circuit other than Texas

may wish to consult with their own counsel regarding their states' requirements with respect to confidentiality.

Program Policy Notice 2016-11: Integrating with Primary Care Providers. The purpose of this PPN is to clarify how Title X recipients may remain in compliance with program expectations for Title X Funded Family Planning Projects when integrating services with Health Resources & Services Administration (HRSA) Health Center Program recipients and look-alikes (i.e., health centers that receive funding under section 330 of the Public Health Service Act, which authorizes the Health Center Program, as well as those that have been determined to meet section 330 requirements but do not receive grant funding under that program). This PPN applies only to integrated settings, and not to settings in which only Health Center Program services are provided. OPA addresses three issues commonly faced by integrated Title X and HRSA-funded health center providers:

- How to bill clients receiving Title X family planning services in compliance with Title X and Health Center Program Sliding Fee Discount Schedules and billing guidelines
- How to report data to the Family Planning Annual Report (FPAR) and to the Uniform Data System (UDS) appropriately
- How to preserve Title X client confidentiality when billing for services provided

Other Program-Related Notices

The notice issued on July 3, 2000, Provision of Abortion-Related Services in Family Planning Services Projects (65 Fed. Reg. 41281), provides guidance to recipients to facilitate their compliance with the section 1008 prohibition against using Title X appropriated funds "in programs where abortion is a method of family planning." These section 1008 interpretations were initially issued in conjunction with the Title X 2000 final rule (65 Fed. Reg. 41270, July 3, 2000), and they were also reinstated in the Title X 2021 final rule, which readopted much of the 2000 regulations.

Nationally Recognized Standards of Care

Both the Title X regulations and the OPA Program Priorities included in the PA-FPH-22-001 NOFO and FY 2022 NOA require Title X recipients to provide quality family planning services that are consistent with nationally recognized standards of care. Nationally recognized standards of care include *Providing Quality Family Planning Services in the United States: Recommendations of the U.S. Office of Population Affairs* (QFP) as well as other nationally recognized standards of care from other governmental institutions and national medical associations.

Providing Quality Family Planning Services: Recommendations of the U.S. Office of Population Affairs (Revised 2024) (QFP)

In 2024, OPA updated the QFP, originally published in 2014. This update aims to provide guidance on the provision of person-centered sexual and reproductive health (SRH) care focused on individuals' needs, values, and preferences. The update offers specific recommendations for how to provide high-quality SRH care and connects users to relevant guidelines, primary research, and other resources to inform best practices. In addition to incorporating new evidence, this update incorporates newer approaches to care that center patient needs and desires. OPA will update these QFP recommendations periodically to reflect new findings in the scientific literature and revisions to the clinical guidelines referenced in this update. To accompany this update, training and technical assistance (TA) resources will be available from OPA, the Reproductive Health National Training Center (RHNTC) and the Clinical Training Center for Sexual and Reproductive Health (CTC-SRH) to facilitate adoption of the QFP recommendations. These resources will include a separate supporting website, managed by the RHTNC—www.QFPguide.org—that will provide a searchable format and links to available TA resources to support implementation of QFP recommendations, including tools, job aids, and interactive training sessions.

Title X projects must provide services in a manner that "ensures equitable and quality service delivery consistent with nationally recognized standards of care" (42 CFR § 59.5(a)(3)). *Providing Quality Family Planning Services in the United States: Recommendations of the U.S. Office of Populations Affairs (Revised 2024)* is a nationally recognized standard of care for services within the scope of the Title X program and for providing quality SRH services for people of reproductive age. Title X recipients, subrecipients, and service sites are expected to review PPN 2024-02: Implementing Quality Family Planning Services Recommendations within Title X Projects whose purpose is to clarify OPA expectations for implementing QFP within Title X projects and incorporate QFP into the care provided to clients.

The table below includes other pertinent nationally recognized standards of care for family planning services that Title X projects may implement, but is not intended to be an exhaustive list.

Standards of Care	**Source**	**Link**
US Medical Eligibility Criteria (MEC)	CDC 2024	https://www.cdc.gov/reproductivehealth/contraception/mmwr/mec/summary.html
US Selected Practice Recommendations (SPR)	CDC 2024	https://www.cdc.gov/contraception/hcp/usspr/index.html
STI Treatment Guidelines, 2021	CDC 2021	https://www.cdc.gov/std/treatment-guidelines/default.htm
Taking a Sexual History	CDC 2024	https://www.cdc.gov/std/treatment/SexualHistory.htm
Cervical and Breast Cancer Screening	United States Preventive Services Taskforce (USPSTF)	• https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/cervical-cancer-screening • https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/breast-cancer-screening
Vaccine-Specific Recommendations	Advisory Committee on Immunization Practices (ACIP)	https://www.cdc.gov/acip-recs/hcp/vaccine-specific/index.html
Cervical Cancer Screening and Management of Abnormal Results	American Society for Colposcopy and Cervical Pathology (ASCCP)	https://www.asccp.org/clinical-practice/guidelines
Cervical and Breast Cancer Screening	American Cancer Society (ACS)	• https://www.cancer.org/cancer/cervical-cancer.html https://www.cancer.org/cancer/breast-cancer.html
Contraception; Cervical and Breast Cancer Screening	American College of Obstetricians and Gynecologists (ACOG)	• https://www.acog.org/womens-health/healthy-living/birth-control • https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2021/04/updated-cervical-cancer-screening-guidelines • https://pubmed.ncbi.nlm.nih.gov/28644335/
Achieving Pregnancy; Basic Infertility Evaluation	American Society for Reproductive Medicine (ASRM)	• https://pubmed.ncbi.nlm.nih.gov/34815068/ • https://pubmed.ncbi.nlm.nih.gov/25936238/ • https://pubmed.ncbi.nlm.nih.gov/25597249/

OPA Program Priorities

OPA program priorities represent Title X's overarching goals and are set out in the NOFO to which applicants apply for Title X grants. The program priorities set out below were included in the PA-FPH-22-001 NOFO, which was used to fund Title X service delivery grants starting on April 1, 2022, for an up to five-year project period. Future NOFOs may include the same or different program priorities.

Title X is and should be the gold standard of high-quality family planning and sexual and reproductive healthcare. Therefore, per regulation, Title X projects must ensure that services are provided in a manner that is client-centered, culturally and linguistically appropriate, inclusive, and trauma-informed; protects the dignity of the individual; and ensures equitable and quality service delivery consistent with nationally recognized standards of care.

Advance Health Equity

Health equity is when all persons have the opportunity to attain their full health potential, and no one is disadvantaged from achieving this potential because of social position or other socially determined circumstances. Advancing equity for all, including people from low-income families, people of color, and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality, is a priority for HHS, OPA, and Title X. By focusing on advancing equity in Title X, we can create opportunities to support communities that have been historically underserved, which benefits everyone. Recipients are expected to ensure that the predominantly low-income clients who rely on Title X services as their usual source of medical care have access to the same quality healthcare, including full medical information and referrals, that higher-income clients and clients with private insurance are able to access. Key strategies for advancing equity include, but are not limited to, removing barriers to accessing services, improving the quality of services, and providing services that are client-centered.

Expand Access

Improving and expanding accessibility of services for all clients, especially low-income clients, means providing client-centered services that are available when and where clients need them and can most effectively access them. Recipients are expected to implement their projects in ways that make services as accessible as possible for clients and are responsive to the diverse needs of the clients and communities served. This includes, but is not limited to, the location of services, hours of services, modality of service provision (e.g., in-person, telehealth, drive-thru, mobile clinics), availability of ancillary services such as translation services and referral linkages, robust education and community outreach, ensuring access to a broad range of acceptable and effective family planning methods and services at service sites, and implementing billing and payment practices that expand access to services.

Deliver High-Quality Care

Title X recipients are expected to provide quality family planning services that are consistent with nationally recognized standards of care. Quality healthcare is safe, effective, client-centered, timely, efficient, and equitable. Furthermore, client-centered care is respectful of, and responsive to, individual client preferences, needs, and values and where client values guide all clinical decisions. Recipients and their subrecipients are expected to have the capacity to support implementation of nationally recognized standards of care and provide initial and ongoing training and professional development for their staff on these standards.

Notice of Award (NOA)

The NOA notifies successful applicants of their selection, award amount, as well as project and budget periods. The NOA also includes any conditions on the award (i.e., those that must be met as a condition

of receiving the grant funds), as well as standard terms, reporting requirements and contact information for OASH's Grants and Acquisition Management (GAM) Division and OPA Program Division.

The Notice of Award is a legal instrument. See 45 CFR § 75.210 for the contents of an NOA.

A recipient indicates acceptance of an award and its associated terms and conditions by drawing or requesting funds from the designated HHS payment system or office. Recipients are expected to draw funds within the first 30 days. Once the award is accepted by the recipient, the contents of the NOA are binding on the recipient unless and until modified by a revised NOA signed by the GMO.

GAM is the official contact for recipients throughout the federal award life cycle. All official communication related to the federal award is between GAM and the recipients. Recipients are expected to review their NOA upon receipt; discuss it with their designated PO; and notify the GMS and PO of any errors noted on their NOA. Recipients should regularly refer to their NOA to ensure they remain in compliance with all the grant terms and conditions.

45 CFR Part 75: Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards

HHS maintains its own implementing regulations for HHS awards at 45 CFR part 75. In September 2024, HHS announced the adoption of 2 CFR part 200, an important step to align with other Federal agencies and reduce administrative burden for the financial assistance community. HHS through the Office of Grants in the Office of the Assistant Secretary for Financial Resources, announced the publication of an Interim Final Rule (IFR) that implements the 2024 Revisions to the Uniform Administrative Requirements for Federal Financial Assistance (Uniform Guidance) at 2 CFR part 200 (89 FR 30046). The IFR presents a phased approach for the implementation of the Uniform Guidance. It delays the effective date to October 1, 2025, for all provisions of the Uniform Guidance at 2 CFR part 200 and HHS-specific modifications at 2 CFR part 300, providing federal agencies critical additional time to prepare to fully implement these revisions. In the interim, HHS is adopting significant changes to monetary thresholds and other administrative processes that have not been updated for many years. As of October 1, 2024, the IFR will implement eight key provisions that add flexibilities and reduce burden for the applicant and recipient community, for awards made on or after October 1, 2024. Any questions related to HHS' adoption of 2 CFR part 200 should be directed to the OASH GMO.

45 CFR Part 75 establishes uniform administrative requirements, cost principles, and audit requirements for federal awards to non-federal entities and prescribes the manner in which federal agencies that administer federal financial assistance programs are to carry out their statutory responsibilities under the Federal Program Information Act (31 U.S.C. § 6101 *et seq.*). The following section details the different subparts of 45 CFR part 75.

45 CFR part 75, Subpart A includes acronyms and definitions.

45 CFR part 75, Subparts B through D (administrative requirements) set forth the uniform administrative requirements for grant and cooperative agreements, including the requirements for HHS awarding agency management of federal grant programs before the federal award has been made, and the requirements HHS awarding agencies may impose on non-federal entities in the federal award.

45 CFR part 75, Subpart E (cost principles) establishes principles for determining the allowable costs incurred by non-federal entities under federal awards. The principles are for the purpose of cost determination and are not intended to identify the circumstances or dictate the extent of federal government participation in the financing of a particular program or project. The principles are designed to

provide that federal awards bear their fair share of cost recognized under these principles except where restricted or prohibited by statute.

45 CFR part 75, Subpart F (single audit requirements and audit follow-up) is issued pursuant to the Single Audit Act Amendments of 1996 (31 U.S.C. 7501 *et seq.*). It sets forth standards for obtaining consistency and uniformity among federal agencies for the audit of non-federal entities expending federal awards. These provisions also provide the policies and procedures for HHS awarding agencies and pass-through entities when using the results of these audits.

HHS Grants Policy Statement

The HHS Grants Policy Statement (GPS) is intended to make available in a single document the policies applicable to HHS discretionary grants, such as Title X Program grants and cooperative agreement awards. These policies are common across all HHS Operating Divisions (OPDIVs) and HHS Staff Divisions (StaffDIVs), including OASH, and are incorporated by reference in the NOA terms. The GPS describes the roles and responsibilities of key HHS and recipient personnel who work with Title X federal awardees.

HHS Personnel

- **Grants Management Officer (GMO)**
  The GMO is the official who handles the non-program parts of an award for the HHS agency. The GMO is the focal point for receiving and acting on requests for prior approval or for changes in the terms and conditions of award. The GMO is the only official authorized to obligate the HHS awarding agency to the expenditure of federal funds or to change the funding, duration, or other terms and conditions of an award.
- **Grants Management Specialist (GMS)**
  Acts as the main grants administration contact for recipients. Handles administrative activities on behalf of the GMO. The GMS contact information can be found on the NOA.
- **Project Officer (PO)**
  Responsible for the programmatic, scientific, and technical sides of award programs, including oversight and monitoring. The PO contact information can be found on the NOA.

Recipient Personnel

- **Authorized Organizational Representative or Authorized Official (AO)**
  The authorized organizational representative has authority to act for the organization and is responsible for meeting award requirements, properly managing the award, and providing oversight. The AO's signature on a grant application guarantees that the information in the application is correct and the organization is responsible for following all requirements.
- **Principal Investigator (PI)/Program or Project Director (PD)**
  The PI/PD is the individual(s) designated by the recipient to direct the project or program being supported by the award. The PI/PD is responsible and accountable to officials of the recipient organization for the proper conduct of the project, program, or activity.

Chapter 3: Title X Program Expectations

Included in this chapter is a summary of program expectations for the Title X Family Planning Services grant program. The Title X program expectations come from the sources described in Chapter 2 and include the Title X statute, implementing regulations, applicable legislative mandates, additional program guidance, the NOFO, and the Notice of Award. This document serves as an update to the *Program Requirements for Title X Funded Family Planning Projects* (also referred to as *Title X Program Requirements*) that was originally published in April 2014 and is now being updated to align with the 2021 Title X Final Rule "Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services."

The expectations included in this chapter are applicable to Title X family planning services recipients and are set out in Title X-specific authorities and documents. All Title X projects are expected to maintain and regularly update written policies, protocols, and procedures demonstrating the projects are compliant with all Title X program expectations. In addition, all Title X recipient, subrecipient, and service site staff are expected to be trained on all Title X expectations, in addition to applicable Title X project policies, protocols, and procedures. Documentation of this training is expected to be maintained and regularly updated.

Project Administration

Title X recipients:

1. Provide services without subjecting individuals to any coercion to accept services or to employ or not to employ any particular methods of family planning. (42 CFR § 59.5(a)(2))

2. Ensure that acceptance of services is solely on a voluntary basis and may not be made a prerequisite to eligibility for, or receipt of, any other services, assistance from or participation in any other program of the recipient. (Sections 1001 and 1007, PHS Act; 42 CFR § 59.5(a)(2))

3. Ensure that staff are informed that any officer or employee of the United States, officer or employee of any State, political subdivision of a State, or any other entity, which administers or supervises the administration of any program receiving federal financial assistance, or person who receives, under any program receiving federal assistance, compensation for services, who coerces or endeavors to coerce any person to undergo an abortion or sterilization procedure by threatening such person with the loss of, or disqualification for the receipt of, any benefit or service under a program receiving federal financial assistance shall be fined not more than $1,000 or imprisoned for not more than one year, or both. (42 U.S.C. § 300a-8, as set out in 42 CFR § 59.5(a)(2) footnote 1)

4. Provide services in a manner that does not discriminate against any client based on religion, race, color, national origin, disability, age, sex, sexual orientation, gender identity, sex characteristics, number of pregnancies, or marital status. (42 CFR § 59.5(a)(4))

5. Provide that priority in the provision of services will be given to clients from low-income families. Low-income family means a family whose total annual income does not exceed 100 percent of the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2). "Low-income family" includes members of families whose annual family income exceeds this amount, but who, as determined by the project director, are unable, for good reasons, to pay for family planning

services. For example, unemancipated minors who wish to receive services on a confidential basis must be considered on the basis of their own resources. (Section 1006(c)(1), PHS Act; 42 CFR § 59.5(a)(6) and 42 CFR § 59.2)

6. Provide services without the imposition of any durational residence requirement or a requirement that the client be referred by a physician. (42 CFR § 59.5(b)(5))

7. Provide that family planning medical services will be performed under the direction of a clinical services provider (CSP). The CSP's direction must be within their scope of practice and allowable under State law, and with special training or experience in family planning. CSPs include physicians, physician assistants, nurse practitioners, certified nurse midwives, and registered nurses with an expanded scope of practice who are trained and permitted by state-specific regulations to perform all aspects of the user (male and female) physical assessments recommended for contraceptive, related preventive health, and basic infertility care. (42 CFR § 59.5(b)(6) and 42 CFR § 59.2)

8. Provide, to the maximum feasible extent, an opportunity for participation in the development, implementation, and evaluation of the project by persons broadly representative of all significant elements of the population to be served, and by others in the community knowledgeable about the community's needs for family planning services. (42 CFR § 59.5(b)(10))

9. Ensure that all information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and must not be disclosed without the individual's documented consent, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality. Information may otherwise be disclosed only in summary, statistical, or other form that does not identify the individual. Reasonable efforts to collect charges without jeopardizing client confidentiality must be made. Recipients must inform the client of any potential for disclosure of their confidential health information to policyholders where the policyholder is someone other than the client. (42 CFR § 59.10(a))

10. Develop plans and strategies for implementing family planning services in ways that make services as accessible as possible for clients. (PA-FPH-22-001 NOFO, FY 22 Notice of Award Special Terms and Requirements)

11. Identify and execute strategies for delivering services that are responsive to the diverse needs of the clients and communities served. (PA-FPH-22-001 NOFO, FY 22 Notice of Award Special Terms and Requirements)

12. Provide notice to OPA in the Title X Clinic Locator Database (https://opa-fpclinicdb.hhs.gov/) of any deletions, additions, or changes to the name, location, street address and email, services provided on-site, and contact information for Title X recipients and service sites. Changes must be entered into the database within 30 days from the official OPA/GAM prior approval for changes in project scope, including clinic closures. (PA-FPH-22-001 NOFO, FY 22 Notice of Award Special Terms and Requirements)

13. Enroll in the 340B Program and comply with all 340B Program requirements, including annual recertification and avoiding diversion or duplicate discounts. 340B Program requirements are

available at https://www.hrsa.gov/opa/program-requirements/index.html. (FY 22 Notice of Award Special Terms and Requirements)

14. In furtherance of maximizing access and best serving individuals in need in the service areas, recipients should make reasonable efforts to avoid duplication of effort in the provision of services across the Title X network. For example, Title X recipients' coverage areas may overlap geographically, but duplication of subrecipient sites could be minimized or avoided to create more opportunities for services. (FY 22 Notice of Award Special, Terms and Requirements)

Provision of High-Quality Family Planning Services

Title X recipients:

1. Provide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, sexually transmitted infection (STI) services, preconception health services, and adolescent-friendly health services). If an organization offers only a single method of family planning, it may participate as part of a project as long as the entire project offers a broad range of acceptable and effective medically approved family planning methods and services. (Section 1001, PHS Act; 42 CFR § 59.5(a)(1))

   Family planning services include a broad range of medically approved services, which includes Food and Drug Administration (FDA)-approved contraceptive products and natural family planning methods, for clients who want to prevent pregnancy and space births, pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, sexually transmitted infection (STI) services, and other preconception health services. (42 CFR § 59.2)

   FDA-approved contraceptive products include Long-Acting Reversible Contraceptives (LARC), contraceptive injection, short-acting hormonal methods, barrier methods, emergency contraception, and permanent sterilization (https://www.fda.gov/consumers/free-publications-women/birth-control).

   Basic infertility services include services for both partners of an infertile couple. Basic infertility services include providing basic evaluation and counseling, sharing resources, and making referrals. The pace and extent of the infertility evaluation should consider the patient's preferences, age, duration of infertility, relationship circumstances, medical history, and, in some cases, geographic location and access to higher levels of care.(QFP, pp.26-27, https://www.qfpguide.org/)

   STI services include services provided in accordance with CDC's STD treatment and HIV testing guidelines. STI services include assessing, screening, treating, and counseling. (QFP, pp.20-25, https://www.qfpguide.org/)

   Preconception health services include counseling about healthy weight; screening for and administration of immunizations; and screening for chronic medical conditions (i.e., hypertension), cancer, mental health, alcohol and other substance abuse, sexual violence and intimate partner violence, and human trafficking. (QFP, pp.30-36, https://www.qfpguide.org/)

   Title X service sites are expected to provide most, if not all, of acceptable and effective medically approved family planning methods and services on site and to detail the referral process for family planning methods and services that are unavailable on-site.

2. Ensure that Title X service sites that are unable to provide clients with access to a broad range of acceptable and effective medically approved family planning methods and services, must be able to provide a prescription to the client for their method of choice or referrals to another provider, as requested. (42 CFR § 59.5(a)(1))

3. Provide services in a manner that is client-centered, culturally and linguistically appropriate, inclusive, and trauma-informed. (42 CFR § 59.5(a)(3))
    - **Client-centered care** is respectful of, and responsive to, individual client preferences, needs, and values; client values guide all clinical decisions. (42 CFR § 59.2)
    - **Culturally and linguistically appropriate services** are respectful of and responsive to the health beliefs, practices and needs of diverse patients. (42 CFR § 59.2)
    - **Inclusive** is when all people are fully included and can actively participate in and benefit from family planning, including, but not limited to, individuals who belong to underserved communities, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality. (42 CFR § 59.2)
    - **Trauma-informed** means a program, organization, or system that is trauma-informed realizes the widespread impact of trauma and understands potential paths for recovery; recognizes the signs and symptoms of trauma in clients, families, staff, and others involved with the system; and responds by fully integrating knowledge about trauma into policies, procedures, and practices, and seeks to actively resist re-traumatization. (42 CFR § 59.2)

4. Provide services in a manner that protects the dignity of the individual. (42 CFR § 59.5(a)(3))

5. Provide services in a manner that ensures equitable and quality service delivery consistent with nationally recognized standards of care. (42 CFR § 59.5(a)(3))

6. Provide quality family planning services that are consistent with the *Providing Quality Family Planning Services in the United States: Recommendations of the U.S. Office of Population Affairs (Revised 2024)* (QFP) and other relevant nationally recognized standards of care. (PA-FPH-22-001 NOFO, FY 22 Notice of Award Special Terms and Requirements, Program Policy Notice 2024-02)

7. Advance health equity through the delivery of Title X services. Health equity is when all persons have the opportunity to attain their full health potential, and no one is disadvantaged from achieving this potential because of social position or other socially determined circumstances. (PA-FPH-22-001 NOFO, FY 22 Notice of Award Special Terms and Requirements, and 42 CFR § 59.2)

8. Improve and expand accessibility of services for all clients, especially low-income clients by providing client-centered services that are available when and where clients need them and can most effectively access them. (PA-FPH-22-001 NOFO, FY 22 Notice of Award Special Terms and Requirements)

9. Offer pregnant clients the opportunity to be provided information and counseling regarding each of the following options: prenatal care and delivery; infant care, foster care, or adoption; and pregnancy termination. If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant client indicates they do not wish to receive such information and counseling. (42 CFR § 59.5(a)(5), Consolidated Appropriations Act, 2024, Pub. L. No. 118-47, 138 Stat. 652 (2024))

10. Provide that family planning medical services will be performed under the direction of a clinical services provider (CSP), with services offered within their scope of practice and allowable under state law, and with special training or experience in family planning. CSPs include physicians, physician assistants, nurse practitioners, certified nurse midwives, and registered nurses with an expanded scope of practice who are trained and permitted by state-specific regulations to perform all aspects of the user (male and female) physical assessments recommended for contraceptive, related preventive health, and basic infertility care. (42 CFR § 59.5(b)(6) and 42 CFR § 59.2)

11. Ensure that non-clinical counseling services (such as contraceptive counseling, nondirective options counseling, reproductive life planning, etc.) are provided by any adequately trained staff member[1] who is involved in providing family planning services to Title X clients. An adequately trained staff member may include CSPs and non-CSPs (e.g., health educators). (2021 Final Rule FAQs)

Adolescent Services

Title X recipients:

1. Apply all expectations listed in the section above, “Provision of High-Quality Family Planning Services,” when providing services to adolescent clients.

2. Provide adolescent-friendly health services, which are services that are accessible, acceptable, equitable, appropriate, and effective for adolescents. (42 CFR § 59.2)

3. To the extent practical, Title X projects shall encourage family participation. However, Title X projects may not require consent of parents or guardians for the provision of services to minors, nor can any Title X project staff notify a parent or guardian before or after a minor has requested and/or received Title X family planning services. (Section 1001, PHS Act; 42 CFR § 59.10(b))

4. Ensure that all applicants for Title X funds certify that they encourage family participation in the decision of minors to seek family planning services. (Consolidated Appropriations Act, 2024, Pub. L. No. 118-47, 138 Stat. 673 Sec. 207 (2024))

5. Ensure that all applicants for Title X funds certify that they provide counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities. (Consolidated Appropriations Act, 2024, Pub. L. No. 118-47, 138 Stat. 673 Sec. 207 (2024))

[1]An “adequately trained staff member” has attended and participated in required orientation, courses, curriculums, and/or teaching/mentoring experiences, maintains appropriate competencies, and is knowledgeable and proficient in providing non-clinical counseling services.

6. No Title X services provider shall be exempt from any State law requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape, or incest. (Consolidated Appropriations Act, 2024, Pub. L. No. 118-47, 138 Stat. 673 Sec. 208 (2024))

Referral for Social and Medical Services

Title X recipients:

1. Provide for medical services related to family planning (including consultation by a clinical services provider, examination, prescription and continuing supervision, laboratory examination, contraceptive supplies), in person or via telehealth, and necessary referral to other medical facilities when medically indicated and provide for the effective usage of contraceptive devices and practices. (42 CFR § 59.5(b)(1))

2. Provide for social services related to family planning, including counseling, referral to and from other social and medical service agencies, and any ancillary services which may be necessary to facilitate clinic attendance. (42 CFR § 59.5(b)(2))

3. Provide for coordination and use of referrals and linkages with primary healthcare providers, other providers of healthcare services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs, who are in close physical proximity to the Title X site, when feasible, in order to promote access to services and provide a seamless continuum of care. (42 CFR § 59.5(b)(8))

4. Ensure service sites and subrecipients that do not have the capacity to offer primary care services have strong linkages to community providers to facilitate referrals for needs identified during SRH visits. Screening services such as, counseling about healthy weight; screening for and administration of immunizations; and screening for chronic medical conditions (i.e., hypertension), cancer, mental health, alcohol and other substance abuse, sexual violence and intimate partner violence, and human trafficking. (QFP, pp.30-36, https://www.qfpguide.org/)

Financial Accountability

Title X recipients:

1. Provide that no charge will be made for services provided to any clients from a low-income family except to the extent that payment will be made by a third party (including a government agency) which is authorized to or is under legal obligation to pay this charge. Low-income family means a family whose total annual income does not exceed 100 percent of the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2). “Low-income family” also includes members of families whose annual family income exceeds this amount, but who, as determined by the project director, are unable, for good reasons, to pay for family planning services. (Section 1006(c)(1), PHS Act; 42 CFR § 59.5(a)(7) and 42 CFR § 59.2)

   Unemancipated minors who wish to receive services on a confidential basis must be considered on the basis of their own resources. (42 CFR § 59.2)

2. Provide that charges will be made for services to clients other than those from low-income families in accordance with a schedule of discounts based on ability to pay, except that charges to persons from families whose annual income exceeds 250 percent of the levels set forth in the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2) will be made in accordance with a schedule of fees designed to recover the reasonable cost of providing services. (42 CFR § 59.5(a)(8))

The schedule of discounts should be updated annually in accordance with the Federal Poverty Level (FPL).

The HRSA Health Center Program and the OPA Title X Program have unique Sliding Fee Discount Schedule (SFDS) program expectations, which include having differing upper limits. Title X agencies (or providers) that are integrated with or receive funding from the HRSA Health Center Program may have dual fee discount schedules: one schedule that ranges from 101% to 200% of the FPL for all health center services, and one schedule that ranges from 101% to 250% FPL for clients receiving **only** Title X family planning services directly related to preventing or achieving pregnancy, and as defined in their approved Title X project. (OPA PPN 2016-11)

3. Ensure that family income is assessed before determining whether copayments or additional fees are charged. (42 CFR § 59.5(a)(8))

4. Ensure that, with regard to insured clients, clients whose family income is at or below 250 percent of the FPL should not pay more (in copayments or additional fees) than what they would otherwise pay when the schedule of discounts is applied. (42 CFR § 59.5(a)(8))

5. Take reasonable measures to verify client income, without burdening clients from low-income families. Recipients that have lawful access to other valid means of income verification because of the client's participation in another program may use those data rather than re-verify income or rely solely on clients' self-report. If a client's income cannot be verified after reasonable attempts to do so, charges are to be based on the client's self-reported income. (42 CFR § 59.5(a)(9))

6. Take all reasonable efforts to obtain the third-party payment without application of any discounts, if a third party (including a government agency) is authorized or legally obligated to pay for services. Where the cost of services is to be reimbursed under title XIX, XX, or XXI of the Social Security Act, a written agreement with the title XIX, XX, or XXI agency is required. (42 CFR § 59.5(a)(10))

7. Provide that all services purchased for project participants will be authorized by the project director or their designee on the project staff. (42 CFR § 59.5(b)(7))

8. Provide that if family planning services are provided by contract or other similar arrangements with actual providers of services, services will be provided in accordance with a plan which establishes rates and method of payment for medical care. These payments must be made under agreements with a schedule of rates and payment procedures maintained by the recipient. The recipient must be prepared to substantiate that these rates are reasonable and necessary. (42 CFR § 59.5(b)(9))

9. Comply with all terms and conditions outlined in the grant award, including grant policy terms and conditions contained in applicable Department of Health and Human Services (HHS) Grant Policy Statements (GPS), (note any references in the GPS to 45 CFR Part 74 or 92 are now replaced by 45 CFR Part 75, and the SF269 is now the SF-425), and requirements imposed by program statutes and regulations, Executive Orders, and HHS grant administration regulations, as applicable; as well as any requirements or limitations in any applicable appropriations acts. (FY 22 Notice of Award Special Terms and Requirements)

10. Ensure that no mobile health unit(s) or other vehicle(s), even if proposed in the application for the Title X award, is purchased with award funds without prior written approval from the grants management officer. Requests for approval of such purchases must include a justification with a cost-benefit analysis comparing both purchase and lease options. Such requests must be submitted as a Budget Revision Amendment in Grant Solutions. (FY 22 Notice of Award Special Terms and Requirements)

11. Include financial support from sources other than Title X as no grant may be made for an amount equal to 100 percent of the project's estimated costs. Although projects are expected to identify additional sources of funding and not solely rely on Title X funds, there is no specific amount of level of financial match requirement for this program. (42 CFR § 59.7(c))
    This cost sharing requirement is waived for any grant made to the U.S. Virgin Islands, Commonwealth of the Northern Mariana Islands, American Samoa, Guam, Republic of Palau, Federated States of Micronesia, and the Republic of the Marshall Islands. (PA-FPH-22-001 NOFO)

12. Ensure that program income (fees, premiums, third-party reimbursements which the project may reasonably expect to receive), as well as State, local and other operational funding, will be used to finance the non-federal share of the scope of project as defined in the approved grant application and reflected in the approved budget. Program income and the level projected in the approved budget will be used to further program objectives. Program Income may be used to meet the cost sharing or matching requirement of the federal award. The amount of the federal award stays the same. Program Income in excess of any amounts specified must be added to the federal funds awarded. They must be used for the purposes and conditions of this award for the duration of the Project period. (45 CFR § 75.307(e); FY 22 Notice of Award Special Terms and Requirements)

13. Ensure that Title X funds shall not be expended for any activity (including the publication or distribution of literature) that in any way tends to promote public support or opposition to any legislative proposal or candidate for public office. (Consolidated Appropriations Act, 2024, Pub. L. No. 118-47, 138 Stat. 652 (2024))

Subrecipient Monitoring and Engagement

Title X recipients:

1. Detail a plan for monitoring the delivery of family planning services under the Title X project, including the monitoring and oversight of subrecipients. (45 CFR § 75.352)

2. Ensure that every subaward is clearly identified to the subrecipient as a subaward and includes the required information at the time of the subaward and if any of these data elements change, include the changes in subsequent subaward modification. When some of this information is not available, the recipient (i.e., pass-through entity) must provide the best information available to describe the federal award and subaward. As noted in 45 CFR § 75.352, the required information includes:
    i. Federal Award Identification:
        a. Subrecipient name (which must match the name associated with its unique entity identifier;
        b. Subrecipient's unique entity identifier;
        c. Federal Award Identification Number (FAIN);

d. Federal award date (see § 75.2 federal award date) of award to the recipient by the HHS awarding agency;
e. Subaward period of performance start and end date;
f. Amount of federal funds obligated by this action by the recipient to the subrecipient;
g. Total amount of federal funds obligated to the subrecipient by the recipient including the current obligation;
h. Total amount of the federal award committed to the subrecipient by the recipient;
i. Federal award project description, as required to be responsive to the Federal Funding Accountability and Transparency Act (FFATA);
j. Name of HHS awarding agency, recipient, and contract information for awarding official of the recipient;
k. CFDA number and name; the recipient must identify the dollar amount made available under each federal award and the CFDA number at time of disbursement;
l. Identification of whether the award is R&D; and
m. Indirect cost rate for the federal award (including if the de minimis rate is charged per § 75.414).

ii. All requirements imposed by the recipient on the subrecipient so that the federal award is used in accordance with federal statutes, regulations and the terms and conditions of the federal award.
iii. Any additional requirements that the recipient imposes on the subrecipient in order for the recipient to meet its own responsibility to the HHS awarding agency including identification of any required financial and performance reports.
iv. An approved federally recognized indirect cost rate negotiated between the subrecipient and the federal government or, if no such rate exists, either a rate negotiated between the recipient and the subrecipient (in compliance with 45 CFR Part 75), or a de minimis indirect cost rate as defined in § 75.414(f).
v. A requirement that the subrecipient permit the recipient and auditors to have access to the subrecipient's records and financial statements as necessary for the recipient to meet the requirements of 45 CFR Part 75.
vi. Appropriate terms and conditions concerning closeout of the subaward.

3. Evaluate each subrecipient's risk of noncompliance with federal statutes, regulations, and the terms and conditions of the subaward for purposes of determining the appropriate subrecipient monitoring in accordance with 45 CFR § 75.352(d) and (e). (45 CFR § 75.352(b)).

4. Consider imposing specific subaward conditions upon a subrecipient if appropriate as described in 45 CFR § 75.207. (45 CFR § 75.352(c)).

5. In accordance with 45 CFR § 75.352(d), monitor the activities of the subrecipient as necessary to ensure that the subaward is used for authorized purposes, in compliance with federal statutes, regulations, and the terms and conditions of the subaward; and that subaward performance goals are achieved. Recipient monitoring of the subrecipient must include:
   i. Reviewing financial and performance reports required by the recipient.
   ii. Following-up and ensuring that the subrecipient takes timely and appropriate action on all deficiencies pertaining to the federal award provided to the subrecipient from the recipient detected through audits, on-site reviews, and other means.
   iii. Issuing a management decision for audit findings pertaining to the federal award provided to the subrecipient from the recipient as required by 45 CFR § 75.521.

6. Depending upon the recipient’s assessment of risk posed by the subrecipient, employ the following monitoring tools that may be useful for the recipient to ensure proper accountability and compliance with program requirements and achievement of performance goals: providing

subrecipients with training and technical assistance on program-related matters; and performing on-site reviews of the subrecipient's program operations; and arranging for agreed-upon-procedures engagements as described in 45 CFR § 75.425. (45 CFR § 75.352(e))

7. Verify that every subrecipient is audited as required by Subpart F of 45 CFR Part 75 when it is expected that the subrecipient's federal awards expended during the respective fiscal year equaled or exceeded the threshold set forth in 45 CFR § 75.501. (45 CFR § 75.352(f))

8. Consider whether the results of the subrecipient's audits, on-site reviews, or other monitoring indicate conditions that necessitate adjustments to the recipient's own records. (45 CFR § 75.352(g)).

9. Consider taking enforcement action against noncompliant subrecipients as described in 45 CFR § 75.371 and in program regulations. (45 CFR § 75.352(h)).

10. Provide that if an application relates to consolidation of service areas or health resources or would otherwise affect the operations of local or regional entities, the applicant must document that these entities have been given, to the maximum feasible extent, an opportunity to participate in the development of the application. Local and regional entities include existing or potential subrecipients which have previously provided or propose to provide family planning services to the area proposed to be served by the applicant. (42 CFR § 59.5(a)(11)(i))

11. Provide an opportunity for maximum participation by existing or potential subrecipients in the ongoing policy decision making of the project. (42 CFR § 59.5(a)(11)(ii))

Community Education, Participation, and Engagement

Title X recipients:

1. Provide for opportunities for community education, participation, and engagement to: achieve community understanding of the objectives of the program; inform the community of the availability of services; and promote continued participation in the project by diverse persons to whom family planning services may be beneficial to ensure access to equitable, affordable, client-centered, quality family planning services. (42 CFR § 59.5(b)(3))

2. Provide, to the maximum feasible extent, an opportunity for participation in the development, implementation, and evaluation of the project by persons broadly representative of all significant elements of the population to be served, and by others in the community knowledgeable about the community's needs for family planning services. (42 CFR § 59.5(b)(10))

Information and Education (I&E)

Title X recipients:

1. Have an advisory committee (sometimes referred to as information and education committee) that reviews and approves print and electronic informational and educational materials developed or made available under the project, prior to their distribution, to assure that the materials are suitable for the population or community to which they are to be made available and the purposes of Title X. The project shall not disseminate any materials which are not approved by the advisory committee. (Section 1006(d)(1) and (2), PHS Act; 42 CFR § 59.6(a))

2. Think specifically about the print and electronic materials made available to Title X clients under the Title X project when considering which materials require review and approval by the advisory committee. To help identify which materials require review and approval by the advisory committee, Title X projects should think specifically about the materials that they are making available to Title X clients under the Title X project. For Title X projects that provide non-Title X services (e.g., hospitals, FQHCs), this does not include all possible materials that a Title X client may find on the organization's website or as they walk through the building, but only those specific materials that are made available to the Title X client under the Title X project and those materials developed specifically for the Title X client. If the material is intended to be provided to the client as information and education, it should be reviewed by the advisory committee (2021 Final Rule FAQs)

   Social media posts, themselves, on platforms such as Facebook, X, and Instagram do not need to go through the I&E materials review process.

3. Establish and maintain an advisory committee that:
   i. consists of no fewer than five members and up to as many members the recipient determines and
   ii. includes individuals broadly representative of the population or community for which the materials are intended (in terms of demographic factors such as race, ethnicity, color, national origin, disability, sex, sexual orientation, gender identity, sex characteristics, age, marital status, income, geography, and including but not limited to individuals who belong to underserved communities, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality). (Section 1006(d)(2), PHS Act; 42 CFR § 59.6(b))

4. Ensure that the advisory committee, in reviewing materials:
   i. consider the educational, cultural, and diverse backgrounds of individuals to whom the materials are addressed,
   ii. consider the standards of the population or community to be served with respect to such materials,
   iii. review the content of the material to assure that the information is factually correct, medically accurate, culturally and linguistically appropriate, inclusive, and trauma-informed,
   iv. determine whether the material is suitable for the population or community to which is to be made available, and
   v. establish and maintain a written record of its determinations. (Section 1006(d)(1), PHS Act; 42 CFR § 59.6(b))

Staff Training

Title X recipients:

1. Provide for orientation and in-service training for all project personnel. (42 CFR § 59.5(b)(4))

2. Ensure routine training of staff on federal/state requirements for reporting or notification of child abuse, child molestation, sexual abuse, rape, or incest, as well as on human trafficking.

3. Ensure routine training on involving family members in the decision of minors to seek family planning services and on counseling minors on how to resist being coerced into engaging in sexual activities.

4. Are expected to provide routine training as noted above on an annual basis. In addition, OPA recommends Title X recipients provide routine training in accordance with the RHNTC's Title X Training Requirements Summary Job Aid.

Quality Improvement (QI) and Quality Assurance (QA)

Title X recipients:

1. Develop and implement a quality improvement and quality assurance plan that involves collecting and using data to monitor the delivery of quality family planning services, inform modifications to the provision of services, inform oversight and decision-making regarding the provision of services, and assess patient satisfaction. (PA-FPH-22-001 NOFO)

2. Address oversight and service provision at the recipient level, the subrecipient level, and the service site level within their QI/QA plan. (PA-FPH-22-001 NOFO and FY 22 Notice of Award Special Terms and Requirements)

3. Submit a Family Planning Annual Report (FPAR). The information collection (reporting requirements) and format for this report have been approved by the Office of Management and Budget (OMB) and assigned OMB No. 0990-0479 (Expires 2/28/2025). The FPAR data elements, instrument, and instructions are found on the OPA Web site at http://opa.hhs.gov. Recipients are expected to use the FPAR data to inform their QI/QA activities. (PA-FPH-22-001 NOFO and FY 22 Notice of Award Special Terms and Requirements)

Prohibition of Abortion

Title X recipients must:

1. Not provide abortion as a method of family planning as part of the Title X project. (Section 1008, PHS Act; Consolidated Appropriations Act, 2024, Pub. L. No. 118-47, 138 Stat. 652 (2024); 42 CFR § 59.5(a)(5))

2. Prohibit providing services that directly facilitate the use of abortion as a method of family planning, such as providing transportation for an abortion, explaining and obtaining signed abortion consent forms from clients interested in abortions, negotiating a reduction in fees for an abortion, and scheduling or arranging for the performance of an abortion, promoting or advocating abortion within Title X program activities, or failing to preserve sufficient separation between Title X program activities and abortion-related activities. (65 Fed. Reg. 41281 (July 3, 2000))

3. Prohibit promoting or encouraging the use of abortion as a method of family planning through advocacy activities such as providing speakers to debate in opposition to anti-abortion speakers, bringing legal action to liberalize statutes relating to abortion, or producing and/or showing films that encourage or promote a favorable attitude toward abortion as a method of family planning.

Films that present only neutral, factual information about abortion are permissible. A Title X project may be a dues paying participant in a national abortion advocacy organization, so long as there are other legitimate program-related reasons for the affiliation (such as access to certain information or data useful to the Title X project). A Title X project may also discuss abortion as an available alternative when a family planning method fails in a discussion of relative risks of various methods of contraception. (65 Fed. Reg. 41281, 41282 (July 3, 2000))

4. Ensure that non-Title X abortion activities are separate and distinct from Title X project activities. Where recipients conduct abortion activities that are not part of the Title X project and would not be permissible if they were, the recipient must ensure that the Title X-supported project is separate and distinguishable from those other activities. What must be looked at is whether the abortion element in a program of family planning services is so large and so intimately related to all aspects of the program as to make it difficult or impossible to separate the eligible and non-eligible items of cost. The Title X project is the set of activities the recipient agreed to perform in the relevant grant documents as a condition of receiving Title X funds. A grant applicant may include both project and non-project activities in its grant application, and, so long as these are properly distinguished from each other and prohibited activities are not reflected in the amount of the total approved budget, no problem is created. Separation of Title X from abortion activities does not require separate recipients or even a separate health facility, but separate bookkeeping entries alone will not satisfy the spirit of the law. Mere technical allocation of funds, attributing federal dollars to non-abortion activities, is not a legally supportable avoidance of section 1008. Certain kinds of shared facilities are permissible, so long as it is possible to distinguish between the Title X supported activities and non-Title X abortion-related activities:
    i. a common waiting room is permissible, as long as the costs properly pro-rated,
    ii. common staff is permissible, so long as salaries are properly allocated, and all abortion related activities of the staff members are performed in a program which is entirely separate from the Title X project,
    iii. a hospital offering abortions for family planning purposes and also housing a Title X project is permissible, as long as the abortion activities are sufficiently separate from the Title X project, and
    iv. maintenance of a single file system for abortion and family planning patients is permissible, so long as costs are properly allocated. (65 Fed. Reg. 41281, 41282 (July 3, 2000)

5. A Title X project may not provide pregnancy options counseling which promotes abortion or encourages persons to obtain abortion, although the project may provide patients with complete factual information about all medical options and the accompanying risks and benefits. While 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. (65 Fed. Reg. 41281 (July 3, 2000))

6. Where a referral to another provider who might perform an abortion is medically indicated because of the patient's condition or the condition of the fetus (such as where the woman's life would be endangered), such a referral by a Title X project is not prohibited by section 1008 and is required by 42 CFR § 59.5(b)(1). The limitations on referrals do not apply in cases in which a referral is made for medical indications. (65 Fed. Reg. 41281 (July 3, 2000)).

Additional Expectations

This section addresses expectations that are applicable to Title X family planning services recipients, and which are set out in authorities and documents that are not specific to Title X.

Additional Special Terms and Requirements and Standard Terms of the FY 22 Title X Notice of Award – OASH

As noted in Chapter 2, the NOA includes applicable terms and conditions of the Title X award. Below are some of the FY 22 Title X NOA Special Terms and Requirements and Standard Terms. Title X recipients should refer to their NOAs for the specific terms and conditions that are applicable to their awards. Included at Appendix D is the FY 22 Title X NOA generic template that includes the complete list of Special Terms and Requirements; Standard Terms; Reporting Requirements; and Contacts.

Special Terms and Requirements

1. Evaluation and Cooperation: Title X recipients are expected to participate in OPA research and evaluation activities, if selected, and must agree to follow all evaluation protocols established by OPA or its designee.

2. Grantee Meetings: Recipients are encouraged to actively participate in all OPA-supported Title X recipient meetings and recipient conferences.

3. Institutional Review Board (IRB): Recipients submit Institutional Review Board (IRB) approvals, when required, via Grant Solutions Grant Notes within 5 business days of receipt from the IRB. No activities that require IRB approval may take place prior to receipt of the IRB approval. For more information on 45 CFR Part 46 Protection of Human Subjects, recipients should refer to the HHS Office of Human Research Protections.

Standard Terms

4. Salary Limitation (Further Consolidated Appropriations Act, 2022, Div. H, Title II, sec. 202): Recipients ensure that "None of the funds appropriated in the HHS Appropriations Act shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II." The Salary Limitation is based upon the Executive Level II of the Federal Executive Pay Scale. Effective January 2022, the Executive Level II salary is $203,700. For the purposes of the salary limitation, the direct salary is exclusive of fringe benefits and indirect costs. An individual's direct salary is not constrained by the legislative provision for a limitation of salary. The rate limitation simply limits the amount that may be awarded and charged to the grant or cooperative agreement. A recipient may pay an individual's salary amount in excess of the salary cap with non-federal funds. (Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, 136 Stat. 49, 467 (2022))

5. Reporting Subawards and Executive Compensation: Recipients report each action that obligates $30,000 or more in federal funds that does not include Recovery Act funds (as defined in section 1512(a)(2) of the American Recovery and Reinvestment Act of 2009, Pub. L. 111–5) for a subaward to an entity, unless they are exempt as defined in their NOA, Standard Terms. Additional details and the full text of this standard term are available in Appendix D. (2 CFR part 170)

6. Intellectual Property and Data Rights: Recipients may copyright any work that is subject to copyright and was developed, or for which ownership was acquired, under a federal award. The federal government reserves a royalty-free, nonexclusive, and irrevocable right to reproduce,

publish, or otherwise use the work for federal purposes, and to authorize others to do so. The awardee is subject to applicable regulations governing patents and inventions, including government- wide regulations issued by the Department of Commerce at 37 CFR part 401. The federal government has the right to: obtain, reproduce, publish, or otherwise use the data produced under this award; and authorize others to receive, reproduce, publish, or otherwise use such data for federal purposes. (45 CFR § 75.322)

7. Acknowledgement of Federal Grant Support: Recipients acknowledge federal funding when issuing statements, press releases, publications, requests for proposal, bid solicitations and other documents --such as tool-kits, resource guides, websites, and presentations (hereafter "statements")-- describing the projects or programs funded in whole or in part with HHS federal funds, the recipient must clearly state the percentage and dollar amount of the total costs of the program or project funded with federal money and the percentage and dollar amount of the total costs of the project or program funded by non-governmental sources. When issuing statements resulting from activities supported by HHS financial assistance, the recipient entity must include an acknowledgement of federal assistance using one of the following or a similar statement:

    i. If the HHS Grant or Cooperative Agreement is NOT funded with other non-governmental sources:
    This [project/publication/program/website, etc.] [is/was] supported by the [full name of the PROGRAM OFFICE] of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling $XX with 100 percent funded by [PROGRAM OFFICE]/OASH/HHS. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by [PROGRAM OFFICE]/OASH/HHS, or the U.S. Government. For more information, please visit [PROGRAM OFFICE website, if available].

    ii. The HHS Grant or Cooperative Agreement IS partially funded with other nongovernmental sources:
    This [project/publication/program/website, etc.] [is/was] supported by the [full name of the PROGRAM OFFICE] of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling $XX with XX percentage funded by [PROGRAM OFFICE]/OASH/HHS and $XX amount and XX percentage funded by non-government source(s). The contents are those of the author (s) and do not necessarily represent the official views of, nor an endorsement, by [PROGRAM OFFICE]/OASH/HHS, or the U.S. Government. For more information, please visit [PROGRAM OFFICE website, if available].

    The federal award total must reflect total costs (direct and indirect) for all authorized funds (including supplements and carryover) for the total competitive segment up to the time of the public statement.

    Any amendments by the recipient to the acknowledgement statement must be coordinated with the OASH federal project officer and the OASH grants management officer.

    If the recipient plans to issue a press release concerning the outcome of activities supported by this financial assistance, it should notify the OASH federal project officer and the OASH grants management officer in advance to allow for coordination.

8. Whistleblower Protections: Recipients are given notice that the 48 CFR § 3.908 (related to the enhancement of contractor employee whistleblower protections), implementing 41 U.S.C. § 4712,

as amended (entitled “Enhancement of contractor protection from reprisal for disclosure of certain information”) applies to their Title X award.

9. Reporting of Matters Related to Recipient Integrity and Performance: Recipients refer to their NOA regarding the reporting of matters related to recipient integrity and performance, specifically the general reporting requirement; proceedings about which recipients must report; reporting procedures and frequency; definitions; and disclosure requirements.

10. Advancing Racial Equity and Support for Underserved Communities Through the Federal Government: Administer projects in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy). This includes taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html

    -- You must take reasonable steps to ensure that your project provides meaningful access to persons with limited English proficiency. For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.

    -- For information on your specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and taking appropriate steps to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.

    -- HHS funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html.

    -- For guidance on administering your project in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/your-protections-against-discrimination-based-on-conscience-and-religion/index.html.

11. Trafficking in Persons: Title X recipients are subject to the requirements of Section 106 (g) of the Trafficking Victims Protection Act of 2000, as amended (22 U.S.C. § 7104) and should refer to their NOA for more information.

12. Prohibition on certain telecommunications and video surveillance services or equipment: Recipients are prohibited to obligate or spend grant funds (to include direct and indirect expenditures as well as cost share and program) to:
    i. procure or obtain,
    ii. extend or renew a contract to procure or obtain, or
    iii. enter into a contract (or extend or renew a contract) to procure or obtain equipment, services, or systems that use covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. As described in Pub. L. 115-232, section 889, covered telecommunications

equipment is telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities).

(a) For the purpose of public safety, security of government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities).
(b) Telecommunications or video surveillance services provided by such entities or using such equipment.
(c) Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of the National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise, connected to the government of a covered foreign country. (2 CFR § 200.216)

Non-Discrimination Legal Requirements - HHS Office for Civil Rights

For more information about the obligations and prohibitions under federal civil rights laws described above in the NOA Standard Term "Advancing Racial Equity and Support for Underserved Communities Through the Federal Government," recipients should contact the HHS Office for Civil Rights at https://www.hhs.gov/ocr/about-us/contact-us/index.html or call 1-800-368-1019 or TDD 1-800-537-7697.

Occupational Safety and Health Administration (OSHA)

Title X recipients:

1. Ensure that their service sites and subrecipients meet applicable fire, building, and licensing codes and standards established by federal, state, and local governments and maintain Exit Routes, Emergency Action Plans, and Fire Prevention Plans in accordance with OSHA.

Recipients should refer to the U.S. Department of Labor's OSHA for more information.

Office of the National Coordinator for Health Information Technology (ONC)

Title X recipients:

1. Must administer projects in compliance with health information technology legislation and regulations under ONC's authority.

Recipients should refer to the Office of the National Coordinator for Health Information Technology for more information.

Chapter 4: Title X Monitoring, Oversight, and Reporting Requirements

Title X recipients are responsible for ensuring that their Title X projects, including their subrecipients and service sites, are compliant with all Title X program expectations. OPA is responsible for oversight and monitoring of Title X recipients to ensure compliance with program expectations, to identify areas for continuous quality improvement, and to provide technical assistance and support to help recipients improve program outcomes. The goal of OPA monitoring and technical assistance is to assist Title X recipients in providing access to equitable, affordable, client-centered, quality family planning services.

OPA monitors Title X recipient compliance by conducting ongoing monitoring calls and recipient correspondence, reviewing recipient progress reports and continuation applications, reviewing recipient Family Planning Annual Report (FPAR) data, and conducting compliance and quality monitoring visits (e.g., program reviews). In addition, OPA provides intensive support, training, and technical assistance to Title X recipients through the OPA-funded Reproductive Health National Training Center (RHNTC) and the Clinical Training Center for Sexual and Reproductive Health (CTC-SRH) formerly National Clinical Training Center for Family Planning), as well as through OPA contractors and OPA staff.

Through its monitoring and oversight activities, OPA may identify areas of non-compliance as well as areas for quality improvement within Title X recipient projects. OPA will document, in writing, any identified areas of concern and will provide a timeline for recipients to respond on how they plan to address any identified concerns. OPA is committed to working collaboratively with recipients and providing ongoing technical assistance and support for recipients to take actions necessary to demonstrate compliance and respond to recommendations for quality improvements. OPA will review the recipient's response and notify them when the identified concerns have been sufficiently addressed. If it is determined that compliance concerns cannot be resolved, OPA will work with the OASH Grants and Acquisition Management (GAM) Division to determine the appropriate next steps.

Reporting Requirements

Financial Reporting Requirement—Federal Financial Report (FFR) SF 425

Recipients are required to submit their expenditure reporting using the SF-425 to OASH using the HHS Payment Management System (PMS) for any OASH awards with a project period ending October 1, 2020, or later. Failure to submit the FFR in the correct system by the due date may delay processing of any pending requests or applications. SF-425 submissions through Grant Solutions will no longer be accepted for OASH awards. To assist in preparation for submission, the SF-425 and instructions are available here: http://apply07.grants.gov/apply/forms/sample/SF425-V1.0.pdf. Recipients are required to complete all sections of the FFR.

FFRs are due 30 days after the end of each quarter in the federal fiscal year.

- Quarter ending September 30, the FFR is due October 30
- Quarter ending December 31, the FFR is due January 30
- Quarter ending March 30, the FFR is due April 30
- Quarter ending June 30, the FFR is due July 30.

If recipients have not submitted by the due date, they receive a message indicating the report is past due. Recipients should ensure their PMS account and contact information are up to date to receive notifications.

Annual Progress Report (APR) Requirement

Recipients are required to submit APRs 90 days after the end of each performance reporting period unless otherwise required under NOA Special Terms and Requirements. Recipient progress reports must address content required by 45 CFR § 75.342(b)(2). Additional progress reporting may be required, as determined by the GMO, in accordance with the NOA Special Terms and Requirements, or specific circumstances warranting additional monitoring. Additional APR guidance is provided by the Program Office. Reports must be submitted electronically via the Performance Progress Report Module in Grant Solutions.

Audit Requirements

The Single Audit Act Amendments of 1996 (31 U.S.C. §§ 7501 *et seq.*) combined the audit requirements for all entities under one Act. An audit is required for all non-federal entities expending federal awards and must be consistent with the standards set out at 45 CFR Part 75, Subpart F ("Audit Requirements"). The audits are due within 30 days of receipt from the auditor or within 9 months of the end of the fiscal year, whichever occurs first. The audit report when completed should be submitted online to the Federal Audit Clearinghouse at https://harvester.census.gov/facides/Account/Login.aspx.

As of October 1, 2024, recipients and their subrecipients must have an audit if either spends $1,000,000 or more in federal awards during its fiscal year (see 2 CFR § 200.501). Even if an audit is not required, keep records available for review by federal officials. Organizations must use an independent auditor who must follow the Government Auditing Standards and the audit requirements in 45 CFR 75, subpart F. Audit costs are allowable and often covered by the indirect cost rate. Recipients are responsible for establishing audit requirements, to ensure compliance by subrecipients. HHS may request more audits, if necessary.

Closeout Requirements

To close an award, recipients do several steps to include submitting a final report. Ask the GMS and review the closeout provisions HHS now follows at 2 CFR § 200.344. The awarding agency will resolve any amounts due to them or to the recipient.

Upon the completion date of an award, recipients have 120 days to liquidate all financial obligations and submit all required reports, including a final FFR, final progress report, tangible and real property reports (if needed), and Final Invention Statement and Certification (if needed). The GMO or their delegate may give an extension upon a written request. Not submitting timely and accurate reports can affect future funding. HHS may close out your award on its own if recipients fail to provide reports on time.

HHS may still disallow costs or recover funds based on an audit or review after a recipient's award is closed out. After closeout, recipients still have to return any funds due to HHS because of refunds, corrections, indirect cost rate adjustments, or other transactions. A recipient still needs to account for property acquired on the award and follow disposition and record retention requirements after close out. HHS adopted two 2 CFR § 200 provisions about equipment and salary disposition:

- 2 CFR § 200.313(e) - Equipment: Increases from $5,000 to $10,000 the value of equipment that at the end of the grant period "may be retained, sold, or otherwise disposed of with no further responsibility to the Federal agency." The provision also clarifies that Indian Tribes may use their own procedures for use, management, and disposal of equipment. If they do not have procedures, then they must follow the ordinary guidance.
- 2 CFR § 200.314(a) - Unused Supplies: Increases from $5,000 to $10,000 the value of unused supplies that recipients of Federal funds are required to sell at the end of the grant award period

as well as clarifying that this amount is the total amount of remaining unused supplies, not just like items. See 45 CFR §§ 75.317-323 for other disposition requirements.

See 45 CFR §§ 75.361-75.365 for record retention requirements. Keep in mind the above changes in equipment and supply costs adopted by HHS in 2 CFR § 200.

Recipients should refer to their specific NOA for more information on award closeout requirements or review the generic template of the NOA Terms and Conditions included in Appendix D.

Additional Monitoring and Oversight

Non-Competing Continuation (NCC)

Generally, Title X grants will initially be for a budget period of one year and subsequent continuation awards will also be for one year at a time. A recipient must submit a separate NCC application to have the support continued for each subsequent year. The NCC application is the recipient's official request to OPA for continued funding for the upcoming budget year. Additional NCC guidance, such as what to include in the application, is provided through Grants Solutions. Pursuant to 42 CFR § 59.8(b), decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the recipient's progress and management practices and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the government.

Program Review

OPA conducts program reviews to ensure recipient compliance; provision of high-quality clinical care; and program integrity. The benefits of program reviews include:

- In-depth engagement with Title X recipients
- Observation of Title X operations
- Strengthen relationships with recipients
- Learn about client experiences
- Showcase recipient projects
- Provide one-on-one support and technical assistance from field experts
- Identify areas of improvement for future and/or ongoing technical assistance
- Provide an opportunity for OPA to learn more about the realities in the field and improve policies and strategies to support those in need of family planning services

The Title X Program Review Tool is intended for use by OPA staff and consultants to conduct program reviews. It can also be used by Title X recipients as a self-assessment and be adapted for use by recipients for monitoring their subrecipients and service sites. The tool is aligned with this document.

In cases where the recipient relies on other entities such as subrecipients to provide family planning services, the recipient is responsible for ensuring that subrecipients are in compliance with the Title X statute, regulations, legislative mandates, other program priorities and guidance. (45 CFR § 75.352)

Grants Management Officer Prior-Approval Requirements

At times, award recipients may need to make changes to the program budget or activities. Some changes require prior written approval. To find out if a change needs prior approval:

- Carefully review your NoA.
- Review 45 CFR § 75.407 for actions needing prior approval.

- Review Appendix E of the GPS for prior approval requirements for certain types of awards.
- Ask your GMS if you are not sure.
- Ask your cognizant agency for indirect costs if you have questions about changes to indirect costs. The cognizant agency is the federal agency that approved your indirect cost proposal.

In many cases, pursuant to 45 CFR § 75.308(c)(1) and the HHS Grants Policy Statement, HHS requires prior written approval. Title X recipients are encouraged to discuss prior approval requests with their respective PO and GMS prior to submission. All amendment requests requiring prior approval must be signed by the recipient authorizing official and PI/PD and submitted through the Grant Solutions Amendment Module. The post-award changes that are considered changes to budgets or program plans and require OASH approval are outlined below. For a complete list of these changes, see 45 C.F.R. § 75.308(c)(1).

- Change in scope which occurs when the recipient proposes changes to project's objectives, aims, or purposes identified in the approved application, such as changing the service area; applying a new technology; adding or eliminating a service delivery site; or making budget changes that cause a project to change substantially from what was originally approved. The Title X Family Planning Change in Scope Worksheet helps identify elements for clinic closures, new clinics, or other programmatic changes which may require a request for a change in scope to the current Title X family planning project. Recipients are not required to use the worksheet but may include the completed worksheet with their amendment submission in Grant Solutions.
- Changes in status of PI/PD or other key personnel named in the NOA such as the replacement, absence for any continuous period of 3 months or more, or reduction of time devoted to project by 25 percent or more from level in approved application.
- Significant revisions to the approved budget.
- Changes in the approved cost sharing or matching (i.e., non-federal share).
- Use of unobligated balances, request to revise the current NOA to authorize the recipient to spend excess funds for additional approved purposes (approval is intended to cover only prospective costs, not costs already incurred by the recipient).

Chapter 5: HHS-Managed and OPA Systems

HHS-Managed Systems

Grant Solutions

Grant Solutions is a web-based system that provides a way for grant recipients to view/print their grant awards, submit post-award actions such as amendments, apply for non-competing continuations and directed supplements, submit reports, etc. This HHS system is used to manage Title X grants throughout the grant lifecycle (project and budget periods). Although a Title X grant recipient may use several other systems for various aspects of the grant, Grant Solutions is the official grant management system for all OASH managed awards, including Title X federal awards.

PDs are required to establish accounts in the system and notify their POs and GMS of any additional recipient individual accounts needing access for the grant. Recipients should contact Grant Solutions User Support to establish an account if they do not have one. The GMS can create a Grant Solutions account for the recipient AO and PI/PD. Financial Officer accounts may only be established by Grant Solutions staff. All account requests should be signed by the prospective user and their supervisor or other authorized organization representative.

For assistance on Grant Solutions issues, recipients should contact:

- Grant Solutions User Support at 866-577-0771
- Email help@grantsolutions.gov Monday – Friday, 8 a.m. – 6 p.m. E.T.
- Frequently Asked Questions and answers are available on the Grant Solutions website.

Title X POs are involved in nearly every aspect of the grant lifecycle. They work very closely with the assigned GMS to ensure that all grant administration and budget needs are aligned with HHS policies and procedures as well as Title X statutory and regulatory requirements. When reviewing a recipient's grant administration or budget needs, the GMO or GMS will consult with POs as well as refer to Title X statute, regulations, and guidance on whether the requested change is allowable, allocable, necessary, and reasonable.

Once a recipient submits an amendment, or change, in Grants Solutions, GAM will review the request first, and then forward the request to the PO for further review and assessment. Programmatic leadership and, finally, the GMO reviews these requests. If approved, you will receive an updated NOA. Additional details on amendments are provided by the PO and GMS upon award; during the award orientation process; and if recipients have questions.

Any other correspondence not relating to a prior approval item should be uploaded to Grant Notes within Grant Solutions. Recipients should include the grant number (or FAIN) and signature of the authorized organizational representative or authorized official and the project director on all such correspondence.

Payment Management System (PMS)

All payments for Title X federal awards are made through the HHS Payment Management System (PMS). PMS is administered by the Program Support Center (PSC). HHS recipients are now required to certify at the time of each drawdown whether the cash drawdown request is either reimbursement of actual expenditures or an advance for immediate disbursement and assert that award funds are used in compliance with all award conditions and federal statutory requirements.

Recipients will also submit their Federal Financial Reports (SF-425) through PMS. On the FFR, line item 10A-Cash Receipts & 10B Cash Disbursements will now be populated based on the recipient's Cash Drawdown. Recipients will no longer need to enter the cash transaction section. Recipients will be able to edit interim data, but not final data, in the cash transaction section. To assist in the preparation for submission you may find the SF-425 and instructions for completing the form on the Web at: http://apply07.grants.gov/apply/forms/sample/SF425-V1.0.pdf.

To establish a PMS account, recipients should request new user access on the PMS website. Inquiries regarding payments should be directed to PMSSupport@psc.hhs.gov or Payment Management Services, P.O. Box 6021, Rockville, MD 20852; or 1-877-614-5533. Recipients can also sign up for the standard FFR trainings listed on the PMS website.

OPA Systems

Family Planning Annual Report (FPAR)

FPAR is the only source of uniform reporting by all Title X services recipients. It provides consistent, national-level data on program users, service providers, utilization of family planning and related preventive health services, and sources of program revenue. Annual submission of FPAR is required of all Title X services recipients for purposes of monitoring and reporting program performance. Title X administrators and recipients use FPAR data to:

- Monitor compliance with statutory requirements.
- Comply with accountability and federal performance reporting requirements for Title X family planning funds, including, but not limited to, the Government Performance and Results Modernization Act and the Office of Management and Budget (OMB).
- Guide strategic and financial planning and respond to inquiries from policy makers about the program.
- Estimate the impact of Title X-funded activities on key reproductive health outcomes, including prevention of unintended pregnancy, infertility, and invasive cervical cancer.

FPAR collects data on Title X activities conducted during each calendar year from January 1 through December 31. Recipients need to collect FPAR data elements from all subrecipients and service sites included in their Title X projects during the calendar year, or for any part of the year that a subrecipient or service site was part of the Title X project. Subrecipients should not submit an FPAR report; instead, subrecipients should follow recipient instructions for collecting and reporting FPAR-related data to the recipient. Recipients compile data from their whole Title X project and submit results through the FPAR data system on or around February 15 of each year.

FPAR 2.0 is the next iteration of FPAR data reporting and collects encounter-level data for Title X family planning services recipients. FPAR 2.0 allows for improved data collection, reporting, and analysis that ultimately allows for more opportunities to improve service delivery. Recipients started collecting encounter-level data in 2022 and reported it for the first time in 2023. The new data system for recipients to upload FPAR data is now publicly available. OPA continues to work with recipients to provide features, analyses, and reports that utilize FPAR data and help inform quality improvement efforts. The system is a secure data management system and is accessible only to authorized users. Each authorized account is assigned a role that defines what features and actions users are allowed to view and perform in the system. The FPAR roles that apply to Title X recipients are:

- Grant Admin – they can view, add, and remove accounts associated with their grant, enter their grant data, and submit their grant data to OPA for review.
- Grant User – they have permission to enter and edit their grant data but do not have permission to submit it to OPA or to add new users.

This new system also houses the Title X Family Planning Clinic Locator Database, discussed below.

For additional FPAR information and resources, visit the https://opa.hhs.gov/research-evaluation/title-x-services-research/family-planning-annual-report. For assistance, Title X recipients should contact the support mailbox FPARSupport@mathematica-mpr.com. Recipients can also access resources on the Help page in the FPAR system.

Title X Family Planning Clinic Locator and Database

The Title X Family Planning Clinic Locator provides information to the public about all Title X family planning clinics and the specific services available at each clinic. The goal of the Title X Family Planning Clinic Locator and Database is to make information about the location, hours, and services of Title X clinics easily accessible to the public to help connect potential clients to available Title X services. Recipients are required through a Special Term on the Notice of Award to keep their organization's records up to date in the Clinic Locator database, which updates the publicly accessible Clinic Locator. It is important for recipients to regularly review and maintain their Clinic Locator database records of service sites and subrecipients to ensure that all records reflect the most current and accurate clinic information available to the public.

This locator website and database are owned and operated by OPA in coordination with OPA's support contractor. The database includes the addresses, hours of operation, and contact information for all open and operating Title X delivery sites such as clinics, service sites, and satellite sites, including mobile clinics. Information is maintained by the Title X recipient on a continuous basis.

As mentioned above, the FPAR system houses the Clinic Locator Database. For the purposes of the database, there are three roles applicable to Title X recipients:

- Grant Admin – they have permission to create or remove grant admins, grant users, and subrecipient users and to view, add, edit, and remove all subrecipients and service sites for their own grant. Grant admins are notified about all their grant subrecipient and service site changes.
- Grant User – they have permission to view and edit subrecipients and service sites for their own grant.
- Subrecipient User – they have permissions to create or remove subrecipient users for their own subrecipient and associated service sites. Subrecipient users can view and edit their own subrecipient and associated service sites and are notified of any changes made to their subrecipient and associated service sites. Subrecipient users only have access to database functions and will not be able to access any FPAR data functions.

To maintain an accurate record of current Title X service sites in the Clinic Locator, recipients are expected to:

- Submit the appropriate amendment in Grant Solutions and receive approval for changes in scope related to deletion and addition of service sites and subrecipients prior to making any changes into the database for publishing on the publicly accessible locator.
- Enter changes to the Title X database within 30 days from the official approval of the change. All changes should be reviewed and approved by the recipient prior to being posted on the Clinic Locator and viewable by the public.

For assistance, users should contact the support mailbox FPARSupport@mathematica-mpr.com. Users can also access resources on the Help page in the FPAR system.

Connect.gov

Connect.gov is a suite of advanced collaboration, information sharing, data collection, publishing, business intelligence and authentication tools and services used to facilitate collaboration and knowledge management.

The OPA Connect.gov website is frequently utilized by OPA's staff and Title X program recipients to provide easy access to guidance documents, maintain the most recent recipient administrative contact information, and to share resources broadly to recipients in one central location. In addition, the system allows for highlighting important information such as trainings and approaching deadlines. OPA continues to explore ways to utilize Connect.gov as a collaboration platform for recipients and will continue to use the site for future Program Reviews as well as to share vital resources and guidance to the Title X network.

Chapter 6: OPA Communication Channels

OPA maintains and updates the following communication channels that are intended to provide federal award recipients and the public with information about OPA programs and additional information pertinent to these programs.

OPA Website

The OPA website provides OPA program and research information, grant information, reproductive and adolescent health information, and other resources. Title X recipients are encouraged to bookmark this website and refer to it for Title X information and resources.

OPA Grantee Digest

The OPA grantee digest is a weekly e-newsletter sent to all OPA recipients and staff only. It is a closed distribution list maintained in Connect.gov. Title X recipient staff listed in the Title X Grantee Contacts section in Connect.gov under “My Forms” receive the digest. Recipients are encouraged to add their staff to the Title X Grantee Contacts section in Connect.gov to ensure they receive the digest. OPA Grantee Digest distribution list questions should be directed to the PO.

OPA Bulletin

The OPA bulletin is a bimonthly e-newsletter to all public subscribers (currently over 40,000); anyone can sign up to receive the bulletin on the OPA website. Title X recipient, subrecipient, and service site staff are encouraged to subscribe to receive the OPA bulletin.

OPA Social Media

LinkedIn

OPA has an official LinkedIn page where practical and timely information and resources on reproductive and adolescent health are shared. Title X recipient, subrecipient, and service site organizations and staff are encouraged to follow OPA’s page.

YouTube

OPA also has a YouTube channel where OPA posts informational and educational videos and webinars.

Chapter 7: Other Pertinent HHS Programs & Resources

In some cases, Title X may interact or collaborate with other HHS programs and offices which include but are not limited to those listed below.

OPA Programs

OPA's Teen Pregnancy Prevention (TPP) Program

OPA's TPP Program is a national, evidence-based program that provides funding to implement effective programs and develop, test, and evaluate innovative approaches to prevent teen pregnancy across the United States. The TPP Program was established in 2010 with a Congressional mandate to fund medically accurate and age-appropriate programs to reduce teen pregnancy. With an annual budget of approximately $101 million, the TPP Program focuses on reaching populations with the greatest need with the goal of improving sexual and reproductive health outcomes for adolescents and promoting positive youth development.

The TPP Program reaches over 200,000 young people each year. In addition to providing young people and their families with evidence-based and innovative prevention programs, TPP program staff connect young people and their families to a wide range of support services, including sexual and reproductive health services. OPA encourages Title X recipients to partner and establish referral systems with TPP recipients in their communities to ensure the reproductive and sexual health needs of their adolescent populations are met.

To learn more about the TPP Program and its current recipients, visit https://opa.hhs.gov/grant-programs/teen-pregnancy-prevention-program-tpp.

OPA's Embryo Adoption Awareness and Services (EAA) Program

OPA's EAA program is a national program that supports grants, cooperative agreements and contracts that aim to increase public awareness of embryo donation and adoption. Program recipients may facilitate the adoption or donation of embryos through public awareness campaigns, medical/administrative services that address common financial and legal obstacles to embryo adoption, or both. OPA encourages Title X recipients to partner with EAA recipients in their communities to promote increased awareness of embryo donation and adoption in the Title X network.

To learn more about the EAA Program and its current recipients, visit https://opa.hhs.gov/grant-programs/embryo-adoption-awareness-eaa.

Other HHS Programs and Offices

HRSA's Health Center Program

The Health Center Program is authorized by section 330 of the Public Health Service (PHS) Act (42 U.S.C. § 254b) ("section 330") and is administered by HRSA. Title X recipients who are also funded under the Health Center Program, as well as those that have been determined to meet section 330 requirements but do not receive grant funding under that program, are required to demonstrate compliance with both Title X expectations and Health Center Program requirements. The Health Center Program Compliance Manual is the principal resource to assist health centers in understanding and demonstrating compliance with Health Center Program requirements. OPA's Program Policy Notice 2016-

11: Integrating with Primary Care Providers, addresses issues commonly faced by integrated Title X and Health Center program providers and is discussed in Chapter 2 above.

To learn more about the HRSA Health Center Program, visit https://bphc.hrsa.gov/.

CDC's Division of Reproductive Health

The Division of Reproductive Health sits in the CDC's National Center for Chronic Disease Prevention and Health Promotion and is the focal point for issues related to reproductive health, maternal health, and infant health. It released, and continues to update, the U.S. Medical Eligibility Criteria for Contraceptive Use (U.S. MEC) which includes recommendations for the use of specific contraceptive methods by women and men who have certain characteristics or medical conditions. The recommendations in the U.S. MEC are intended to assist health care providers when they counsel women, men, and couples about contraceptive method choice. In addition, it released, and continues to update, the U.S. Selected Practice Recommendations for Contraceptive Use (U.S. SPR) which addresses a select group of common issues regarding initiation and use of specific contraceptive methods. The recommendations in the U.S. SPR are intended to serve as a source of clinical guidance for health care providers and provide evidence-based guidance to reduce medical barriers to contraception access and use. Health care providers in Title X settings are encouraged to utilize these recommendations to ensure accessible, equitable, and high-quality service delivery.

To learn more about CDC's Division of Reproductive Health, visit https://www.cdc.gov/reproductivehealth/index.html.

CDC's Division of STD Prevention

The Division of STD Prevention within the CDC's National Center for HIV, Viral Hepatitis, STD, and TB Prevention is charged with the mission of providing national leadership, research, policy development, and scientific information to help people live safer, healthier lives by the prevention of STDs and their complications. It maintains, updates, and releases the STI Treatment Guidelines which provide current evidence-based prevention, diagnostic and treatment recommendations. The recommendations are intended to be a source for clinical guidance. Health care providers in Title X settings are encouraged to utilize these recommendations to ensure accessible, equitable, and high-quality service delivery.

To learn more about CDC's Division of STD Prevention, visit https://www.cdc.gov/nchhstp/divisions/std-prevention.html.

Office of Infectious Disease and HIV/AIDS Policy (OIDP)

Located within OASH, OIDP's mission is to provide strategic leadership and management, while encouraging collaboration, coordination, and innovation among federal agencies and stakeholders to reduce the burden of infectious diseases. OIDP spearheads the federal HIV/AIDS response through a number of activities: Ending the HIV Epidemic: A Plan for America Initiative, HIV.gov, Minority HIV/AIDS Fund, National HIV/AIDS Strategy, and the Presidential Advisory Council on HIV/AIDS.

To learn more about OASH's Office of Infectious Disease and HIV/AIDS Policy, visit https://www.hhs.gov/oidp/index.html.

Chapter 8: Title X Program Training and Technical Assistance & OPA Contractual Support

Title X Program Training and Technical Assistance

Clinical Training Center for Sexual and Reproductive Health (CTC-SRH)

Since 2006, OPA has funded the CTC-SRH to collaboratively deliver continuous, high-quality clinical skills training and resources to health care providers within the Title X and related public health communities. By providing current clinical protocols using new technologies and national standards, the CTC-SRH trains and supports clinical family planning providers at varying levels of intensity (universal, selected, and targeted) using diverse modalities, including but not limited to, in-person or online training and follow-up support, training of trainers, individual or group technical assistance, coaching, mentoring, peer-to-peer support, interviews and podcasts, videos, syntheses of available research and best practices, development of resources and tools, and virtual skills-building. The CTC-SRH also hosts the annual National Reproductive Health Conference. Title X recipients, service sites, and subrecipient staff are encouraged to subscribe to CTC-SRH's mailing list to receive their emails, training notifications, monthly newsletter, *Clinical Connections*, and updates about the annual conference.

Reproductive Health National Training Center (RHNTC)

OPA funds and collaborates with the RHNTC to address the needs of Title X family planning service delivery recipients and TPP recipients through training and technical assistance (TA). The RHNTC exists to ensure that personnel working in OPA-funded Title X and TPP projects have the knowledge, skills, and attitudes necessary to deliver high-quality services and programs. Title X recipients may request the RHNTC to provide targeted TA to help them address Title X implementation challenges they may encounter. The RHNTC collaborates closely with CTC-SRH to address the needs of Title X family planning service recipients and providers in a continuous and comprehensive manner. Title X recipients, service sites, and subrecipient staff are encouraged to subscribe to RHNTC's mailing list to receive their monthly newsletter, which includes new resources, webinars, and training opportunities.

OPA Contractual Support

FPAR 2.0 and Clinic Locator and Database Contract

OPA and its contractor are tasked with providing comprehensive TA using a collaborative and coordinated approach to help recipients transition to the new FPAR 2.0 data system. The FPAR 2.0 contractor collaborates closely with the RHNTC and the CTC-SRH to ensure that Title X recipients receive the support they need to successfully transition to FPAR 2.0 data collection and reporting. These activities include group and individualized TA to end users of the system via formal trainings, written materials, and other documentation. TA materials and assistance is available to recipients, subrecipients, and electronic health record vendors. Inquiries regarding the data system, data elements, implementation guide, waiver process, or FAQs can be emailed to the help desk at FPARSupport@mathematica-mpr.com and to the assigned OPA PO. Title X recipients are encouraged to refer to the FPAR 2.0 resources and frequently asked questions on the OPA FPAR webpage and Connect.gov.

OPA's Clinic Locator and Database contractor operates, enhances, and maintains the OPA Clinic Locator and Database. The contractor works closely with OPA POs and Title X recipients to ensure that the

information in the Clinic Locator and Database is accurate. Title X POs assist recipients with any Clinic Locator and Database issues in coordination with the contractor. Refer to Chapter 5, for more information on the Clinic Locator and Database.

Appendices

A. Resources

Resource	Link
2 CFR part 200	https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200
2021 Title X Final Rule Frequently Asked Questions	https://community.connect.gov/download/attachments/2137218186/Title%20X%202021%20Final%20Rule%20FAQs_Final%2011.15.2021.pdf?version=1&modificationDate=1638284508890&api=v2
2021 Title X Final Rule Resources	https://opa.hhs.gov/2021TitleXRule
340B Drug Pricing Program	https://www.hrsa.gov/opa/index.html
42 CFR Part 50, Subpart B "Sterilization of Persons in Federally Assisted Family Planning Projects"	https://www.ecfr.gov/current/title-42/part-50
42 CFR Part 59, Subpart A "Project Grants for Family Planning Services"	https://www.ecfr.gov/current/title-42/part-59/subpart-A
45 CFR Part 75, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards.	https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-75
Clinical Training Center for Sexual and Reproductive Health	https://ctcsrh.org/
Embryo Adoption Awareness and Services Program	https://opa.hhs.gov/grant-programs/embryo-adoption-awareness
Family Planning Annual Report	• https://opa.hhs.gov/research-evaluation/title-x-services-research/family-planning-annual-report • https://fpar.opa.hhs.gov/
Federal Program Information Act, 31 U.S.C. § 6101 *et seq.*	https://www.govinfo.gov/link/uscode/31/6101
Grant Solutions	https://home.grantsolutions.gov/home/
Healthy People 2030	https://health.gov/healthypeople
HHS Grants Policy Statement	https://www.hhs.gov/sites/default/files/hhs-grants-policy-statement-october-2024.pdf
HHS Office for Civil Rights: Federal Religious and Conscience Protection Nondiscrimination Laws	• https://www.hhs.gov/conscience/your-protections-against-discrimination-based-on-conscience-and-religion/index.html

HHS Office for Civil Rights: Non-Discrimination Requirements	• https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html • https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html
HRSA's Health Center Program	https://bphc.hrsa.gov/
OPA Clinical Locator and Database	• https://reproductivehealthservices.gov/ • https://fpar.opa.hhs.gov/
OPA social media	• https://www.linkedin.com/company/hhs-office-of-population-affairs-opa/ • https://www.youtube.com/c/HHSOfficeofPopulationAffairs
OPA website	https://opa.hhs.gov/
Payment Management System	https://pms.psc.gov/
Program Policy Notice 2016-11: Integrating with Primary Care Providers	https://opa.hhs.gov/grant-programs/title-x-service-grants/about-title-x-service-grants/program-policy-notices/opa-program-policy-notice-2016-11-integrating-with-primary-care-providers
Program Policy Notice 2024-01: Clarification Regarding Confidential Services to Adolescents under the Title X Program.	https://opa.hhs.gov/grant-programs/title-x-service-grants/about-title-x-service-grants/program-policy-notices/opa-program-policy-notice-2024-01-clarification-regarding-confidential-services-to-adolescents-under-the-title-x-program
Program Policy Notice 2024-02: Implementing Quality Family Planning Services Recommendations within Title X Projects.	https://opa.hhs.gov/node/4173
Providing Quality Family Planning Services in the United States: Recommendations of the U.S. Office of Population Affairs (Revised 2024) (QFP)	• https://opa.hhs.gov/grant-programs/title-x-service-grants/about-title-x-service-grants/quality-family-planning • www.qfpguide.org
Provision of Abortion-Related Services in Family Planning Services Projects (65 Fed. Reg. 41281, July 3, 2000)	https://opa.hhs.gov/sites/default/files/2021-09/provision-abortion-services-family-planning-july-2000.pdf
Reproductive Health National Training Center	https://rhntc.org/
Single Audit Act Amendments of 1996, 31 U.S.C. § 7501 *et seq.*	https://www.govinfo.gov/link/uscode/31/7501
Sterilization Consent Form: English	https://opa.hhs.gov/sites/default/files/2022-07/consent-for-sterilization-english-2025.pdf

Sterilization Consent Form: Spanish	https://opa.hhs.gov/sites/default/files/2022-07/consent-for-sterilization-spanish-2025.pdf
STI Treatment Guidelines	https://www.cdc.gov/std/treatment-guidelines/default.htm
Teen Pregnancy Prevention Program	https://opa.hhs.gov/grant-programs/teen-pregnancy-prevention-program-tpp/about-tpp
Title X Final Rule: "Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services" (86 Fed. Reg. 56144, Oct. 7, 2021).	https://www.govinfo.gov/content/pkg/FR-2021-10-07/pdf/2021-21542.pdf
Title X of the Public Health Service Act, 42 U.S.C. § 300 *et seq.*	https://opa.hhs.gov/sites/default/files/2020-07/title-x-statute-attachment-a_0.pdf
Trafficking Victims Protection Act of 2000	https://www.govinfo.gov/content/pkg/USCODE-2010-title22/html/USCODE-2010-title22-chap78-sec7104.htm)
U.S. Medical Eligibility Criteria for Contraceptive Use	https://www.cdc.gov/reproductivehealth/contraception/mmwr/mec/summary.html
U.S. Selected Practice Recommendations for Contraceptive Use	https://www.cdc.gov/contraception/hcp/usspr/index.html

B. Title X Statute: POPULATION RESEARCH AND VOLUNTARY FAMILY PLANNING PROGRAMS

(Note: References in brackets [] are to title 42, United States Code)

PROJECT GRANTS AND CONTRACTS FOR FAMILY PLANNING SERVICES SEC. 1001 [300]

(a) Authority of Secretary

The Secretary is authorized to make grants to and enter into contracts with public or nonprofit private entities to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents). To the extent practicable, entities which receive grants or contracts under this subsection shall encourage family participation[1] in projects assisted under this subsection.

(b) Factors determining awards; establishment and preservation of rights of local and regional entities

In making grants and contracts under this section the Secretary shall take into account the number of patients to be served, the extent to which family planning services are needed locally, the relative need of the applicant, and its capacity to make rapid and effective use of such assistance. Local and regional entities shall be assured the right to apply for direct grants and contracts under this section, and the Secretary shall by regulation fully provide for and protect such right.

(c) Reduction of grant amount

The Secretary, at the request of a recipient of a grant under subsection (a), may reduce the amount of such grant by the fair market value of any supplies or equipment furnished the grant recipient by the Secretary. The amount by which any such grant is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies or equipment on which the reduction of such grant is based. Such amount shall be deemed as part of the grant and shall be deemed to have been paid to the grant recipient.

(d) Authorization of appropriations

For the purpose of making grants and contracts under this section, there are authorized to be appropriated $30,000,000 for the fiscal year ending June 30, 1971; $60,000,000 for the fiscal year ending June 30, 1972; $111,500,000 for the fiscal year ending June 30, 1973, $111,500,000 each for the fiscal years ending June 30, 1974, and June 30, 1975; $115,000,000 for fiscal year 1976; $115,000,000 for the fiscal year ending September 30, 1977; $136,400,000 for the fiscal year ending September 30, 1978; $200,000,000 for the fiscal year ending September 30, 1979; $230,000,000 for the fiscal year ending September 30, 1980; $264,500,000 for the fiscal year ending September 30, 1981; $126,510,000 for the fiscal year ending September 30, 1982; $139,200,000 for the fiscal year ending September 30, 1983; $150,030,000 for the fiscal year ending September 30, 1984; and $158,400,000 for the fiscal year ending September 30, 1985.

[1] So in law. See section 931(b)(I) of Public Law 97-35 (95 Stat. 570). Probably should be “family”.

FORMULA GRANTS TO STATES FOR FAMILY PLANNING SERVICES SEC. 1002 [300a]

(a) Authority of Secretary; prerequisites
The Secretary is authorized to make grants, from allotments made under subsection (b), to State health authorities to assist in planning, establishing, maintaining, coordinating, and evaluating family planning services. No grant may be made to a State health authority under this section unless such authority has submitted, and had approved by the Secretary, a State plan for a coordinated and comprehensive program of family planning services.

(b) Factors determining amount of State allotments

The sums appropriated to carry out the provisions of this section shall be allotted to the States by the Secretary on the basis of the population and the financial need of the respective States.

(c) "State" defined

For the purposes of this section, the term "State" includes the Commonwealth of Puerto Rico, the Northern Mariana Islands, Guam, American Samoa, the Virgin Islands, the District of Columbia, and the Trust Territory of the Pacific Islands.

(d) Authorization of appropriations

For the purpose of making grants under this section, there are authorized to be appropriated $10,000,000 for the fiscal year ending June 30, 1971; $15,000,000 for the fiscal year ending June 30, 1972; and $20,000,000 for the fiscal year ending June 30, 1973.

TRAINING GRANTS AND CONTRACTS; AUTHORIZATION OF APPROPRIATIONS SEC. 1003 [300a-1]

(a) The Secretary is authorized to make grants to public or nonprofit private entities and to enter into contracts with public or private entities and individuals to provide the training for personnel to carry out family planning service programs described in section 1001 or 1002 of this title.

(b) For the purpose of making payments pursuant to grants and contracts under this section, there are authorized to be appropriated $2,000,000 for the fiscal year ending June 30, 1971; $3,000,000 for the fiscal year ending June 30, 1972; $4,000,000 for the fiscal year ending June 30, 1973; $3,000,000 each for the fiscal years ending June 30, 1974 and June 30, 1975; $4,000,000 for fiscal year ending 1976; $5,000,000 for the fiscal year ending September 30, 1977; $3,000,000 for the fiscal year ending September 30, 1978; $3,100,000 for the fiscal year ending September 30, 1979; $3,600,000 for the fiscal year ending September 30, 1980; $4,100,000 for the fiscal year ending September 30, 1981; $2,920,000 for the fiscal year ending September 30, 1982; $3,200,000 for the fiscal year ending September 30, 1983; $3,500,000 for the fiscal year ending September 30, 1984; and $3,500,000 for the fiscal year ending September 30, 1985.

RESEARCH SEC. 1004 [300a-2]

The Secretary may –

(1) conduct, and

(2) make grants to public or nonprofit private entities and enter into contracts with public or private entities and individuals for projects for,

research in the biomedical, contraceptive development, behavioral, and program implementation fields related to family planning and population.

INFORMATIONAL AND EDUCATIONAL MATERIALS
SEC. 1005 [300a-3]

(a) The Secretary is authorized to make grants to public or nonprofit private entities and to enter into contracts with public or private entities and individuals to assist in developing and making available family planning and population growth information (including educational materials) to all persons desiring such information (or materials).

(b) For the purpose of making payments pursuant to grants and contracts under this section, there are authorized to be appropriated $750,000 for the fiscal year ending June 30, 1971; $1,000,000 for the fiscal year ending June 30, 1972; $1,250,000 for the fiscal year ending June 30, 1973; $909,000 each for the fiscal years ending June 30, 1974, and June 30, 1975; $2,000,000 for fiscal year 1976; $2,500,000 for the fiscal year ending September 30, 1977; $600,000 for the fiscal year ending September 30, 1978; $700,000 for the fiscal year ending September 30, 1979; $805,000 for the fiscal year ending September 30, 1980; $926,000 for the fiscal year ending September 30, 1981; $570,000 for the fiscal year ending September 30, 1982; $600,000 for the fiscal year ending September 30, 1983; $670,000 for the fiscal year ending September 30, 1984; and $700,000 for the fiscal year ending September 30, 1985.

REGULATIONS AND PAYMENTS
SEC. 1006 [300a-4]

(a) Promulgation of regulations governing execution; amount of grants

Grants and contracts made under this subchapter shall be made in accordance with such regulations as the Secretary may promulgate. The amount of any grant under any section of this title shall be determined by the Secretary; except that no grant under any such section for any program or project for a fiscal year beginning after June 30, 1975, may be made for less than 90 per centum of its costs (as determined under regulations of the Secretary) unless the grant is to be made for a program or project for which a grant was made (under the same section) for the fiscal year ending June 30, 1975, for less than 90 per centum of its costs (as so determined), in which case a grant under such section for that program or project for a fiscal year beginning after that date may be made for a percentage which shall not be less than the percentage of its costs for which the fiscal year 1975 grant was made.

(b) Payment of grants

Grants under this title shall be payable in such installments and subject to such conditions as the Secretary may determine to be appropriate to assure that such grants will be effectively utilized for the purposes for which made.

(c) Prerequisites; “low-income family” defined

A grant may be made or contract entered into under section 1001 or 1002 for a family planning service project or program only upon assurances satisfactory to the Secretary that—

(1) priority will be given in such project or program to the furnishing of such services to persons from low-income families; and

(2) no charge will be made in such project or program for services provided to any person from a low-income family except to the extent that payment will be made by a third party (including a government agency) which is authorized or is under legal obligation to pay such charge.

For purposes of this subsection, the term "low-income family" shall be defined by the Secretary in accordance with such criteria as he may prescribe so as to insure that economic status shall not be a deterrent to participation in the programs assisted under this title.

(d) Suitability of informational or educational materials

(1) A grant may be made or a contract entered into under section 1001 or 1005 only upon assurances satisfactory to the Secretary that informational or educational materials developed or made available under the grant or contract will be suitable for the purposes of this title and for the population or community to which they are to be made available, taking into account the educational and cultural background of the individuals to whom such materials are addressed and the standards of such population or community with respect to such materials.

(2) In the case of any grant or contract under section 1001, such assurances shall provide for the review and approval of the suitability of such materials, prior to their distribution, by an advisory committee established by the grantee or contractor in accordance with the Secretary's regulations. Such a committee shall include individuals broadly representative of the population or community to which the materials are to be made available.

VOLUNTARY PARTICIPATION
SEC. 1007 [300a-5]

The acceptance by any individual of family planning services or family planning or population growth information (including educational materials) provided through financial assistance under this title (whether by grant or contract) shall be voluntary and shall not be a prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, any other program of the entity or individual that provided such service or information.

PROHIBITION OF ABORTION
SEC. 1008[2] [300a-6]

None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning.

[2] Section 1009 was repealed by section 601(a)(1)(G) of Public Law 105-362 (112 Stat. 3285).

C. Title X Final Rule: "Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services" (86 Fed. Reg. 56144, Oct. 7, 2021)

42 CFR Part 59, Subpart A - Project Grants for Family Planning Services

Authority: 42 U.S.C. 300a-4.

§ 59.1 To what programs do these regulations apply?

The regulations of this subpart are applicable to the award of grants under section 1001 of the Public Health Service Act (42 U.S.C. 300) to assist in the establishment and operation of voluntary family planning projects. These projects shall consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children.

§ 59.2 Definitions.

As used in this subpart:

Act means the Public Health Service Act, as amended.

Adolescent-friendly health services are services that are accessible, acceptable, equitable, appropriate and effective for adolescents.

Clinical services provider includes physicians, physician assistants, nurse practitioners, certified nurse midwives, and registered nurses with an expanded scope of practice who are trained and permitted by state-specific regulations to perform all aspects of the user (male and female) physical assessments recommended for contraceptive, related preventive health, and basic infertility care.

Client-centered care is respectful of, and responsive to, individual client preferences, needs, and values; client values guide all clinical decisions.

Culturally and linguistically appropriate services are respectful of and responsive to the health beliefs, practices and needs of diverse patients.

Family means a social unit composed of one person, or two or more persons living together, as a household.

Family planning services include a broad range of medically approved services, which includes Food and Drug Administration (FDA)-approved contraceptive products and natural family planning methods, for clients who want to prevent pregnancy and space births, pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, sexually transmitted infection (STI) services, and other preconception health services.

Health equity is when all persons have the opportunity to attain their full health potential and no one is disadvantaged from achieving this potential because of social position or other socially determined circumstances.

Inclusive is when all people are fully included and can actively participate in and benefit from family planning, including, but not limited to, individuals who belong to underserved communities, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.

Low-income family means a family whose total annual income does not exceed 100 percent of the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2). “Low-income family” also includes members of families whose annual family income exceeds this amount, but who, as determined by the project director, are unable, for good reasons, to pay for family planning services. For example, unemancipated minors who wish to receive services on a confidential basis must be considered on the basis of their own resources.

Nonprofit, as applied to any private agency, institution, or organization, means that no part of the entity’s net earnings benefit, or may lawfully benefit, any private shareholder or individual.

Quality healthcare is safe, effective, client-centered, timely, efficient, and equitable.

Secretary means the Secretary of Health and Human Services (HHS) and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

Service site is a clinic or other location where Title X services are provided to clients. Title X recipients and/or their subrecipients may have service sites.

State includes, in addition to the several States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, American Samoa, the U.S. Outlaying Islands (Midway, Wake, et al.), the Marshall Islands, the Federated State of Micronesia, and the Republic of Palau.

Trauma-informed means a program, organization, or system that is trauma-informed realizes the widespread impact of trauma and understands potential paths for recovery; recognizes the signs and symptoms of trauma in clients, families, staff, and others involved with the system; and responds by fully integrating knowledge about trauma into policies, procedures, and practices, and seeks to actively resist re-traumatization.

§ 59.3 Who is eligible to apply for a family planning services grant?

Any public or nonprofit private entity in a State may apply for a grant under this subpart.

§ 59.4 How does one apply for a family planning services grant?

(a) Application for a grant under this subpart shall be made on an authorized form.

(b) An individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the terms and conditions of the grant, including the regulations of this subpart, must sign the application.
(c) The application shall contain

(1) A description, satisfactory to the Secretary, of the project and how it will meet the requirements of this subpart;

(2) A budget and justification of the amount of grant funds requested;

(3) A description of the standards and qualifications which will be required for all personnel and for all facilities to be used by the project; and

(4) Such other pertinent information as the Secretary may require.

§ 59.5 What requirements must be met by a family planning project?

(a) Each project supported under this part must:

(1) Provide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, STI services, preconception health services, and adolescent-friendly health services). If an organization offers only a single method of family planning, it may participate as part of a project as long as the entire project offers a broad range of acceptable and effective medically approved family planning methods and services. Title X service sites that are unable to provide clients with access to a broad range of acceptable and effective medically approved family planning methods and services, must be able to provide a prescription to the client for their method of choice or referrals to another provider, as requested.

(2) Provide services without subjecting individuals to any coercion to accept services or to employ or not to employ any particular methods of family planning. Acceptance of services must be solely on a voluntary basis and may not be made a prerequisite to eligibility for, or receipt of, any other services, assistance from or participation in any other program of the applicant.[1]

[1] 42 U.S.C. 300a-8 provides that any officer or employee of the United States, officer or employee of any State, political subdivision of a State, or any other entity, which administers or supervises the administration of any program receiving Federal financial assistance, or person who receives, under any program receiving Federal assistance, compensation for services, who coerces or endeavors to coerce any person to undergo an abortion or sterilization procedure by threatening such person with the loss of, or disqualification for the receipt of, any benefit or service under a program receiving Federal financial assistance shall be fined not more than $1,000 or imprisoned for not more than one year, or both.

(3) Provide services in a manner that is client-centered, culturally and linguistically appropriate, inclusive, and trauma-informed; protects the dignity of the individual; and ensures equitable and quality service delivery consistent with nationally recognized standards of care.

(4) Provide services in a manner that does not discriminate against any client based on religion, race, color, national origin, disability, age, sex, sexual orientation, gender identity, sex characteristics, number of pregnancies, or marital status.

(5) Not provide abortion as a method of family planning.[2] A project must:

(i) Offer pregnant clients the opportunity to be provided information and counseling regarding each of the following options:

(A) Prenatal care and delivery;

(B) Infant care, foster care, or adoption; and

(C) Pregnancy termination.

(ii) If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and, referral upon request, except with respect to any option(s) about which the pregnant client indicates they do not wish to receive such information and counseling.

(6) Provide that priority in the provision of services will be given to clients from low-income families.

(7) Provide that no charge will be made for services provided to any clients from a low-income family except to the extent that payment will be made by a third party (including a government agency) which is authorized to or is under legal obligation to pay this charge.

(8) Provide that charges will be made for services to clients other than those from low-income families in accordance with a schedule of discounts based on ability to pay, except that charges to persons from families whose annual income exceeds 250 percent of the levels set forth in the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2) will be made in accordance with a schedule of fees designed to recover the reasonable cost of providing services.

(i) Family income should be assessed before determining whether copayments or additional fees are charged.

(ii) With regard to insured clients, clients whose family income is at or below 250 percent of the FPL should not pay more (in copayments or additional fees) than what they would otherwise pay when the schedule of discounts is applied.

(9) Take reasonable measures to verify client income, without burdening clients from low-income families. Recipients that have lawful access to other valid means of income verification because of the client's participation in another program may use those data rather than re-verify income or rely solely on clients' self-report. If a client's income cannot be verified after reasonable attempts to do so, charges are to be based on the client's self-reported income.

(10) If a third party (including a Government agency) is authorized or legally obligated to pay for services, all reasonable efforts must be made to obtain the third-party payment without application of any

[2] Providers may be covered by federal statutes protecting conscience and/or civil rights.

discounts. Where the cost of services is to be reimbursed under title XIX, XX, or XXI of the Social Security Act, a written agreement with the title XIX, XX, or XXI agency is required.

(11) (i) Provide that if an application relates to consolidation of service areas or health resources or would otherwise affect the operations of local or regional entities, the applicant must document that these entities have been given, to the maximum feasible extent, an opportunity to participate in the development of the application. Local and regional entities include existing or potential subrecipients which have previously provided or propose to provide family planning services to the area proposed to be served by the applicant.
(ii) Provide an opportunity for maximum participation by existing or potential subrecipients in the ongoing policy decision making of the project.

(b) In addition to the requirements of paragraph (a) of this section, each project must meet each of the following requirements unless the Secretary determines that the project has established good cause for its omission. Each project must:

(1) Provide for medical services related to family planning (including consultation by a clinical services provider, examination, prescription and continuing supervision, laboratory examination, contraceptive supplies), in person or via telehealth, and necessary referral to other medical facilities when medically indicated, and provide for the effective usage of contraceptive devices and practices.

(2) Provide for social services related to family planning, including counseling, referral to and from other social and medical service agencies, and any ancillary services which may be necessary to facilitate clinic attendance.

(3) Provide for opportunities for community education, participation, and engagement to:

(i) Achieve community understanding of the objectives of the program;

(ii) Inform the community of the availability of services; and

(iii) Promote continued participation in the project by diverse persons to whom family planning services may be beneficial to ensure access to equitable, affordable, client-centered, quality family planning services.

(4) Provide for orientation and in-service training for all project personnel.

(5) Provide services without the imposition of any durational residency requirement or requirement that the patient be referred by a physician.

(6) Provide that family planning medical services will be performed under the direction of a clinical services provider, with services offered within their scope of practice and allowable under state law, and with special training or experience in family planning.

(7) Provide that all services purchased for project participants will be authorized by the project director or their designee on the project staff.

(8) Provide for coordination and use of referrals and linkages with primary healthcare providers, other providers of healthcare services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs, who are in close physical proximity to the Title X site, when feasible, in order to promote access to services and provide a seamless continuum of care.

(9) Provide that if family planning services are provided by contract or other similar arrangements with actual providers of services, services will be provided in accordance with a plan which establishes rates and method of payment for medical care. These payments must be made under agreements with a schedule of rates and payment procedures maintained by the recipient. The recipient must be prepared to substantiate that these rates are reasonable and necessary.

(10) Provide, to the maximum feasible extent, an opportunity for participation in the development, implementation, and evaluation of the project by persons broadly representative of all significant elements of the population to be served, and by others in the community knowledgeable about the community's needs for family planning services.

§ 59.6 What procedures apply to assure the suitability of informational and educational material (print and electronic)?

(a) A grant under this section may be made only upon assurance satisfactory to the Secretary that the project shall provide for the review and approval of informational and educational materials (print and electronic) developed or made available under the project by an Advisory Committee prior to their distribution, to assure that the materials are suitable for the population or community to which they are to be made available and the purposes of Title X of the Act. The project shall not disseminate any such materials which are not approved by the Advisory Committee.

(b) The Advisory Committee referred to in paragraph (a) of this section shall be established as follows:

(1) Size. The committee shall consist of no fewer than five members and up to as many members the recipient determines, except that this provision may be waived by the Secretary for good cause shown.

(2) Composition. The committee shall include individuals broadly representative of the population or community for which the materials are intended (in terms of demographic factors such as race, ethnicity, color, national origin, disability, sex, sexual orientation, gender identity, sex characteristics, age, marital status, income, geography, and including but not limited to individuals who belong to underserved communities, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality).
(3) Function. In reviewing materials, the Advisory Committee shall:

(i) Consider the educational, cultural, and diverse backgrounds of individuals to whom the materials are addressed;

(ii) Consider the standards of the population or community to be served with respect to such materials;

(iii) Review the content of the material to assure that the information is factually correct, medically accurate, culturally and linguistically appropriate, inclusive, and trauma informed;

(iv) Determine whether the material is suitable for the population or community to which is to be made available; and

(v) Establish a written record of its determinations.

§ 59.7 What criteria will the Department of Health and Human Services use to decide which family planning services projects to fund and in what amount?

(a) Within the limits of funds available for these purposes, the Secretary may award grants for the establishment and operation of those projects which will in the Department's judgment best promote the purposes of section 1001 of the Act, taking into account:

(1) The number of clients, and, in particular, the number of low-income clients to be served;

(2) The extent to which family planning services are needed locally;

(3) The ability of the applicant to advance health equity;

(4) The relative need of the applicant;

(5) The capacity of the applicant to make rapid and effective use of the federal assistance;

(6) The adequacy of the applicant's facilities and staff;

(7) The relative availability of non-federal resources within the community to be served and the degree to which those resources are committed to the project; and

(8) The degree to which the project plan adequately provides for the requirements set forth in these regulations.

(b) The Secretary shall determine the amount of any award on the basis of an estimate of the sum necessary for the performance of the project. No grant may be made for less than 90 percent of the project's costs, as so estimated, unless the grant is to be made for a project which was supported, under section 1001, for less than 90 percent of its costs in fiscal year 1975. In that case, the grant shall not be for less than the percentage of costs covered by the grant in fiscal year 1975.

(c) No grant may be made for an amount equal to 100 percent for the project's estimated costs.

§ 59.8 How is a grant awarded?

(a) The notice of grant award specifies how long HHS intends to support the project without requiring the project to recompete for funds. This anticipated period will usually be for three to five years.

(b) Generally, the grant will initially be for one year and subsequent continuation awards will also be for one year at a time. A recipient must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the recipient's progress and management practices and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the government.

(c) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

§ 59.9 For what purpose may grant funds be used?

Any funds granted under this subpart shall be expended solely for the purpose for which the funds were granted in accordance with the approved application and budget, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed in 45 CFR Part 75.

§59.10 Confidentiality.

(a) All information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and must not be disclosed without the individual's documented consent, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals. Reasonable efforts to collect charges without jeopardizing client confidentiality must be made. Recipient must inform the client of any potential for disclosure of their confidential health information to policyholders where the policyholder is someone other than the client.
(b) To the extent practical, Title X projects shall encourage family participation.[3] However, Title X projects may not require consent of parents or guardians for the provision of services to minors, nor can any Title X project staff notify a parent or guardian before or after a minor has requested and/or received Title X family planning services.

§59.11 Additional conditions.

The Secretary may, with respect to any grant, impose additional conditions prior to, at the time of, or during any award, when in the Department's judgment these conditions are necessary to assure or protect advancement of the approved program, the interests of public health, or the proper use of grant funds.

[3] 42 U.S.C. 300(a).

D. Generic Template: FY 22 Title X Notice of Award Terms and Conditions

(Note: The generic NOA template is set out below. Title X recipients should refer to their own NOAs for the specific terms and conditions applicable to their awards.)

SPECIAL TERMS AND REQUIREMENTS

1. Program Income Use. Program income (fees, premiums, third-party reimbursements which the project may reasonably expect to receive), as well as State, local and other operational funding, will be used to finance the non-federal share of the scope of project as defined in the approved grant application and reflected in the approved budget. Program income and the level projected in the approved budget will be used to further program objectives. Box 28 on this Notice of Award (NoA) indicates Other. Program Income may be used to meet the cost sharing or matching requirement of the federal award. The amount of the federal award stays the same. Program Income in excess of any amounts specified must be added to the federal funds awarded. They must be used for the purposes and conditions of this award for the duration of the Project period. 45 C.F.R. § 75.307 (e).

2. Program Specific Regulation. In accepting this award, the grantee stipulates that the award and any activities thereunder are subject to all provisions of 42 CFR Part 59, Subpart A.

3**. OPA Program Priorities.** All recipients must comply with the requirements regarding the provision of family planning services that can be found in the statute (Title X of the Public Health Service Act, 42 U.S.C. § 300 et seq.) and the implementing regulations (42 C.F.R. Part 59, Subpart A), and any legislative mandates. In addition, sterilization of clients as part of the Title X program must be consistent with 42 C.F.R. Part 50, Subpart B ("Sterilization of Persons in Federally Assisted Family Planning Projects").

In addition to the statute, regulations, legislative mandates, and additional program guidance that apply to Title X, OPA establishes program priorities that represent overarching goals for the Title X program. OPA expects recipients to develop and implement plans to address program priorities. The current priorities are: 1) advance health equity through the delivery of Title X services; 2) improve and expand access to Title X services; and 3) deliver Title X services of the highest quality.

4. Notice of Change in Service Sites. In order to maintain an accurate record of current Title X service sites, grantees must provide notice to the Office of Population Affairs (OPA) of any deletions, additions, or changes to the name, location, street address and email, services provided on-site, and contact information for Title X grantees and service sites. This database will also be used to verify eligibility for 340B program registration and recertification. You must enter your changes to the Title X database within 30 days from the official approval of the change at https://opa-fpclinicdb.hhs.gov/ This does not replace the prior approval requirement under HHS grants policy for changes in project scope, including clinic closures.

5. 304B Program Participation. If you or your sub-recipient(s) enrolls in the 340B Program, you must comply with all 340B Program requirements. You may be subject to audit at any time regarding 340B Program compliance. 340B Program requirements are available at https://www.hrsa.gov/opa/program-requirements/index.html.

6. FPAR reporting. For each calendar year covered by the project period, you will be required to submit a Family Planning Annual Report (FPAR). The information collection (reporting requirements) and format for this report have been approved by the Office of Management and Budget (OMB) and assigned OMB No. 0990-0479 (Expires 9/30/2024). The FPAR data elements, instrument, and instructions are found on the OPA Web site at http://opa.hhs.gov. You are expected to use the FPAR data to inform your QI/QA activities.

7. Evaluation Cooperation. The grantee is expected to participate in OPA research and evaluation activities, if selected, and must agree to follow all evaluation protocols established by OPA or its designee.

8. Grantee Meetings. The grantee is encouraged to actively participate in all OPA-supported Title X grantee meetings and grantee conferences. In addition to training and technical assistance available from the Reproductive Health National Training Center and the National Clinical Training Center for Family Planning, OPA is planning to conduct two Title X grantee trainings in 2022 and a Title X grantee conference in 2023.

9. Institutional Review Board (IRB). Institutional Review Board (IRB) approvals, when required, must be submitted via Grant Solutions Grant Notes within 5 business days of receipt from the IRB. No activities that require IRB approval may take place prior to your receipt of the IRB approval.

10. Maximizing Access. In furtherance of maximizing access and best serving individuals in need in the service areas, recipients should make reasonable efforts to avoid duplication of effort in the provision of services across the Title X network. For example, Title X recipients' coverage areas may overlap geographically, but duplication of subrecipient sites could be minimized or avoided to create more opportunities for services.

11. Prior Approval for Vehicle Purchases. No mobile health unit(s) or other vehicle(s), even if proposed in the application for this award, may be purchased with award funds without prior written approval from the grant management officer. Requests for approval of such purchases must include a justification with a cost-benefit analysis comparing both purchase and lease options. Such requests must be submitted as a Budget Revision Amendment in Grant Solutions.

STANDARD TERMS

1. Compliance with Terms and Conditions. You must comply with all terms and conditions outlined in the grant award, including grant policy terms and conditions contained in applicable Department of Health and Human Services (HHS) Grant Policy Statements (GPS), (note any references in the GPS to 45 C.F.R. Part 74 or 92 are now replaced by 45 C.F.R. Part 75, and the SF-269 is now the SF-425), and requirements imposed by program statutes and regulations, Executive Orders, and HHS grant administration regulations, as applicable; as well as any requirements or limitations in any applicable appropriations acts. By drawing or otherwise obtaining funds for the award from the grant payment system or office, you accept the terms and conditions of the award and agree to perform in accordance with the requirements of the award. The HHS Grants Policy Statement is available at: http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf. Uniform

Administrative Requirements, Cost Principles, and Audit Requirements for HHS awards are at 45 C.F.R. Part 75.

2. Grants Management Officer Prior Approval Requirements. Certain changes to your project or personnel require prior approval from the Grants Management Officer (GMO). (See Part II, HHS Grants Policy Statement (GPS), any references in the GPS to 45 C.F.R. Part 74 or 92 are now replaced by 45 C.F.R. Part 75). All amendment requests requiring prior approval must be signed by the grantee authorizing official and or PI/PD and submitted through the GrantSolutions Amendment Module. Only responses signed by the GMO are considered valid. If you take action on the basis of responses from other officials or individuals, you do so at your own risk. Such responses will not be considered binding by or upon any OASH Office or HHS component. Any other correspondence not relating to a prior approval item should be uploaded to Grant Notes within the GrantSolutions system. Include the federal grant number and signature of the authorized business official and the project director on all such correspondence.

3. Salary Limitation (Further Consolidated Appropriations Act, 2022, Div. H, Title II, sec. 202). "None of the funds appropriated in this title shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II."

The Salary Limitation is based upon the Executive Level II of the Federal Executive Pay Scale. Effective January 2022, the Executive Level II salary is $203,700. For the purposes of the salary limitation, the direct salary is exclusive of fringe benefits and indirect costs. An individual's direct salary is not constrained by the legislative provision for a limitation of salary. The rate limitation simply limits the amount that may be awarded and charged to the grant or cooperative agreement. A recipient may pay an individual's salary amount in excess of the salary cap with non-federal funds.

4. Reporting Subawards and Executive Compensation.

A. Reporting of first-tier subawards.

1) Applicability.

Unless you are exempt as provided in paragraph D. of this award term, you must report each action that obligates $30,000 or more in federal funds that does not include Recovery Act funds (as defined in section 1512(a)(2) of the American Recovery and Reinvestment Act of 2009, Pub. L. 111–5) for a subaward to an entity (see definitions in paragraph e. of this award term).

2) Where and when to report.

You must report each obligating action described in paragraph A.1. of this award term to the Federal Funding Accountability and Transparency Act Subaward Reporting System (FFRS). For subaward information, report no later than the end of the month following the month in which the obligation was made. (For example, if the obligation was made on November 7, 2010, the obligation must be reported by no later than December 31, 2010.)

3) What to report.

You must report the information about each obligating action as specified in the submission instructions posted at http://www.fsrs.gov.

B. Reporting Total Compensation of Recipient Executives.

1) Applicability and what to report.

You must report total compensation for each of your five most highly compensated executives for the preceding completed fiscal year, if—

a) The total federal funding authorized to date under this award is $30,000 or more;

b) In the preceding fiscal year, you received—

(1) 80 percent or more of your annual gross revenues from federal procurement contracts (and subcontracts) and federal financial assistance subject to the Transparency Act, as defined at 2 C.F.R. §170.320 (and subawards); and

(2) $25,000,000 or more in annual gross revenues from federal procurement contracts (and subcontracts) and federal financial assistance subject to the Transparency Act, as defined at 2 C.F.R. §170.320 (and subawards); and

c) The public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. § 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at the Executive Compensation page of the SEC website.)

2) Where and when to report.

You must report executive total compensation described in paragraph B.1. of this award term:

a) As part of your registration profile in the System for Award Management (SAM).

b) By the end of the month following the month in which this award is made, and annually thereafter.

C. Reporting of Total Compensation of Subrecipient Executives.

1) Applicability and what to report.

Unless you are exempt as provided in paragraph D of this award term, for each first-tier subrecipient under this award, you shall report the names and total compensation of each of the subrecipient's five most highly compensated executives for the subrecipient's preceding completed fiscal year, if—

a) In the subrecipient's preceding fiscal year, the subrecipient received—

(1) 80 percent or more of its annual gross revenues from federal procurement contracts (and subcontracts) and federal financial assistance subject to the Transparency Act, as defined at 2 C.F.R. § 170.320 (and subawards); and

(2) $25,000,000 or more in annual gross revenues from federal procurement contracts (and subcontracts), and federal financial assistance subject to the Transparency Act (and subawards); and

b) The public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. § 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at the Executive Compensation page of the SEC website.)

2) Where and when to report.

You must report subrecipient executive total compensation described in paragraph C.1. of this award term:

a) To the recipient.

b) By the end of the month following the month during which you make the subaward. For example, if a subaward is obligated on any date during the month of October of a given year (i.e., between October 1 and 31), you must report any required compensation information of the subrecipient by November 30 of that year.

D. Exemptions.

If, in the previous tax year, you had gross income, from all sources, under $300,000, you are exempt from the requirements to report:

1) Subawards, and

2) The total compensation of the five most highly compensated executives of any subrecipient.

E. Definitions.

For purposes of this award term:

1) “Entity”

This term means all of the following, as defined in 2 C.F.R. Part 25:

a) A Governmental organization, which is a State, local government, or Indian tribe;

b) A foreign public entity;

c) A domestic or foreign nonprofit organization;

d) A domestic or foreign for-profit organization;

e) A federal agency, but only as a subrecipient under an award or subaward to a non-federal entity.

2) “Executive”

This term means officers, managing partners, or any other employees in management positions.

3) “Subaward”:

a) This term means a legal instrument to provide support for the performance of any portion of the substantive project or program for which you received this award and that you as the recipient award to an eligible subrecipient.

b) The term does not include your procurement of property and services needed to carry out the project or program (for further explanation, see Sec. ll .210 of the attachment to OMB Circular A–133, ‘‘Audits of States, Local Governments, and Non-Profit Organizations’’).

c) A subaward may be provided through any legal agreement, including an agreement that you or a subrecipient considers a contract.

4) “Subrecipient”

This term means an entity that:

a) Receives a subaward from you (the recipient) under this award; and

b) Is accountable to you for the use of the federal funds provided by the subaward.

5) “Total compensation”

This term means the cash and noncash dollar value earned by the executive during the recipient’s or subrecipient’s preceding fiscal year and includes the following (for more information see 17 C.F.R. § 229.402(c)(2)):

a) Salary and bonus.

b) Awards of stock, stock options, and stock appreciation rights. Use the dollar amount recognized for financial statement reporting purposes with respect to the fiscal year in accordance with the Statement of Financial Accounting Standards No. 123 (Revised 2004) (FAS 123R), Shared Based Payments.

c) Earnings for services under non-equity incentive plans. This does not include group life, health, hospitalization, or medical reimbursement plans that do not discriminate in favor of executives and are available generally to all salaried employees.

d) Change in pension value. This is the change in present value of defined benefit and actuarial pension plans.

e) Above-market earnings on deferred compensation which is not tax-qualified.

f) Other compensation, if the aggregate value of all such other compensation (e.g., severance, termination payments, value of life insurance paid on behalf of the employee, perquisites, or property) for the executive exceeds
$10,000.

5. Intellectual Property and Data Rights.

A. Data. The federal government has the right to: 1) Obtain, reproduce, publish, or otherwise use the data produced under this award; and 2) Authorize others to receive, reproduce, publish, or otherwise use such data for federal purposes.

B. Copyright. The awardee may copyright any work that is subject to copyright and was developed, or for which ownership was acquired, under a federal award. The federal government reserves a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use the work for federal purposes, and to authorize others to do so.

C. Patents and Inventions. The awardee is subject to applicable regulations governing patents and inventions, including government- wide regulations issued by the Department of Commerce at 37 CFR part 401.

6. Acknowledgement of Federal Grant Support. When issuing statements, press releases, publications, requests for proposal, bid solicitations and other documents --such as toolkits, resource guides, websites, and presentations (hereafter “statements”)--describing the projects or programs funded in whole or in part with U.S. Department of Health and Human Services (HHS) federal funds, the recipient must clearly state:

1) the percentage and dollar amount of the total costs of the program or project funded with federal money; and,

2) the percentage and dollar amount of the total costs of the project or program funded by non-governmental sources.

When issuing statements resulting from activities supported by HHS financial assistance, the recipient entity must include an acknowledgement of federal assistance using one of the following or a similar statement.

If the HHS Grant or Cooperative Agreement is NOT funded with other non-governmental sources:

This [project/publication/program/website, etc.] [is/was] supported by the [full name of the PROGRAM OFFICE] of the
U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling $XX with 100 percent funded by [PROGRAM OFFICE]/OASH/HHS. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by [PROGRAM OFFICE]/OASH/HHS, or the U.S. Government. For more information, please visit [PROGRAM OFFICE website, if available].

The HHS Grant or Cooperative Agreement IS partially funded with other nongovernmental sources:

This [project/publication/program/website, etc.] [is/was] supported by the [full name of the PROGRAM OFFICE] of the
U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling $XX with XX percentage funded by [PROGRAM OFFICE]/OASH/HHS and $XX amount and XX percentage funded by
non-government source(s). The contents are those of the author (s) and do not necessarily represent the official views of, nor an endorsement, by [PROGRAM OFFICE]/OASH/HHS, or the U.S. Government. For more information, please visit [PROGRAM OFFICE website, if available].

The federal award total must reflect total costs (direct and indirect) for all authorized funds (including supplements and carryover) for the total competitive segment up to the time of the public statement.

Any amendments by the recipient to the acknowledgement statement must be coordinated with the OASH federal project officer and the OASH grants management officer.

If the recipient plans to issue a press release concerning the outcome of activities supported by this financial assistance, it should notify the OASH federal project officer and the OASH grants management officer in advance to allow for coordination.

7. Whistleblower Protections. You are hereby given notice that the 48 C.F.R. § 3.908 (related to the enhancement of contractor employee whistleblower protections), implementing 41 U.S.C. § 4712, as amended (entitled “Enhancement of contractor protection from reprisal for disclosure of certain information”) applies to this award.

8. Reporting of Matters Related to Recipient Integrity and Performance.

A. General Reporting Requirement

If the total value of your currently active grants, cooperative agreements, and procurement contracts from all federal awarding agencies exceeds $10,000,000 for any period of time during the period of performance of this federal award, then you as the recipient during that period of time must maintain the currency of information reported to the System for Award Management (SAM) that is made available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)) about civil, criminal, or administrative proceedings described in paragraph 2 of this award term and condition. This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. § 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for federal procurement contracts, will be publicly available.

B. Proceedings About Which You Must Report

Submit the information required about each proceeding that:

1) Is in connection with the award or performance of a grant, cooperative agreement, or procurement contract from the federal government;

2) Reached its final disposition during the most recent five-year period; and

3) If one of the following:

a) A criminal proceeding that resulted in a conviction, as defined in paragraph 5 of this award term and condition;

b) A civil proceeding that resulted in a finding of fault and liability and payment of a monetary fine, penalty, reimbursement, restitution, or damages of $5,000 or more;

c) An administrative proceeding, as defined in paragraph 5 of this award term and condition, that resulted in a finding of fault and liability and your payment of either a monetary fine or penalty of $5,000 or more or reimbursement, restitution, or damages in excess of $100,000; or

d) Any other criminal, civil, or administrative proceeding if:

(1) It could have led to an outcome described in paragraph 2.c.(1), (2), or (3) of this award term and condition;

(2) It had a different disposition arrived at by consent or compromise with an acknowledgement of fault on your part; and

(3) The requirement in this award term and condition to disclose information about the proceeding does not conflict with applicable laws and regulations.

C. Reporting Procedures

Enter in the SAM Entity Management area the information that SAM requires about each proceeding described in paragraph B of this award term and condition. You do not need to submit the information a second time under assistance awards that you received if you already provided the information through SAM because you were required to do so under federal procurement contracts that you were awarded.

D. Reporting Frequency

During any period of time when you are subject to this requirement in paragraph A of this award term and condition, you must report proceedings information through SAM for the most recent five-year period, either to report new information about any proceeding(s) that you have not reported previously or affirm that there is no new information to report. Recipients that have federal contract, grant, and cooperative

agreement awards with a cumulative total value greater than $10,000,000 must disclose semiannually any information about the criminal, civil, and administrative proceedings.

E. Definitions

For purposes of this award term and condition:

1) Administrative proceeding means a non-judicial process that is adjudicatory in nature in order to make a determination of fault or liability (e.g., Securities and Exchange Commission Administrative proceedings, Civilian Board of Contract Appeals proceedings, and Armed Services Board of Contract Appeals proceedings). This includes proceedings at the federal and state level but only in connection with performance of a federal contract or grant. It does not include audits, site visits, corrective plans, or inspection of deliverables.

2) Conviction, for purposes of this award term and condition, means a judgment or conviction of a criminal offense by any court of competent jurisdiction, whether entered upon a verdict or a plea, and includes a conviction entered upon a plea of nolo contendere.

3) Total value of currently active grants, cooperative agreements, and procurement contracts includes—

a) Only the federal share of the funding under any federal award with a recipient cost share or match; and

b) The value of all expected funding increments under a federal award and options, even if not yet exercised.

F. Disclosure Requirements.

Consistent with 45 C.F.R. § 75.113, applicants and recipients must disclose, in a timely manner, in writing to the HHS Awarding Agency, with a copy to the HHS Office of the Inspector General, all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. Subrecipients must disclose, in a timely manner, in writing to the prime recipient (pass through entity) and the HHS Office of the Inspector General all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. Disclosures must be sent in writing to the awarding agency and to the HHS OIG at the following addresses:

HHS OASH Grants and Acquisitions Management
1101 Wootton Parkway, Plaza Level
Rockville, MD 20852

AND

US Department of Health and Human Services Office of Inspector General
ATTN: OIG HOTLINE OPERATIONS—MANDATORY GRANT DISCLOSURES PO Box 23489
Washington, DC 20026

URL: http://oig.hhs.gov/fraud/report-fraud/index.asp
(Include "Mandatory Grant Disclosures" in subject line)
Fax: 1-800-223-8164 (Include "Mandatory Grant Disclosures" in subject line)

Failure to make required disclosures can result in any of the remedies described in 45 C.F.R. § 75.371 ("Remedies for noncompliance"), including suspension or debarment (See also 2 C.F.R. Parts 180 & 376 and 31 U.S.C. § 3321).

The recipient must include this mandatory disclosure requirement in all subawards and contracts under this award.

9. Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. You must administer your project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy). This includes taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html.

-- You must take reasonable steps to ensure that your project provides meaningful access to persons with limited English proficiency. For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficient individuals, see

https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.

-- For information on your specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and taking appropriate steps to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.

-- HHS funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html.

-- For guidance on administering your project in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

10. Trafficking in Persons. This award is subject to the requirements of Section 106 (g) of the Trafficking Victims Protection Act of 2000, as amended (22 U.S.C. § 7104)

A. Provisions applicable to a recipient that is a private entity.

1) You as the recipient, your employees, subrecipients under this award, and subrecipients' employees may not

a) Engage in severe forms of trafficking in persons during the period of time that the award is in effect;

b) Procure a commercial sex act during the period of time that the award is in effect; or

c) Use forced labor in the performance of the award or subawards under the award.

2) We as the federal awarding agency may unilaterally terminate this award, without penalty, if you or a subrecipient that is a private entity –

a) Is determined to have violated a prohibition in paragraph A.1 of this award term; or

b) Has an employee who is determined by the agency official authorized to terminate the award to have violated a prohibition in paragraph A.1 of this award term through conduct that is either-

(1) Associated with performance under this award; or

(2) Imputed to you or the subrecipient using the standards and due process for imputing the conduct of an individual to an organization that are provided in 2 C.F.R. Part 180, "OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement)," as implemented by our agency at 2 C.F.R. Part 376.

B. Provision applicable to a recipient other than a private entity.

We as the federal awarding agency may unilaterally terminate this award, without penalty, if a subrecipient that is a private entity-

1) Is determined to have violated an applicable prohibition in paragraph a.1 of this award term; or

2) Has an employee who is determined by the agency official authorized to terminate the award to have violated an applicable prohibition in paragraph a.1 of this award term through conduct that is either

a) Associated with performance under this award; or

b) Imputed to the subrecipient using the standards and due process for imputing the conduct of an individual to an organization that are provided in 2 C.F.R. Part 180, "OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement)," as implemented by our agency at 2 C.F.R. Part 376.

C. Provisions applicable to any recipient.

1) You must inform us immediately of any information you receive from any source alleging a violation of a prohibition in paragraph A.1 of this award term

2) Our right to terminate unilaterally that is described in paragraph A.2 or B of this section:

a) Implements section 106(g) of the Trafficking Victims Protection Act of 2000 (TVPA), as amended (22 U.S.C. § 7104(g)), and

b) Is in addition to all other remedies for noncompliance that are available to us under this award.

3) You must include the requirements of paragraph A.1 of this award term in any subaward you make to a private entity.

D. Definitions. For purposes of this award term:

1) “Employee” means either:

a) An individual employed by you or a subrecipient who is engaged in the performance of the project or program under this award; or

b) Another person engaged in the performance of the project or program under this award and not compensated by you including, but not limited to, a volunteer or individual whose services are contributed by a third party as an
in-kind contribution toward cost sharing or matching requirements.

2) “Forced labor” means:

Labor obtained by any of the following methods: the recruitment, harboring, transportation, provision, or obtaining of a person for labor or services, through the use of force, fraud, or coercion for the purpose of subjection to involuntary servitude, peonage, debt bondage, or slavery.

3) “Private entity”:

a) Means any entity other than a State, local government, Indian tribe, or foreign public entity, as those terms are defined in 2 C.F.R. § 175.25.

b) Includes:

(1) A nonprofit organization, including any nonprofit institution of higher education, hospital, or tribal organization other than one included in the definition of Indian tribe at 2 C.F.R. § 175.25(b).

(2) A for-profit organization.

4) “Severe forms of trafficking in persons,” “commercial sex act,” and “coercion”

These terms have the meanings given at section 103 of the TVPA, as amended (22 U.S.C. § 7102)

11. Prohibition on certain telecommunications and video surveillance services or equipment.

A. As described in CFR 200.216, recipients and subrecipients are prohibited to obligate or spend grant funds (to include direct and indirect expenditures as well as cost share and program) to:

1) Procure or obtain,

2) Extend or renew a contract to procure or obtain; or

3) Enter into contract (or extend or renew contract) to procure or obtain equipment, services, or systems that use covered telecommunications equipment or services as a substantial or essential component of any system, or as critical

technology as part of any system. As described in Pub. L. 115-232, section 889, covered telecommunications equipment is telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities).

a) For the purpose of public safety, security of government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities).

b) Telecommunications or video surveillance services provided by such entities or using such equipment.

c) Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of the National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise, connected to the government of a covered foreign country.

REPORTING REQUIREMENTS

1. Financial Reporting Requirement—Federal Financial Report (FFR) SF 425. Effective October 1, 2020, you must submit your SF-425 to OASH using the Department of Health and Human Services (HHS) Payment Management System for any OASH awards with a project period ending October 1, 2020, or later. Failure to submit the FFR in the correct system by the due date may delay processing of any pending requests or applications.

OASH and the Program Support Center are collaborating in the submission of the SF-425 to reduce the burden on grantees and assist with the reconciliation of expenditures and disbursements, and to allow for timely closeout of grants. Your submission must be through the HHS Payment Management System. SF-425 submissions through Grant Solutions will no longer be accepted for OASH awards.

You must use the SF-425 Federal Financial Report (FFR) for expenditure reporting. To assist in your preparation for submission you may find the SF-425 and instructions for completing the form on the Web at: http://apply07.grants.gov/apply/forms/sample/SF425-V1.0.pdf. You must complete all sections of the FFR.

A. Quarterly FFR Due Date.

Your FFR is due 30 days after the end of each Quarter in the federal fiscal year. That is for the:

Quarter ending September 30, your FFR is due October 30
Quarter ending December 31, your FFR is due January 30
Quarter ending March 30, your FFR is due April 30
Quarter ending June 30, your FFR is due July 30.

B. Final FFR Due Date.

Your final FFR covering the entire project is due 90 days after the end date for your project period.

C. Past due reports.

If you have not submitted by the due date, you will receive a message indicating the report is Past Due. Please ensure your Payment Management System account and contact information are up to date so you receive notifications.

D. Electronic Submission.

Electronic Submissions are accepted only via the HHS Payment Management System – No other submission methods will be accepted without prior written approval from the GMO. You must be assigned to the grant with authorized access to the FFR reporting Module when submitting. If you encounter any difficulties, contact the HHS Payment Management System Help Desk or your assigned Grants Management Specialist. Please reference the CONTACTS section of NoA Terms and Conditions to locate the name of your assigned Grants Management Specialist.

2. Annual Progress Report Requirements. You must submit annual progress reports 90 days after the end of each performance reporting period unless otherwise required under the Special Terms and Requirements for this award. Your progress reports must address content required by 45 CFR § 75.342(b)(2). Additional progress reporting may be required under Special Terms and Requirements as required by statute, regulation, or specific circumstances warranting additional monitoring. Additional guidance may be provided by the Program Office. Reports must be submitted electronically via upload to Grant Notes in GrantSolutions.

3. Audit Requirements. The Single Audit Act Amendments of 1996 (31 U.S.C. §§ 7501-7507) combined the audit requirements for all entities under one Act. An audit is required for all non-federal entities expending federal awards and must be consistent with the standards set out at 45 CFR Part 75, Subpart F (“Audit Requirements”). The audits are due within 30 days of receipt from the auditor or within 9 months of the end of the fiscal year, whichever occurs first. The audit report when completed should be submitted online to the Federal Audit Clearinghouse at https://harvester.census.gov/facides/Account/Login.aspx.

CONTACTS

1. Fraud, Waste, and Abuse. The HHS Inspector General accepts tips and complaints from all sources about potential fraud, waste, abuse, and mismanagement in Department of Health and Human Services' programs. Your information will be reviewed promptly by a professional staff member. Due to the high volume of information that they receive, they are unable to reply to submissions. You may reach the OIG through various channels.

Internet: https://forms.oig.hhs.gov/hotlineoperations/index.aspx
Phone: 1-800-HHS-TIPS (1-800-447-8477)

Mail: US Department of Health and Human Services Office of Inspector General
ATTN: OIG HOTLINE OPERATIONS PO Box 23489
Washington, DC 20026

For additional information visit https://oig.hhs.gov/fraud/report-fraud/index.asp

2. Payment Procedures. Payments for grants awarded by OASH Program Offices are made through Payment Management Services (previously known as the Division of Payment Management) https://pms.psc.gov/home.html PMS is administered by the Program Support Center (PSC), HHS. NOTE: Please contact the Payment Management Services to establish an account if you do not have one.

Inquiries regarding payments should be directed to https://pms.psc.gov/home.html; or Payment Management Services, P.O. Box 6021, Rockville, MD 20852; or 1-877-614-5533.

3. Use of Grant Solutions. GrantSolutions is our web-based system that will be used to manage your grant throughout its life cycle. Please contact GrantSolutions User Support to establish an account if you do not have one. Your Grants Management Specialist has the ability to create a GrantSolutions account for the Grantee Authorized Official and Principal Investigator/Program Director roles. Financial Officer accounts may only be established by GrantSolutions staff. All account requests must be signed by the prospective user and their supervisor or other authorized organization official.

For assistance on GrantSolutions issues please contact: GrantSolutions User Support at 202-401-5282 or 866-577-0771, email help@grantsolutions.gov, Monday – Friday, 8 a.m. – 6 p.m. ET. Frequently Asked Questions and answers are available at https://home.grantsolutions.gov/home/frequently-asked-questions/.

4. Grants Administration Assistance. For assistance on grants administration issues please contact the Grants Management Specialist listed in Box 9 on page 1 of this Notice of Award or mail:

OASH Grants and Acquisitions Management Division
Department of Health and Human Services
Office of the Secretary
Office of the Assistant Secretary for Health
1101 Wootton Parkway, Rockville, MD 20852

EXHIBIT D

American Journal of
Preventive Medicine

SPECIAL ARTICLE

Providing Quality Family Planning Services in the United States: Recommendations of the U.S. Office of Population Affairs (Revised 2024)

Sarah E. Romer, DNP, FNP,[1] Jennifer Blum, MPH,[2] Sonya Borrero, MD, MS,[3] Jacqueline M. Crowley, MPH,[2] Jamie Hart, PhD, MPH,[4] Maggie M. Magee, MPH,[2] Jamie L. Manzer, PhD, MPP,[2] Lisa Stern, RN, MSN, MA[4]

This update, titled Providing Quality Family Planning Services[a] in the United States: Recommendations of the U.S. Office of Population Affairs (Revised 2024), provides recommendations developed by the Office of Population Affairs (OPA) within the Office of the Assistant Secretary for Health at the U.S. Department of Health and Human Services (HHS). These recommendations represent an update to Providing Quality Family Planning (QFP) Services: Recommendations of the Centers for Disease Control and Prevention (CDC) and the U.S. Office of Population Affairs (OPA), originally published in 2014. The updated recommendations outline how to provide quality sexual and reproductive health (SRH) services for people of reproductive age but can also be used to guide the care of people of any age when the content is relevant to their needs, including family-building services, contraception, pregnancy testing and counseling, early pregnancy management, sexually transmitted infections (STIs) and human immunodeficiency virus (HIV) prevention and testing services, and other preventive health services. The recommendations aim to enable health care providers with the knowledge, skills, and attitudes to ensure that all people, regardless of individual characteristics such as sex, sexual orientation and gender identity, age, disability, or race, can have their SRH needs met. The primary audience for these recommendations is providers and potential providers of SRH services to people of reproductive age, such as providers working in clinical settings dedicated to SRH service delivery, including those funded by the Title X family planning program[b] as well as primary care providers and other subspecialty providers who may identify SRH needs and make referrals.

During the past decade, several changes have taken place in the United States that have affected SRH care delivery, including technological advances, recognition of long-standing inequities, and other legal and regulatory changes. This broader context has been considered in designing the updated recommendations.

This update of the QFP aims to provide guidance on the provision of person-centered SRH care focused on individuals' needs, values, and preferences. The update offers specific recommendations for how to provide high-quality SRH care and connects users to relevant guidelines, primary research, and other resources to inform best practices. In addition to incorporating new evidence,

[a]The title of this document is Providing Quality Family Planning Services, to retain consistency with the title of the initial 2014 publication. However, the recommendations included in this document are broader than the provision of family planning services, and include recommendations for providing quality sexual and reproductive health services. For purposes of this document, "family planning services" are defined as a broad range of medically approved services, which include Food and Drug Administration (FDA)-approved or FDA-cleared contraceptive products and natural family planning methods for patients who want to prevent pregnancy and space births; pregnancy testing and counseling; assistance to achieve pregnancy; basic infertility services; sexually transmitted infection (STI) services; and other pre-pregnancy health services. Family planning services do not include abortion.

From the [1]Office of Population Affairs, U.S. Department of Health and Human Services, Rockville, Maryland; [2]Mathematica, Washington, District of Columbia; [3]University of Pittsburgh, Pittsburgh, Pennsylvania; and [4]Coalition to Expand Contraceptive Access (CECA), Washington, District of Columbia

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this update incorporates newer approaches to care, including adopting a health equity lens that recognizes the impact of structural and interpersonal racism, classism, ableism, and bias based on sexual orientation and/or gender identity on health and the provision of quality SRH care. OPA will update these QFP recommendations periodically to reflect new findings in the scientific literature and revisions to the clinical guidelines referenced in this update.

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SECTION 1: INTRODUCTION

Sexual and reproductive health (SRH) is a key aspect of people's overall health and quality of life that is defined as a state of physical, emotional, mental, and social well-being in relation to all aspects of sexuality and reproduction, not merely the absence of disease, dysfunction, or infirmity.[1,2] Quality SRH care supports United States public health objectives, including improving birth outcomes, reducing the rate of sexually transmitted infections (STI), and preventing pregnancy-related mortality and morbidity.[3] These recommendations outline how to provide people of reproductive age with high-quality SRH services, including family-building services, contraceptive services, pregnancy testing and counseling, early pregnancy management, STI and human immunodeficiency virus (HIV) prevention and testing services, and other screening and preventive health services. These recommendations aim to enable health care providers to help ensure that all people, regardless of individual characteristics such as sex, gender identity, sexual orientation, age, ability, race, or ethnicity, can meet their SRH goals and needs.

These recommendations were developed by the Office of Population Affairs (OPA) within the Office of the Assistant Secretary for Health at the U.S. Department of Health and Human Services (HHS). OPA promotes health across the reproductive lifespan through innovative, evidence-based adolescent health and family planning programs, services, strategic partnerships, evaluation, and research. OPA's Title X family planning program has served as the national leader in direct family planning service delivery since the Title X program was established in 1970.[4]

These recommendations represent an update to Providing Quality Family Planning Services: Recommendations of the CDC and the U.S. Office of Population Affairs, originally published in 2014.[4] OPA followed a rigorous process in consultation with a wide array of experts in the fields of family planning (FP), SRH, and health equity (see Appendix 4). These recommendations intend to set the standard of SRH care and can be used by all current and potential providers of SRH services.

These recommendations can be implemented in varied settings, including primary care, specialty care (for example, obstetrics/gynecology, neurology, rheumatology), and community settings (for example, mobile clinics, schools, pharmacies). These recommendations are specifically intended for all current and potential providers of SRH services, including, but not limited to, those funded by the Title X family planning program. These recommendations apply to care delivered both in person and by telehealth. This update offers specific recommendations for how to provide high-quality SRH care and connects users to guidelines, primary research, and other resources to inform practice.

In addition to incorporating new evidence, this update includes newer approaches to care by adopting a health equity lens and recognizing the impact of structural and interpersonal racism, classism, ableism, and bias based on sexual orientation and/or gender identity on health and SRH care. The main revisions since the 2014 report are summarized in Exhibit 1.

Inclusion and Equity

Improving the quality of SRH services can lead to improved health outcomes, both directly and through improved patient experiences of care.[1] However, many people have long faced barriers to high-quality SRH care, including inequitable access to information; cost and insurance gaps; unnecessary, inadequate, or biased medical practices; and institutional barriers, such as lack

[b]Title X projects must comply with statutory and regulatory requirements set out in the Title X statute (42 U.S.C. §300 et seq.), any legislative mandates included in annual HHS appropriations, Title X implementing regulations at 42 CFR Part 59, Subpart A (86 Fed. Reg. 56144), and any applicable court orders. As these requirements include restrictions related to abortion and certain related activities, Title X providers are prohibited from using Title X funds for some of the recommendations set out in this document. A separate guidance has been issued to current Title X recipients, which clearly specifies which services in this QFP document are outside the scope of Title X and may not be paid for with Title X funding. This guidance can be found at https://opa.hhs.gov/grant-programs/title-x-service-grants/about-title-x-service-grants/program-policy-notices. Additionally, in places where recommendations in this QFP document may conflict with the Title X statute, legislative mandates, regulations, or court orders, the Title X federal requirements control.

Exhibit 1. Main Differences Between 2014 Report and 2024 QFP Update

2014 QFP Report	2024 QFP Update
Defined quality of care according to National Academies of Sciences, Engineering and Medicine (NASEM) (formerly IOM) **six dimensions of quality** (safe, effective, timely, patient-centered, efficient, and equitable)[5]	Maintains multidimensional definition of quality, with expanded emphasis on **person centeredness** and **equity** by using a sexual and reproductive health equity framework
Focused on **women** as recipients of care, with some specific content for male clients	Takes a **gender-inclusive** approach and uses language throughout to recognize that people of all genders may need and access SRH care
Described how to consider the needs of and provide care to **special populations**, including adolescents, people with disabilities, and others with reduced access to quality care	Integrates and prioritizes the needs of groups and individuals who experience **SRH inequities** in shaping the recommendations, rather than considering "special populations" separately; when relevant, highlights evidence or recommendations that may be specific to or more relevant for some groups or individuals
Focused on care provided **within the formal health care system**, particularly specialized family planning service sites	Includes care from a broad range of provider specialties in varied settings, **both within and beyond the formal health care system**, including patient-led and self-care options
Drew from existing **guidelines and published evidence** in establishing recommendations; when evidence was inconclusive or incomplete, recommendations were made on the basis of expert opinion	In addition to incorporating published scientific evidence and existing guidelines, includes **more expansive types of evidence, including qualitative evidence and** direct input from users and people with lived experience, as well as expert opinion
Offered recommendations on how to provide **quality family planning services**, including contraceptive services, pregnancy testing and counseling, helping clients achieve pregnancy, basic infertility services, "preconception health services," and STI services	Adds **technical content and expands the scope of services to encompass more elements of SRH care,** including the following: • Guiding principles: (1) person centeredness, (2) evidence informed, (3) inclusive, (4) accessible, (5) sex and body positive, and (6) trauma informed • Details on approaches to care to help providers carry out these guiding principles: (1) quality counseling, including shared decision making; (2) informed consent; and (3) privacy and confidentiality • New care delivery strategies, such as telehealth and over-the-counter (OTC) oral contraception • Broader content on early pregnancy management and resources • Expanded approach to family building • New or expanded preventive health care services related to mental health, healthy weight, perimenopausal care, gender-affirming care, and human trafficking • New STI and HIV prevention strategies, including self-care approaches and post- and pre-exposure prophylaxis (PEP and PrEP)
Recommended that all persons capable of having a child should have a **reproductive life plan** (RLP) and that providers should discuss the RLP with clients receiving contraceptive, pregnancy testing and counseling, basic infertility, sexually transmitted disease, and preconception health services	Advises discussing reproductive desires with a **person-centered approach** that focuses on open-ended communication and nonjudgmental counseling and support; does not endorse a single framework

of trained staff.[6] Black, indigenous, people of color; lesbian, gay, bisexual, transgender, queer or questioning, and intersex (LGBTQI+) people; people living in poverty; people with disabilities; people with larger bodies; immigrants; and others with (often intersecting) marginalized identities are more likely to face the barriers described above and experience unique systemic barriers to SRH care and discrimination within and beyond the health care system.[7–10] These groups also have a history and continued experiences of reproductive injustices, including forced sterilizations and coercive use of contraception.[11,12]

Delivery of high-quality, unbiased SRH care is one critical step in achieving sexual and reproductive health

Exhibit 2. Overarching Equity Principles Guiding Development of QFP

1. Ground QFP in a holistic vision of SRH that centers justice, equity, and autonomy.
2. Integrate rigorous scientific evidence to benefit the health of individuals and communities while recognizing the limitations of the current evidence base and applying an equity lens in its interpretation.
3. Use inclusive, person-centered definitions and language, driven by diverse partner input.
4. Prioritize inclusion throughout the development and implementation processes so QFP meets the needs of individuals and communities and does not cause unintentional harm.
5. Understand and reflect on the impact of the historical, sociocultural, political, geographical, and economic contexts that influence the lived experiences of communities and the delivery of care.
6. Design QFP so it will expand access to quality care for all, with a particular emphasis on those most impacted by SRH inequities and injustices.
7. Design QFP so the information is easily accessible, user-friendly, and facilitates dissemination and implementation.

*Note: Developed for QFP update and approved by OPA and Expert Workgroup.

equity (SRHE).[8] SRHE is defined as a state in which all people across the range of age, gender, disability, race, and other intersectional identities have what they need to attain their highest level of SRH, including the ability to self-determine and achieve their reproductive goals.[1] SRHE draws from human rights, health equity, and reproductive justice[13] frameworks and requires policies, healthcare systems, and other structures to ensure its advancement.[14]

The SRHE framework shaped the development of these recommendations, including through the incorporation of the overarching equity principles that were developed to guide this QFP update (Exhibit 2).[1] These principles, detailed further in the methods section, have included the engagement of users of the QFP recommendations and users of SRH services through listening sessions, visioning sessions, and lived experience panels; the use of equity review guides and checklists; and the incorporation of various forms of evidence. The recommendations aim to support the delivery of inclusive, person-centered care. With this goal in mind, this QFP update uses gender-inclusive language throughout and includes a wider range of methods of family building.[15] The term "assigned female at birth" (AFAB) is used to describe particular considerations for people who were born with and may or may not currently have a uterus, ovaries, fallopian tubes, vagina, and vulva without connecting this anatomy to the experience of gender identity.[16] Similarly, the term "assigned male at birth" (AMAB) is used for people who were born with and may or may not currently have a penis and testes without connecting this anatomy to the experience of gender identity. Because these recommendations apply beyond the formal health care system, the terms "person," "individual," "client," "user," and "patient" are all used to refer to people who may seek or desire SRH care. Additionally, the term "clinic" is used to define broadly the various types of service sites, health centers, and clinical settings where SRH care is provided.

Historical Context

Past and ongoing reproductive mistreatment of people belonging to communities that have been marginalized is of clinical relevance because it has shaped many present-day health inequities and contributes to ongoing mistrust of the health care system.

Twentieth-century violations of reproductive autonomy include the testing of the oral contraceptive pill on women in Puerto Rico without appropriate informed consent; coercive sterilization of people with physical and intellectual disabilities, those living in poverty, and from marginalized racial and ethnic groups; and the Tuskegee experiment, in which hundreds of Black men were deprived of treatment for syphilis.[11,17–21] Coercive sterilization practices continue into the 21st century, including among women in carceral settings.

Public health prerogatives to advance science and improve the gene pool were used to justify many of the actions now recognized as unjust.[22] These past actions serve as a reminder to providers to interrogate programs and practices, and to engage patients and communities in program development and system redesign to avoid neglecting or misunderstanding community needs and to reduce the risk of additional harm.

Current Context

During the past decade, several changes have taken place in the United States that have affected the delivery of SRH care and understandings of what constitutes quality. This broader context shaped these recommendations. Important considerations include the following:

- *Technological advances* include new contraceptive methods (for example, vaginal pH modulator gel), modifications to existing contraceptive methods (for example, new doses and formulations of hormonal contraceptives and intrauterine devices), new ways of preventing STIs (for example, pre-exposure prophylaxis for HIV), and more widely adopted service delivery options (for example, online platforms, self-care, and over-the-counter access to oral contraceptives).

Existing technologies such as telehealth have also expanded and become more user-friendly.

- *Enhanced recognition of long-standing inequities* within and beyond the health care realm have influenced what is considered high-quality SRH care. Systemic inequalities have long impeded people's ability to receive high-quality SRH care, including, but not limited to, contraceptive care. To advance SRHE, entities delivering SRH care are expected to actively attend to and work to redress inequities and to reform systems. These efforts include offering supportive resources such as transportation assistance to increase access to care, addressing provider bias through ongoing and effective anti-bias training and community engagement, and adopting quality measures that reflect the broad range of experiences and needs of diverse people. SRHE also includes acknowledging and accepting that many people prefer to seek care outside of the formal health care system; therefore, it is crucial to empower them with the resources they may need to do this, including accurate information.
- *Legal and regulatory changes at the federal, state, and local levels* have affected access to SRH care through various mechanisms, including funding, insurance coverage, legal restrictions, public programs, and provider availability. Some of these changes have had the effect of limiting access, whereas others have enhanced access.

Providers should be attentive to and remain aware of new developments that influence the delivery of high-quality SRH care. The Reproductive Health National Training Center (RHNTC) at www.RHNTC.org and the Clinical Training Center for Sexual and Reproductive Health (CTC-SRH) at www.CTCSRH.org offer training on these topics. Other organizations specializing in training on specific health topics covered in this update are listed in the relevant sections. Please refer to Appendix 3 for a glossary of terms used throughout this update and in the broader SRH field.

SECTION 2: METHODS

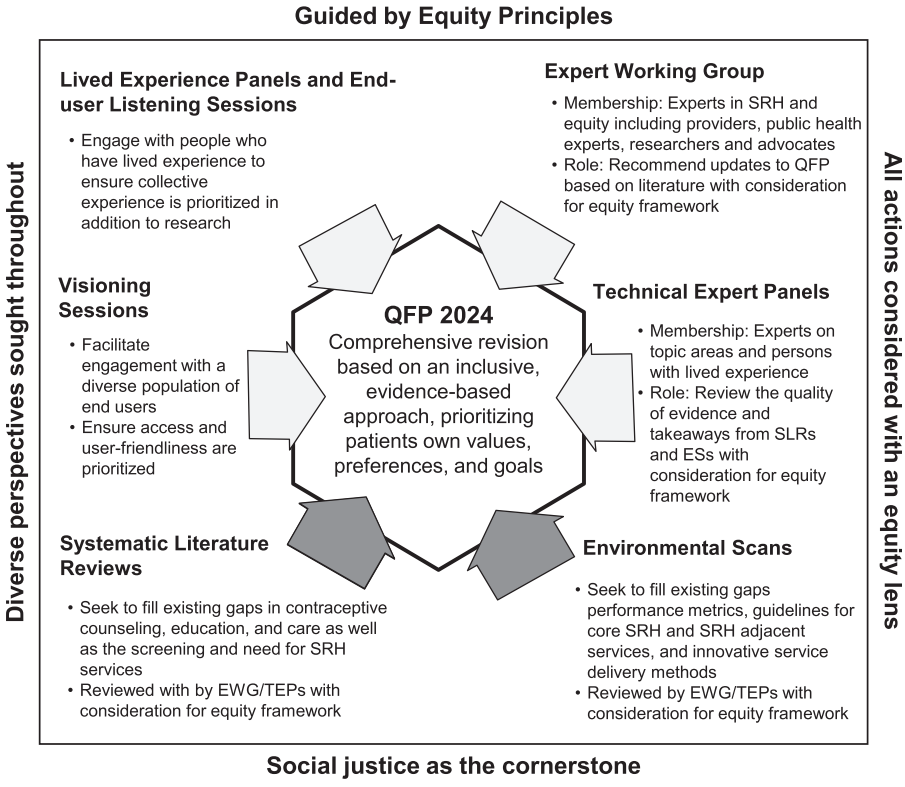
Recommendations Development Process

OPA developed these recommendations in consultation with a wide array of experts and partners. OPA hired a contractor to convene an Expert Workgroup (EWG) comprising experts in the fields of SRH and health equity who had relevant professional and lived experience representing a broad range of sectors and communities. The EWG and OPA identified research gaps in a series of systematic literature reviews and environmental scans. The contractor then assembled technical expert panels (TEPs) of subject matter experts for each of the topics. The TEPs reviewed the results of the literature reviews and the quality of the evidence and provided feedback on recommendations supported by a rigorous review of the evidence and the use of established equity principles (see Exhibit 2).

Drawing from established procedures for developing clinical guidelines and recommendations, including the National Academies of Sciences, Engineering and Medicine (NASEM) (formerly IOM) standards,[5] OPA adapted a multistage process in crafting this QFP update. The recommendations were drawn from an extensive literature review; individual feedback from subject matter experts, including persons with lived experience and members of the EWG and the TEPs; and a group of external reviewers (Appendix 4). Federal agencies and relevant professional organizations were consulted for updated clinical practice guidelines and recommendations. Guidelines, recommendations, statements, and committee opinions from the following organizations are included in this QFP update: Centers for Disease Control and Prevention (CDC), United States Preventive Services Task Force (USPSTF), the Health Resource and Services Administration (HRSA), Women's Preventive Services Initiative (WSPI), American Academy of Pediatrics (AAP), American Society for Colposcopy and Cervical Pathology (ASCCP), American College of Obstetrics and Gynecology (ACOG), American Society of Reproductive Medicine (ASRM), American Urological Association (AUA), Society of Family Planning (SFP), American Cancer Society (ACS), National Comprehensive Cancer Network, World Sexual Health Association, Center for Excellence for Transgender Health, and World Professional Association for Transgender Health (WPATH). In instances where the guidance or related materials of other organizations are described, specific organizational affiliations are included. The systematic literature reviews and other evidence used to prepare these recommendations are published in the *American Journal of Preventive Medicine*.[23–26] OPA funded all work contributing to this update.

Audience

The primary audience for this update is clinical providers and potential providers of SRH services to people of reproductive age. They include clinicians, educators, community health workers, and other licensed and non-licensed health care providers. These recommendations are addressed to providers working in service sites dedicated to SRH service delivery, including Title X-funded clinics and federally qualified health clinics (FQHCs), as well as primary care



providers, specialists, and other providers who may identify SRH needs and make referrals. Medical directors and others responsible for developing clinical protocols may also use the QFP recommendations to support policy and protocol development.

Equity Approach

Acknowledging the importance of incorporating equity throughout SRH services, OPA engaged with the HHS Equity Technical Assistance Center (ETAC) in 2022 to conduct an equity-focused review of the QFP update and recommendations.

The approach sought to reflect QFP's role in supporting SRH care provision that is person-centered, inclusive, equitable, and accessible to ensure high-quality care for all and facilitate dissemination and implementation. A set of equity tools was developed and used throughout the process to ensure a commitment to the stated goal of advancing SRHE.[26] These tools were integrated into the review process to ensure all updates and changes were considered through an equity lens and served the larger mission of integrating equity in SRH services. The overarching equity principles were developed to guide all activities involved in the QFP update process and serve as a foundation for QFP recommendations' equity focus. Specific to the systematic literature reviews, the review team drew from an adapted version of the PRISMA Extension for Equity Review Checklist, as opposed to the standard PRISMA checklist, to confirm equity was appropriately considered throughout the evidence.[27] Together, these tools were used to ensure that equity remained the focus of all recommendations at each step in the process.

Incorporating Lived Experience

OPA engaged with people with diverse lived experiences to ensure that recommendations were informed by various perspectives in addition to the published evidence. The following approaches were used:

- Formation of EWG and TEPs to ensure inclusion of persons representative of the diversity of racial, ethnic, disability, sex, sexual orientation and gender identities across the United States, as well as multidisciplinary academic and professional experience, including researchers, clinical providers, and patient advocates (see roster in Appendix 4).
- Listening sessions with FP clinical providers and administrators: Advised OPA on an individual basis on the content and usability of the original QFP report, discussed proposed updates to the QFP

recommendations and opportunities to improve the QFP update's inclusivity and functionality.
- Visioning sessions with Title X providers: Discussed strategies for making the QFP recommendations user-friendly and adaptable.
- Lived experience panels (LEPs) with users of SRH services: Provided individual feedback on proposed changes to QFP and related research, potential impact of those changes, and the extent to which the evidence reflected their preferences and lived experiences.

Literature Reviews

OPA commissioned a set of systematic literature reviews on the following topics: Contraceptive Counseling, Education, and Care and Screening for the Need and Desire for SRH Care.[23–26] OPA also commissioned two environmental scans on Performance Measures to Improve the Quality of SRH Services and Guidelines for Core SRH and Adjacent Services (unpublished). Given existing clinical guidelines and recommendations, OPA determined that the largest gaps were related to contraceptive counseling and provision. This determination corresponded well with OPA's core mandate to provide guidance to FP providers. A more detailed description of the methods used to conduct the literature reviews is provided in the accompanying journal supplement.[23–25] In addition, OPA commissioned a rapid systematic review of SRH Services Delivered via Telehealth.[28]

Orientation and Organization of the Recommendations

The QFP update is divided into 11 sections. The initial sections describe the context for this update and the methods used to develop the QFP recommendations. Subsequent sections describe the fundamentals of SRH care and how to assess an individual's need and desire for SRH services, the provision of person-centered contraceptive care, STI and HIV screening and treatment, family building, pregnancy testing and counseling, early pregnancy management, screening and other preventive health care services, and how to use performance measures to track and improve the quality of SRH care.

To accompany this update, technical assistance (TA) resources will be available from OPA, the RHNTC, and the CTC-SRH to facilitate adoption of the QFP recommendations. These resources will include a separate supporting website, managed by the RHTNC—www.QFPguide.org—that will provide a searchable format and links to available TA resources to support implementation of QFP recommendations, including tools, job aids, and interactive training sessions.

Exhibit 3. What Services Are Considered Part of SRH Care?

- Services intended to help people achieve their reproductive desires, such as contraception, pregnancy testing and counseling, achieving healthy pregnancy, and family building and adoption
- Prevention and detection of disease, including screening, testing, treatment, vaccination and prophylaxis for STI
- Provision of or referral to pregnancy-related care, including abortion, prenatal care, and treatment of pregnancy loss
- Gender-affirming care
- Screening for health issues that can affect SRH, such as hypertension, mental health conditions, and substance abuse, and either treatment or referral, when indicated

SECTION 3: FUNDAMENTALS OF SEXUAL AND REPRODUCTIVE HEALTH CARE DELIVERY

SRH care encompasses a broad range of services aimed at helping people define and achieve their highest level of health (Exhibit 3). The QFP update offers recommendations on how to deliver high-quality SRH services commonly provided in primary care, women's health, and other outpatient settings. The specific services offered in any given setting depend on community needs, provider scope, facility capacity, and the legal and regulatory environment. Providers who do not offer full-scope SRH care should screen for the need and desire for SRH services, share the limits of their practice, and refer or connect patients to other settings where they can obtain quality services, as indicated. Given the definition of SRH and the range of services it encompasses, it is important to note that SRH care is not just for people who can or want to become pregnant; rather, it should be accessible and welcoming for all people, regardless of gender, sexuality, disability, or age.

This section explains how the equity principles, described in Exhibit 2, can be integrated into program design and clinical care. It offers guidance about overarching approaches to care and discusses processes for screening individuals for various aspects of SRH care.

Guiding Principles for SRH Care

High-quality SRH care should be free from all forms of bias, including racism, classism, and bias based on disability status, weight, age, sexual orientation, and/or gender identity. Six principles guide the delivery of quality SRH care: (1) person-centered, (2) evidence based, (3) inclusive, (4) accessible, (5) sex and body positive, and (6) trauma-informed. These principles were designed for the QFP update based on a review of relevant literature and input from the EWG and the LEP. Descriptions of each are included below.

Person-centered. Person-centeredness, defined as a focus on an individual person's needs, values, and preferences, is among the essential domains of health care quality.[29] Advancing equity and minimizing harm necessitate providing SRH care in a person-centered framework by orienting the clinical team to everyone's unique life context, preferences, and social and structural realities. Respect for individual autonomy is critical, including the right to use or not use contraception, select or decline recommended screening tests, or pursue any preferred pregnancy option.[30]

Evidence based. Evidence based means the use of evidence to inform clinical care, develop programs, and conduct quality improvement.[5,31] Providers can consult evidence-based guidelines, such as those referenced throughout this update of the QFP, as part of providing quality care. Primary research and clinical resources such as UpToDate are also useful sources of information. Health systems and other employers can provide access to timely evidence-based resources to support staff in providing evidence-based care.

Inclusive. Inclusivity enables all people to participate in and benefit from services; the goal is for all services to reflect a patient's circumstances appropriately without bias. Efforts to create inclusion should specifically consider the needs of LGBTQI+ people, who often experience discrimination and mistreatment in the health care setting, contributing to disparities in SRH outcomes.[32] Inclusiveness involves standardizing and normalizing sexual orientation and gender identity (SOGI) conversations.[33–35] To establish an inclusive clinical environment, it is essential to address both administrative processes, such as registration and documentation, as well as patient care practices. This includes ensuring that patient information in medical records and portals accurately reflects their identity. Rather than making assumptions, healthcare providers should ask patients about their sex assigned at birth, current anatomy, preferred name, gender identity, and pronouns. These details should be carefully documented in the medical record to ensure respectful and personalized care throughout the patient's journey, including follow-up. The CDC offers suggested language for these questions, and for electronic health record (EHR) documentation.[36] These questions should be asked routinely of all patients to normalize and standardize interactions and enable people to describe themselves accurately without being targeted.[37,38]

Inclusive care is also culturally and linguistically affirming, meaning that services respond to diverse cultural health beliefs and practices, preferred language, health literacy, and other communication needs of patients. The National Culturally and Linguistically Appropriate Services (CLAS) standards should be applied. The National Coalition for Sexual Health offers resources on how to create a more inclusive clinic environment, including self-assessment tools.[39]

Workforce composition is an essential element of inclusion. Patients benefit when providers and staff in clinical settings are representative of communities being served and made up of individuals of diverse background and identities in terms of age, race, ethnicity, gender identity, disability status, sexual orientation, and other characteristics. The CLAS standards mentioned above include recommendations for recruiting a diverse clinical workforce.[40] People seeking SRH care value providers' clinical expertise, skill sets, and characteristics—such as empathy and nonjudgmental attitudes—regardless of health professional type, and collaborative interdisciplinary care teams can best deliver quality care.[40]

Specific considerations for providing care inclusive of adolescents are described in Exhibit 4.

Exhibit 4. Providing Care Inclusive of Adolescents

Confidential SRH services should be made available to adolescents while observing state laws and any legal obligations for reporting.

1. Ensure adolescents know their rights. Adolescents feel safer accessing care and more comfortable sharing personal information during appointments when they know their rights related to confidentiality, including how billing and insurance notifications are handled.
2. Know your state laws and clinic policies. Statutes on rights of minors to consent to health care vary by state. Be familiar with clinic policies around billing for minors and possible limitations of confidentiality related to insurance.
3. Address young people's needs, desires, and concerns. Routinely address needs and preferences for SRH care and individual goals, including those related to pregnancy prevention, enabling healthy pregnancy, and disease prevention, regardless of a person's age or sexual activity. Address relationships, sexual behaviors, and needs for the full range of SRH services.
4. Provide youth-friendly services. Peer educators and support groups can improve clinical outcomes and patient satisfaction with care. The involvement of a trusted adult, with permission, can also improve similar outcomes.
5. Integrate SRH care into other settings, including schools, to increase access and improve educational opportunities for adolescents.
6. Access specialized training. Trainings specific to adolescent care may include adolescent brain development, contraceptive provision, including IUD placement, appropriate referrals, and familiarity with confidentiality laws and policies.

Source: These key steps were adapted from ACOG's Committee Opinion Number 710, Counseling Adolescents About Contraception,[41] and the American Academy of Pediatrics Policy Statement, April 2024.[42]

Accessible. Care should be logistically, financially, and physically accessible to patients. All clinic settings should be aware of barriers to care and implement policies and procedures to help patients overcome barriers. For example, offering expanded hours, telehealth options, and walk-in appointments assists patients in obtaining timely care. Adopt flexible approaches to late-arrival policies, particularly for adolescents and individuals facing transportation challenges. Aim to reduce the number of visits required, recognizing the burden of multiple visits. Additionally, offering childcare services during appointments can increase accessibility for patients who are parents or caregivers.

Clinics should be familiar with out-of-pocket costs for services, medications, and supplies, whether provided on-site or through referrals. They should also be knowledgeable about coverage options available through commonly used public and private insurance programs. Offering guidance and resources to patients in need of financial assistance can help ensure access to care and reduce financial barriers.

Provider training on how to adapt clinical care to meet the needs of people of all abilities and sizes can improve quality of care. People with disabilities experience disparities in access to quality SRH services. Federal civil rights statutes, such as Section 504 of the Rehabilitation Act, Section 1557 of the Affordable Care Act, and the Americans with Disabilities Act (ADA), require providers to accommodate the needs of people with disabilities. The implementing regulations for Section 504 and Section 1557 further detail the obligations to individuals with disabilities under the statutes for health care programs and activities that receive federal financial assistance.[43] Important considerations include examination tables that are easy for individuals to transfer on and off, availability of interpreters for deaf and hard-of-hearing people, and provider training.[44] The Northwest ADA Center has developed a toolkit that providers can consult to provide accessible care.[45] Educational resources explain various approaches to improving SRH care for people with disabilities.[46]

Sex- and body-positive. Care should be affirming and supportive of all bodies and sexual activity that is safe and consensual. Wanted, noncoercive, pleasurable sexual activity has many physical, emotional, and social benefits.[47] Providing sex-positive SRH care is important to helping people achieve their highest level of sexual health.[48] Providers should promote open dialogue about sexual functioning and pleasure by using nonjudgmental, open-ended language.[39]

Trauma-informed. Providers should recognize the high prevalence of trauma, including sexual violence, and its many documented effects on SRH and health in general.[49] As service sites work toward becoming trauma-informed, there are many resources available, including universal trauma precautions or trauma-informed screening protocols. Trauma screening is an approach that refers to a brief, focused tool used to determine whether an individual has experienced or had reactions to traumatic events. Patients should be reassured that they are in control of any details they share.[8]

Providers should practice universal trauma precautions and trauma-informed care with all patients (Exhibit 5).[50,51] This kind of care involves a strengths-based approach emphasizing autonomy, safety, trust, and empowerment. The goal of universal trauma precautions is not disclosure but rather to acknowledge the presence and impact of trauma. It assumes that all patients have been exposed to negative conditions or traumatic events.

The Substance Abuse and Mental Health Services Administration (SAMHSA) established a framework to support implementation of trauma-informed approaches grounded in a set of four assumptions:[52]

Exhibit 5. Key Considerations and Actions to Implement Trauma-Informed Care

Before Exam	During Exam	After Exam
• Consider the physical environment • Offer a support person • Establish rapport • Discuss goals and involve patients in the treatment process • Ask how you can support the patient throughout visit • Discuss the exam process • Repeatedly assure patients that they are in control • Observe for signs of distress	• Explain the steps of the exam • Describe what you are going to do, and why • Ask questions to gain permission at every step of the examination or procedure • Allow the patient to be in control • Practice preventive strategies to avoid retraumatization • Watch for discomfort or distress • Stop exam immediately if the patient is distressed	• Allow the patient to get dressed prior to finishing the visit • Discuss and summarize the visit • Make an action plan with the patient for follow-up • Share the timeline for any follow-up needs • Share contact information for further discussion • Provide referrals and resources • Confirm documentation preferences

Source: Clinical Training Center for Sexual and Reproductive Health (CTC-SRH).

(1) realize the widespread effects of trauma; (2) recognize the signs of trauma in patients, families, staff, and others involved with the system; (3) respond by fully integrating knowledge about trauma into policies, procedures, and practices; and (4) resist retraumatization of patients and staff. SAHMSA also recommends adherence to six principles of a trauma-informed approach:[53] (1) safety; (2) trustworthiness and transparency; (3) peer support; (4) collaboration and mutuality; (5) empowerment, voice, and choice; and (6) cultural, historical, and gender issues. To support full implementation of trauma-informed approaches to care, changes should involve both organizational and clinical practices.

The following resources offer further guidance:

- The CTC-SRH clinician guide for trauma-informed care and accompanying video.
- The Trauma-Informed Care Implementation Resource Center resources to guide diverse health care organizations in adopting best practices.
- The National Center for PTSD, U.S. Department of Veterans Affairs provider screening questionnaire and patient tools for post-traumatic stress disorder (PTSD) self-screening.

Approaches to Care

Three approaches to care help providers carry out the principles described above: (1) quality counseling, (2) informed consent, and (3) privacy and confidentiality. Descriptions of each are included below.

Quality counseling. Quality counseling is fundamental to the delivery of person-centered care. Five key principles guide quality counseling:

1. *Establish and maintain rapport with the person.* Rapport is fundamental for establishing trust and open communication and has been shown to affect outcomes, including patient satisfaction.

Several elements build rapport:

- Simple acts such as a warm welcome, a handshake, and "taking the time to connect as human beings"[54]
- Ensuring privacy and confidentiality
- Asking permission to discuss SRH topics as well as inquiring, acknowledging, and centering the person's goals and desires for the visit
- Matching the patient's tone, paraphrasing what the patient has said, and asking if you got it right
- Focus more attention on respectful listening versus talking "at the patient"

2. *Assess the person's preferences, values, and goals; personalize discussions accordingly.* Both open-ended discussion and structured questionnaires can contribute to understanding patient preferences, values, and goals. Assessment should encompass not only the type of care but also the type of information a person might want or need as well as how the person prefers to receive information and make decisions. Meet people where they are. Avoid attempts to redirect their goals. Set aside personal biases that may conflict with patient preferences and work to support the patient's desired outcomes.
3. *Work with the person to interactively establish a plan.* Establishing a plan includes setting goals, using a strengths-based approach in discussing possible difficulties, and developing action plans to deal with these difficulties. Ground all plans in the individual's own goals, interests, and readiness for change.
4. *Provide accurate and understandable information that supports the person's desires.* Provide information that is balanced, nonjudgmental, and supported by scientific research. Educational materials and decision aids should be offered in a variety of formats (written, audio/visual, video, interactive) to enable patients to select the format(s) that work best for them. Visual and tactile aids can help patients integrate new information that is relevant to their decision making.[55–57] Many people have basic or below-basic health literacy; understanding health information improves short- and long-term health outcomes and is essential for shared decision making.[58] The Agency for Healthcare Research and Quality (AHRQ) offers resources for evaluating educational materials to ensure that they are easy to read and understand.[59] Test all educational materials with the intended audiences for clarity and comprehension before wide-scale use, specifically involving individuals who are representative of the populations served.
5. *Confirm understanding.* Most people do not understand or recall all the information they are offered in a clinical encounter.[60] Asking people to repeat back what they heard ("teach-back") can be a helpful way of confirming their understanding and determining what additional information sharing may be needed.[59] For example, *"I've shared a lot of information and I want to be sure I was clear, can you tell me what you understood about [topic]?*"

Shared Decision Making (SDM), which is one approach to quality counseling, is a joint process in which the health care provider and patient work jointly to help the patient make decisions about their care. For all of the components described above, a shared decision-making approach is recommended. In an SDM model, the patient shares their values and preferences, and the provider shares relevant information with the

patient. The provider and patient then work together to determine what clinically appropriate course of action suits the patient's preferences, clinical needs, and goals. Not all patients wish to engage in SDM, and the patient's decision-making preferences should be respected. In the SRH context, SDM has been shown to improve the quality of contraceptive counseling and contraceptive method satisfaction and is recommended in the delivery of a wide range of SRH services, including pelvic examinations and HIV pre-exposure prophylaxis (PrEP).[61–63]

Informed consent. As defined by The Joint Commission, informed consent is "a *process of communication* between a clinician and a patient that results in the patient's authorization or agreement to undergo a specific medical intervention."[64] Informed consent enables individuals to make decisions about their own care and is necessary for their safety. The process of informed consent involves disclosing relevant information, such as the rationale for a recommendation, anticipated benefits, possible risks and complications, and alternatives, including no intervention. This information can be offered both verbally and in writing, using language that the person can understand. Written consent is one way of documenting that the informed consent process has taken place. Institutions may require written consent in some circumstances (for example, initial consent to care and procedures, such as contraceptive device placement), whereas other circumstances only require a verbal agreement. Each facility should develop a policy and procedure for informed consent processes.

To apply a trauma-informed approach to informed consent in SRH care, providers should have an ongoing and transparent dialogue with patients during the clinical visit that honors patient autonomy and decision making. In this approach, providers should ask for permission to discuss sensitive topics (for example, sexual history, substance use) and to provide the recommended physical exam.

There is long-standing legal support for young people to independently consent to SRH care. At the time of publication, no state requires parental consent for STI services, and most states explicitly allow minors to consent to contraceptive services.[65,66] Consult official state resources and databases to better understand specific laws and regulations.

Privacy and confidentiality[d]. Privacy and confidentiality should be guaranteed for all people seeking SRH care to ensure safety and trust. Confidentiality is especially important in the SRH context due to the personal nature of this care and the potential familial, legal, relational, and professional ramifications of breaches of confidentiality. Limitations of confidentiality, including mandated disclosure and reporting requirements, should be discussed with all patients. It is expected that all providers should educate themselves on all relevant federal, state, and local laws and any legal obligations.

Confidentiality matters for all individuals, and special consideration should be given to the needs of adolescents, given that confidentiality can greatly influence their willingness to access and use services.[67] The American Academy of Pediatrics (AAP) offers recommendations on education, office policies and procedures, and communications for upholding adolescent confidentiality as well as resources like those giving suggested language.[68] Recommendations include talking directly with adolescent patients and their families about the protections and limitations of confidentiality, and reserving time for one-on-one conversation between the provider and the adolescent at each visit, beginning as early as age 11. Telehealth appointments may be a strategy to increase access for adolescents. During telehealth visits, providers can take additional steps to enhance safety and confidentiality by, for example, recommending the use of headphones, using online chat functions, and having a plan in place in case safety concerns arise.

Importantly, maintaining privacy and confidentiality does *not* mean that family members and other trusted parties cannot be engaged in SRH care. When possible, patients can request that a person of their choosing be present when they are receiving care, particularly education, informed consent, or invasive exams. This practice can enhance patient comfort, empowerment, and shared decision making. Providers can encourage adolescents to discuss their SRH with trusted adults in their life, including but not limited to their parent(s) or legal guardian(s).

[d]In April 2024, the HHS Office for Civil Rights (OCR) issued a Final Rule, entitled HIPAA Privacy Rule to Support Reproductive Health Care Privacy (89 Fed. Reg. 32976), which strengthens the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule by prohibiting the disclosure of protected health information related to lawful reproductive health care in certain circumstances. The Final Rule will bolster patient-provider confidentiality and help promote trust and open communication between individuals and their health care providers or health plans, which is essential for high-quality health care. For more information about this Final Rule and other OCR guidance documents related to privacy and reproductive health care, see https://www.hhs.gov/hipaa/for-professionals/special-topics/reproductive-health/index.html.

SECTION 4: DETERMINING AN INDIVIDUAL'S NEED AND DESIRE FOR SERVICES

To determine what services may be appropriate for a patient, a provider can begin by asking about the person's needs and expectations. Additionally, taking an initial open-ended sexual history and screening for specific services can help providers with the following:

- Ensure people get services, including counseling and education, which are clinically appropriate and in line with their personal needs and preferences.
- Inform people about available services (both on-site and by referral) and what might be recommended for them.
- Educate people about how they can care for themselves, including health-promoting behaviors, where and how to seek additional information, and over-the-counter tests and treatments.[69]

Essentials of Screening

Providers should be aware of the risks of screening. When undertaken without a person-centered approach, screening can mistakenly communicate implicit expectations or assumptions about people's reproductive needs or desires. People may feel that they are being "targeted" for STI screening or contraception if the screening process is not explained or normalized. To minimize these risks, the following principles can guide screening:

- Explain why screening is being conducted. It is important to explain that screening is conducted routinely, that it is part of determining what services a person might benefit from, and that the answers to the screening questions are private and will not affect a person's eligibility for care.
- Use a standardized, evidence-based, person-centered tool when possible. Specific tools for screening for reproductive desires and related services are described below and samples are listed in Exhibit 7. Tools can be brief and user-friendly.[70,71] Although screening is most frequently conducted verbally, written or online questionnaires can also be used for screening, either in person or remotely.
- Recognize that disclosure is not always the goal and that patients may choose to omit aspects of their history for a variety of reasons.

Taking a Sexual History

An open-ended sexual history can help a provider assess what resources and services can be offered to the patient

Exhibit 6. 6 Ps of Sexual History

Topic	Sample question(s)
Partners	• Are you currently having sex of any kind—oral, vaginal, or anal—with anyone? (Are you having sex?) • If no, have you ever had sex of any kind with another person? • In recent months, how many sex partners have you had? • Do you or your partner(s) have other sex partners? • Could you tell me about your current sexual partners? OR Tell me about your sex partners—genders, how many partners in the past three months, whatever you think is relevant for me to know.
Practices	• I need to ask some more specific questions about the kinds of sex you have had over the last 12 months to better understand if you have risk factors for STIs. Would that be OK? • We have different tests that are used for the different body parts people use to have sex. What parts of your body are involved when you have sex? - Do you have penis-in-vagina sex? - Anal sex (penis in the anus)? - Oral sex (mouth on penis, vagina, or anus)?
Protection from STIs	• Do you and your partner(s) talk about STI protection? • If you use prevention tools, what methods do you use (for example, condoms or PrEP)? • Have you received vaccines for HPV, hepatitis A, and/or hepatitis B?
Past History of STIs	• Have you ever been tested for STIs? • Have you ever been diagnosed with an STI in the past? When? Did you get treatment? • Have you had any symptoms that keep coming back? • Has your partner or any former partners ever been diagnosed or treated for an STI?
Plus*	• Pleasure: Is the sex you're having pleasurable for you? • Problems: Are you having any difficulties when you have sex?
Pregnancy Preferences	See Exhibit 7 on screening for reproductive desires and related care

Source: The 5 Ps were developed by the CDC. (https://www.cdc.gov/hiv/clinicians/screening/sexual-health.html#5ps-approach; the National Coalition for Sexual Health (NCSH) expands the "6th P" further to include "pleasure, problems, and pride."39

and guide appropriate counseling and information. Even if a person does not currently consider themselves sexually active, it is still important to take a sexual history. Approach and questions can be tailored to each person's identity and understanding.[4,72] Providers can take a few steps to reduce stigma and build rapport at the outset of taking a sexual history:

- Ensure that the patient understands that they can decline answering questions or sharing information; respect their right to decline.
- Avoid any judgment of the patient's behavior or preferences.
- Avoid using terms that make assumptions about sexual behavior or orientation.
- Ensure shared understanding around terminology and pronunciation to avoid confusion.
- Use a sensitive tone that normalizes the topics being discussed.

The 6 Ps, described in Exhibit 6, can be a useful way to remember the main elements of the sexual history. To complete a full sexual history, providers may consider adding questions about sexual satisfaction and sexual (dys)function. Open-ended questions can introduce each of these topics, with more specific questions being used to obtain more information when and if needed. NCSH resources offer examples to guide providers in asking about—and responding to—patients' sexual health needs and desires.[39] Providers should be prepared to answer patients' questions and concerns about sex and make referrals to appropriate care. Patients experiencing sexual concerns or dysfunction can be referred to a qualified sex therapist or a physical therapist. Online resources such as Bedsider.org offer sources of additional information and sex-positive perspectives on sexuality and sexual health for both patients and providers.[41]

Screening for Reproductive Desires and Related Care

A variety of approaches have been tested for screening patients for those SRH services that relate to preventing or preparing for pregnancy—that is, contraceptive care, family building, and preventive health services. There is not sufficient evidence to recommend a particular tool or approach. Given the centrality of these topics in quality SRH care, this section describes a range of evidence- or theory-based and person-centered approaches and how to integrate them into care. In addition to pregnancy-related services, there are a variety of other preventive health services that may be relevant for people, depending on their health needs and goals (for example, STI screening/testing, tobacco cessation, treatment for substance use disorder). Screening tools for other health care services are described more in depth in pertinent sections. People should be made aware of services available on-site and by referral.

There are two main frameworks for approaching screening for reproductive desires and related care: (1) reproductive desires and (2) service based. Exhibit 7 offers sample tools for conducting each screening approach, though more are available.[70] Providers and health care settings may select a tool or suite of tools to use based on where these tools have been tested, the population(s) being served, and health records considerations. It is generally recommended to screen patients at first encounter and then on a regular basis as determined by a schedule that providers or their organizations create based on patient needs, performance indicators, and other factors. It is not recommended to screen at every clinical encounter.

Screening for Reproductive Desires. Multiple studies show that screening for reproductive desires can increase counseling rates and patient satisfaction.[70] Using these screening tools enables providers to offer appropriate services for those patients who are seeking to avoid pregnancy as well as for those who are open to or seeking pregnancy and those interested in other mechanisms to build their families. These tools can be broadly used. In particular, they can open the door for discussing reproductive desires in non-SRH-related encounters or in settings for all people—particularly among those for whom such discussions may be medically relevant (for example, people with chronic medical conditions or those considering a therapeutic treatment that may affect current or future fertility or pregnancy health). They can also be helpful to initiate discussion of family-building interest among LGBTQI+ people and others who may need or desire medical assistance to build their family. Additionally, many people build their families outside of a pregnancy (adoption, fostering, surrogacy).

Screening for reproductive desires is not synonymous with reproductive life planning (RLP), the approach endorsed in the previous QFP recommendations.[73] The RLP framework encourages providers to work with all patients to identify their reproductive goals and construct a life plan based on these goals, including shaping their clinical care. This approach is no longer endorsed, given the body of literature suggesting that many people do not relate to the idea of RLP and that a strict pregnancy planning framework may be discordant with

Exhibit 7. Approaches and Sample Tools for Screening for Reproductive Desires and Related Care

Sample Tools	Tool Content	Considerations
Reproductive desires		
Parenthood/Pregnancy Attitude, Timing, and How important is pregnancy prevention (PATH)[73]	Three questions: 1. Do you think you might like to have (more) children at some point? 2. When do you think that might be? 3. How important is it to you to prevent pregnancy (until then)?	• Can be used for people of any gender • Job aids and other resources available through Envision SRH and RHNTC
One Key Question© (OKQ)[78]	Single question/prompt: Would you like to become pregnant in the next year? You can answer yes, no, unsure, or okay either way	• Copyright and fee based • Not applicable for people who cannot become pregnant and may lead to bias in screening • Most studied of these tools and approaches • Can be programmed into EHR and used in conjunction with electronic clinical quality measures (eCQMs) • Training and resources, including follow-up prompts, available through Power to Decide
Service-based		
Self-Identified Need for Contraception (SINC)[79]	Single question/prompt: We ask everyone about their reproductive health needs. Do you want to talk about contraception or pregnancy prevention during your visit today?	• Should be asked at least once per calendar year • Can be programmed into EHR and used in conjunction with eCQMs • Implementation resources, including follow-up prompts, available through University of California San Francisco Person-Centered Reproductive Health Program
Reproductive Health Services Screening Question[80]	Single question: Can I help you with any reproductive health services today, such as preventing pregnancy or planning a healthy pregnancy?	• Can be used for people of any gender

Source: Tools suggested identified by an environmental scan commissioned by OPA.

many people's lived realities.[74,75] Reproductive desires can be discussed with a person-centered approach that focuses on open-ended communication and nonjudgmental counseling and support.[73]

Service-Based Screening. Concepts such as "pregnancy intention" or "planning pregnancy" do not always resonate with people because they do not accommodate nuanced, fluctuating, and sometimes contradictory thoughts and feelings that people can hold regarding future pregnancy. Sometimes pregnancy ambivalence stems from unstable social and structural circumstances, such as housing, relationship, and employment or income insecurity[74,76,77] that can influence reproductive decision making. Service-based approaches have emerged that involve simply offering a health service such as contraception or the provision of health information about ways to prepare for a potential future pregnancy. Another advantage of service-based screening approaches is that they are more applicable for people who are interested in contraception for reasons other than pregnancy prevention (for example, menstrual regulation).

SECTION 5: PERSON-CENTERED CONTRACEPTIVE CARE DELIVERY

Person-centered contraceptive services are an essential component of SRH care that can increase patients' satisfaction with and participation in that care.[4,55,81,82] Person-centered contraceptive care focuses on providing contraception services in alignment with each individual's values, preferences, needs, and desires. This approach presents a shift from previous models that prioritized efficacy and the use of the most effective methods of contraception among patients.[83,84] Instead,

providers should offer information about and access to a full range of hormonal and nonhormonal contraceptive options, including permanent and reversible methods, either on-site or by referral, but not prioritize one method over the other. This section outlines key steps for offering person-centered contraceptive care regardless of professional role or service delivery setting.

Person-centered care requires providers to put aside their assumptions and opinions about what they believe is best for the patient to identify and center their patients' preferences for contraceptives based on their own goals and values. There is no "best" method of contraception for everyone, nor is the success of care defined by contraceptive uptake and use. People may choose not to use contraceptive methods or opt for less effective pregnancy prevention strategies for various reasons, including concerns about side effects, influences from social media or friends' experiences, shifting or complex needs, religious or personal beliefs, and/or difficulty finding a method that works well for them.[85] Providers should also support people interested in using birth control methods for reasons other than contraception. Noncontraceptive indications for some methods include STI prevention; gender-affirming care; menstrual management or suppression; and treatment of acne, premenstrual dysphoric disorder (PMDD), heavy or painful periods, polycystic ovary syndrome (PCOS), and endometriosis.

Steps for Contraceptive Care Delivery

Key steps in providing contraceptive services are outlined in Exhibit 8.

Step 1: Establish and maintain rapport with the patient. Establishing rapport with patients is a cornerstone of patient-centered care.[86,87] Opportunities for rapport begin with the first point of contact and continue through every interaction with the health care system. In addition to the rapport-building steps described in Section 3, these steps can be taken specifically in contraceptive counseling:

- Respectfully elicit and respond to patients' concerns about contraceptive methods. Demonstrate empathy when a patient appears distressed and validate concerns, especially about risks and side effects.
- Cultivate an awareness of the ways personal biases may influence information shared, language used, counseling practices, and recommendations.[88–90]
- Focus on patient preferences to guide counseling, with the recognition that contraceptive use is not compulsory and highly preference sensitive. Therefore, providers should not form opinions about people's contraceptive use and related reproductive behaviors or engage in directive counseling.
- Assure patients that you are there to help them achieve whatever the patient determines is best for them. Proactively communicate that they are not required to choose a method or methods for pregnancy prevention. Remind people that their needs may change, and every person's body is different, so stopping or switching methods is common and can be done any time.

Step 2: Personalize contraceptive discussions by asking about individuals' contraceptive preferences, based on their needs, desires, and prior experiences. Patients are more satisfied with visits where providers ask about and personalize contraceptive discussions to meet their individual needs.[55,61,86] Ask open-ended questions to elicit people's preferences; for instance: *"Can you tell me something (or some things) that are important to you in your contraception?"* and *"What else are you looking for?"* or *"Is there anything else you're hoping to get out of your contraception?"* or *"Is there anything you don't want (or want to avoid) in a method?"* Open-ended questions enable the patient to explore and express what matters to them and enable the provider to tailor relevant information. For patients who may benefit from follow-up prompts, consider questions that help patients think about method characteristics that are important to them. For example, providers can ask patients about previous side effects that were undesired and what side effects a patient wishes to avoid in the future. Providers can also probe about preferences, such as about menstrual changes. After visits in which this type of counseling is practiced, patients report feeling that they received information in alignment with their needs[56,81] and they made an informed decision.[91] This type of communication can also reduce bias and

Exhibit 8. Key Steps in Providing Contraceptive Services

Step 1. Establish and maintain rapport with the patient.
Step 2. Personalize contraceptive discussions by asking about individuals' contraceptive preferences, based on their desires, needs, and prior experiences.
Step 3. Collaboratively determine which contraception (if any) aligns with the patient's preferences.
Step 4. Conduct a physical assessment related to contraceptive use, when indicated.
Step 5. Provide or refer for the contraceptive method, along with instructions about correct and consistent use; help the patient develop a plan for using the selected method and for follow-up; and confirm understanding.

Source: These key steps were adapted from steps outlined in Providing Quality Family Planning: Recommendations of CDC and the U.S. Office of Population Affairs (2014). Updates were made based on recommendations from experts and then approved by the EWG.

Exhibit 9. Illustrative Framework: PHI CARE

Topic	Sample Approach(es)
P—Past Experience	• It is common to switch methods along your "contraceptive journey"; tell me what methods you have used—what have you liked and disliked?
H—Health History	• I'd like to review your medical history together to understand which options you could use safely.
I—Important	• What is important to you about your contraceptive method?
C—Counsel	• [When using a decision aid] I'd like to share this decision aid with you to discuss your contraceptive options and tell you how the preferences you shared with me apply to the different methods. • [For patients who know what they want] Do you want to hear about other potential options, or should we go ahead with the choice you've shared with me?
A—Autonomy	• What do you think of the contraceptive options we discussed? • Is there anything else you would like to talk about? • While you can start a method, you also do not need to choose a method today.
R—Review	• In order to access and use [method(s)], this is what you need to know. . .
E—Experience	• Remember you can always stop or switch methods at any time. Whatever you experience when using the method, I'll respect it. Everybody is different. I am also here to help you manage side effects. Contraception is a journey, and as your life changes, your needs around contraception may change as well. Come back to see me if you would like to adjust your plan. • [When no method is chosen] I am here to support you, and you can always come back to see me.

Source: PHI CARE, a provider tool for operationalizing patient-centered contraceptive counseling.[92]

mistreatment.[88–90] The PHI CARE counseling framework described in Exhibit 9 is an illustrative model providers can use to remember the main elements of person-centered contraceptive conversations.

People also have specific preferences for when and how conversations about contraception should occur. For example, patients who seek specialty care for health conditions may prefer to consult with their specialist before selecting contraceptives. For patients with serious medical conditions for whom pregnancy may confer significantly increased risk, for instance, a provider might say, *"This medical condition" or "This medication carries a risk to a developing pregnancy" or "I don't want to make any assumptions, but given this, would you like to talk about ways to safely prevent pregnancy or plan for a pregnancy?"* Providers should be mindful of the timing and approach when offering contraceptive counseling to patients who are peri- and postpartum, and those who have just had an abortion or miscarriage, as well as patients seeking care for issues unrelated to pregnancy prevention, as patients can perceive mistimed contraceptive counseling as coercive. During non-contraceptive visits, if a provider determines that a conversation about reproductive desires or pregnancy prevention may be useful, it is appropriate to offer care while honoring autonomy.

Step 3: Collaboratively determine which contraceptive method (if any) aligns with the patients' values and preferences. Once a patient has identified what matters to them, providers can discuss the methods that align with those preferences and that are medically safe. It is important to recognize that there are diverse preferences and priorities that can guide a patient's method selection. In some cases, the counseling in Step 2 may reveal that patients' preferences for methods conflict. For instance, patients might want to use a method that will ensure regular monthly bleeding (that is, pill, patch, or ring) but also want a method that they do not need to think about often (that is, shot, implant, or IUD). When this situation occurs, providers can help patients prioritize preferences relative to each other. Exhibit 10 provides some sample language that can be used to describe various features of contraceptive methods with patients. Additionally, providers should consider using visual tools to help map preferences onto available contraceptive methods, available at QFPguide.org.

As part of this discussion, providers should assess for and integrate information about potential contraindications to certain methods, as required. Providers should refer to the U.S. Medical Eligibility Criteria for Contraceptive Use 2024 (U.S. MEC) in Appendix 2 for recommendations on safe use of contraception among patients who have certain medical conditions or who are taking certain medications that may interact with contraception.[93] If a patient has a medical condition for which certain methods might be unsafe for use, offer to discuss the risks and alternative methods that might be safer, based on the U.S. MEC.

Shared decision making, as described in Section 3, can improve patient satisfaction and helps people make

Exhibit 10. Sample Contraceptive Counseling Language

Proactive and candid description of possible side effects	"Some people who use this IUD have heavier or crampier or longer periods than they did before they got the IUD. What would that be like for you?"
Non-contraceptive health benefits	"I can see why you would want to find a method that also can help with your painful periods. These methods here (show on visual decision aid) can all do that."
Discreetness of a method/ privacy	"Since you've said privacy is important to you, and you can't use anything that changes your period, would you like to talk about the IUD (hand them a sample IUD)? This needs no supplies, and you will still get your period."
Effect on future fertility	"Your ability to get pregnant goes back to whatever is normal for you once you stop using the patch."
Control over discontinuation	"You mentioned that you want to use something you can stop any time. Barrier methods like condoms and some of the hormonal methods like the pill, patch, and ring can be stopped any time, and the hormones in those methods leave your body quickly."

Source: Adapted from PHI CARE,[92] a provider tool for operationalizing patient-centered contraceptive counseling: https://picck.org/wp-content/uploads/2022/09/PICCK-PHI-CARE-Infographic.pdf and Contraceptive Technology.

contraceptive decisions consistent with their preferences and medical context.[61] Although the process of soliciting preferences and mapping them to the available methods is collaborative, the decision about which method to use should be made by the patient. When patients indicate they are ready to initiate a method or methods, providers can ask open-ended summary questions such as "Given what we talked about and what is important to you about your method, what do you think would be the best choice for you at this time?"[4] Some patients may explicitly ask for guidance from the provider; in that case, providers can rely on their knowledge of the patient's preferences and medical history to suggest a method that is likely to be a good fit.

Providers should explore resources helpful to engaging in person-centered contraceptive counseling and using decision aids or tools in the digital version of the QFP at www.QFPguide.org.

Step 4: Conduct a physical assessment related to contraceptive use, if indicated. Physical assessments are rarely needed for contraceptive use and can pose unnecessary barriers for patients. Patients initiating a combined hormonal contraceptive (pill, patch, ring) should have a blood pressure check. Patient self-report of blood pressure (that is, normal versus elevated) is acceptable, especially to facilitate telehealth provision of birth control.[94] A cervical inspection and bimanual examination are needed for IUD placement. However, no examinations or tests are needed before initiating any other nonhormonal or progestin-only methods. [94]

Step 5: Provide or refer for the contraceptive method, along with instructions about correct and consistent use; help the patient develop a plan or supports for using the selected method; and confirm patient understanding. Once a patient has selected a method, it should be provided without delay. Providers can refer to the U.S. Selected Practice Recommendations (U.S. SPR) to guide method initiation and management. A broad range of Food and Drug Administration (FDA)-approved or FDA-cleared contraceptive products should be available on-site, with strong referral networks for contraceptive methods or products not available on-site. Patients selecting natural family planning methods should be offered counseling and education on the different natural family planning methods (FDA-cleared app, calendar calculation, basal body temperature charting, cervical mucus monitoring, lactational amenorrhea). If STI screening or other preventive services are indicated, these should be offered that day if feasible. Requiring that the patient accept the offer of screening before prescribing contraception, however, has no medical justification and is coercive.[94]

Providers should offer same-day initiation (or "quick start") of all methods, including implants and IUDs, whenever possible as a patient-centered best practice to increase timeliness of contraceptive care. Prior to placement, providers can be reasonably certain that a person is not pregnant if they have no signs or symptoms of pregnancy, and they meet any one of the following criteria:[94]

- Is ≤7 days after the start of normal menses
- Has not had penis-in-vagina sex since the start of last normal menses
- Has been correctly and consistently using a reliable method of contraception
- Is ≤7 days after spontaneous or induced abortion
- Is within four weeks postpartum
- Is fully or nearly fully breast(chest)feeding (≥85 percent of feeds), amenorrheic, and <6months postpartum

The following tools and algorithms can help providers determine whether there is reasonable certainty that a patient is not pregnant, the appropriateness of quick starting a particular method, and the need for back-up contraception:

- How to Be Reasonably Certain That a Woman is Not Pregnant
- Quick Start Algorithm

A urine pregnancy test can be used alongside these criteria. However, a negative urine pregnancy test alone is insufficient to establish reasonable certainty that a person is not pregnant. Early in pregnancy, a person may have a low level of bHCG present in their urine, and this may result in a false-negative result on a standard urine pregnancy test. High-sensitivity pregnancy tests should be recommended for better accuracy early in pregnancy. Routine urine pregnancy testing is not always required and is often unnecessary.[94]

In situations in which a provider cannot be reasonably certain that a person is not pregnant, the benefits of starting most methods likely exceed risks.[94] Providers can advise patients that, if they desire, they can start the implant, pill, patch, ring, or shot at any time, with follow-up pregnancy testing in two to four weeks. If the patient's preferred method is an IUD, they should be offered a contraceptive method other than an IUD to use until the provider can be reasonably certain that they are not pregnant and can place the Cu-IUD or LNG-IUD. Although the Cu-IUD is not FDA- approved as emergency contraception, it may be considered for such use by a provider based on a determination that it is appropriate for a particular patient.[94]

Emergency contraception (EC) should be offered to all patients as appropriate. For more information on EC, please refer to the section on strategies to increase access to care, where there are detailed instructions about provision of EC pills (ECP).

Working with a patient interactively to establish a plan helps ensure people access and use their preferred method and switch or discontinue their method when desired. This includes discussing issues surrounding access (for example, getting to a pharmacy for refills), use (for example, having condoms and ECPs available when needed), and discontinuation (for example, getting an IUD or implant removed without delay) as well as what to expect and how to manage side effects. Providers should also recognize preferences can change over time and that discontinuation or switching of a method is normal and expected. Providers should also counsel around and ensure same-day removal of contraceptive implants and IUDs when patients request it. Side effects are one of the most common reasons for discontinuation, so addressing them in a person-centered and timely way is critical. If a patient is initiating a new method, providers can share information and support to optimize the patient's correct use of the method in the context of their unique life circumstances. For example, providers can work with patients to develop a personal technique to remember to take a pill every day. Making a plan can also involve anticipating problems, like what to do if a dose of the shot is late or missed.

Strategies to Increase Access to Care

Many factors affect individuals' ability to access contraceptive services. This section explores strategies that providers and systems can take to address the multilevel barriers that people encounter.

Extended contraceptive supply. Providers can prescribe a full year's supply of combined hormonal methods at the time of the visit.[94] This is 13 cycles (for example, pill pack, box of patches, rings) for those using hormone-free intervals, or 16 for those using combined hormonal contraception continuously. Although payers vary in how many cycles they reimburse for at a single fill, prescribing a full-year supply enables the patient to receive the maximum number possible.

Advance provision of emergency contraception pills (ECPs). Providers should offer patients an advance supply of ECPs to ensure that the ECPs will be immediately accessible when needed.[95,96] A review of the evidence showed that advanced provision increases use of ECPs.[96] There was no difference in contraceptive use, pregnancy rates, and incidence of STIs in those who received advanced provision and those that did not.[96] Advance provision of ECPs should be coupled with counseling and education on proper use. Advance provision of ECPs is particularly important for expediting access to ulipristal acetate (UPA), which is more effective than levonorgestrel (LNG) ECP but available by prescription only. Although LNG ECP is available over the counter, some payers will not cover the cost without a prescription, so writing a prescription can reduce cost barriers for patients. When possible, it is preferable to provide pills directly to patients instead of writing a prescription, as patients may experience barriers to ECPs at pharmacies.[95]

When offering advance provision of ECPs, it can be helpful to also offer additional guidance on

contraceptive initiation. People using LNG ECPs can start, continue, or resume any method immediately.[96] People who receive an advance prescription for UPA should be advised that although it is more effective, it may interact with progestin-containing contraceptives, possibly lowering ECP effectiveness. People using UPA should therefore start or resume hormonal contraception no sooner than five days after using UPA.

If a patient wishes to use UPA and is initiating a progestin-containing method that is initiated in the clinical setting (such as DMPA, implant, or LNG IUD), a shared decision-making approach can be used to weigh the risk of reduced UPA effectiveness against the need to return for method initiation.

As described in the U.S. MEC and U.S. SPR, ECPs might be less effective among persons with BMI ≥30 kg/m^2 than among persons with BMI <25 kg/m.^{2} ECPs are classified as U.S. MEC category 2 for persons with BMI ≥30 kg/m2, meaning the benefits outweigh the risks. Regardless of a person's weight or BMI, all methods of EC can be offered, with complete counseling and clear information.[93]

Same-day access to contraception. When patients are asked to return at a later date to receive their selected contraceptive method, this creates a barrier to care and reduces the chance of the patient ultimately accessing their method.[97–99] Logistic and administrative factors can create challenges to providing same-day contraception even when patients are clinically eligible and desiring to start a method. In particular, same-day provision of implants and IUDs can be difficult for some service sites to accommodate due to factors including provider availability, clinic flow, and insurance verification processes. To reduce this barrier, providers and administrators can work to implement clinical practices to facilitate the ability to offer same-day initiation of all contraceptive methods. Partners in Contraceptive Choice and Knowledge (PICCK) provides clinical and administrative resources for implementing same-day contraception. If, for any reason, a provider is unable to provide a patient's method of choice on the same day that they request it, a bridge method should be offered. As part of standard practice, providers should support patients to access methods unavailable through their clinic by facilitating a warm hand-off or referral and offering information about where and how to access methods affordably. Clinics should keep a current list of local experienced providers that provide any services or methods not offered on-site.

Pharmacist-prescribed contraception. Many states permit pharmacists to directly prescribe hormonal contraceptives.[100] This can enable people to access a range of contraceptive options without a separate visit to another provider to obtain a prescription. Providers should be aware of the pharmacist prescribing policies in their state, and, where available, inform patients of what may be available by pharmacist prescription.

Alternative locations. Mobile clinics, co-locating services, or offering services in temporary pop-up locations support access by meeting people where they are most comfortable receiving care. For example, research suggests co-locating contraceptive services with mental health or substance use disorder services can improve access to contraceptive care.[101]

Telehealth. Telehealth encompasses a wide range of services, including videoconferencing, telephone calls, remote patient monitoring, and secure messaging, which can occur in real time or asynchronously.[102,103] Most commonly, telehealth refers to providers using virtual platforms to communicate with and provide care to patients in lieu of—or in addition to—in-person visits. Research has found that telehealth for contraceptive care is acceptable to patients and providers and effective in delivering services, especially for people who wish to avoid a physical exam, reduce wait times, or have privacy concerns.[103] A wide range of contraceptive services can be safely and effectively provided via telehealth, and telehealth can also be used for contraceptive counseling and management of side effects and other follow-up.[104,105] In addition, online platforms offer contraceptives to patients with and without insurance through online consultation, and ship methods directly to patients in unmarked packaging.

Contraceptive services that are *suitable for telehealth* provision include:[106]

- Contraceptive counseling
- Prescription (initiation or continuation) of oral contraceptive pills, transdermal patch, or vaginal ring
- Discussion of EC options and provision of oral ECP
- Prescription (initiation or continuation) and instruction on self-administered subcutaneous depot medroxyprogesterone acetate (DMPA-SC)
- Prescription of barrier and other peri-coital methods (including diaphragm, cervical cap, spermicides, external and internal condoms, and vaginal pH modulator gel)
- Counseling prior to IUD and implant placement, removal, or replacement
- Evaluation and potential management of side effects (such as unexpected bleeding)
- Consultation for permanent contraception

Strategies for Informing and Empowering Patients for Self-Care

Expanding the range of contraceptive services that people can access and use on their own or with reduced reliance on a clinic or provider can help people overcome barriers to accessing contraceptive care. The World Health Organization (WHO) defines self-care broadly as "the ability of individuals, families, and communities to promote health, prevent disease, maintain health and cope with illness and disability with or without the support of a health worker" and includes "drugs, devices, diagnostics and/or digital interventions that can be provided fully or partially outside formal health services and be used with or without a health worker."[107] Self-care interventions include provision of user-administered methods, including contraceptive pills, rings, patch, injection, and barrier methods, as well as strategies to enable patients to access methods without a provider. Options for self-care shift frequently due to innovation, new technologies, and evidence as well as changes in clinical guidance and federal and state policy. Providers should be aware of what is permissible in their state and stay abreast of changes that allow or constrain self-managed care to enable patients to access care in alignment with their personal preferences.

Self-administered subcutaneous depot medroxyprogesterone acetate (DMPA-SC). DMPA-SC self-administration is safe and effective and should be offered when possible along with a full range of contraceptive methods, including provider-administered DMPA.[108,109] Providers can share information—with patients who are interested—about how to administer DMPA-SC, including how to safely dispose of sharps and that administration could be done by the patient or the patient's partner, friends, and family.[105]

Over-the-counter progestin-only pills (OTC POPs). A progestin-only daily oral contraceptive pill is FDA approved and available OTC, online, and in stores. Providers should be prepared to support users of OTC oral contraceptive pills in the successful use and management of this method. Consult ACOG guidance for further information about supporting patients in using OTC oral contraceptives.[110]

Fertility awareness apps. Fertility awareness–based methods (FABM) are among the oldest methods of self-managed contraception. Many mobile applications exist to track people's fertility and help them either achieve or avoid pregnancy as well as gain more familiarity with their own cycle. The FABM app that is FDA cleared and CE marked has an algorithm that uses each person's body temperature to predict their fertile window.

Providers can include a discussion of these tools as part of person-centered contraceptive care. Relevant information about apps includes whether they are effective and evidence based, whether they are intended for pregnancy prevention or pregnancy planning or both, and the value of additional items for purchase advertised on the sites. Patients interested in fertility awareness apps can be encouraged to explore data privacy, sharing, and security standards related to mHealth apps broadly and fertility apps in particular.[109] Evidence suggests that the accuracy of these apps to predict fertile windows and ovulation can vary because of multiple factors, including variation in individual cycles, which fertility indicators the apps track, and completeness of information entered into the apps by the users. Apps use proprietary algorithms, and those that collect a combination of indicators such as basal body temperature and characteristics of cervical mucus in addition to calendar dates of menses may be more accurate.[111]

SECTION 6: STI AND HIV SERVICES

Person-centered prevention, screening, treatment and education about STIs and HIV is an essential part of SRH care. It is important to meet patients "where they are," using the principles outlined in Section 3. This means using non-stigmatizing approaches, engaging patients in decision making, and providing patients with the services that meet their needs and goals.

This section covers STI and HIV behavioral risk assessment; prevention strategies, including prevention counseling, pre-exposure vaccination, and prophylactic measures; and screening for STI and HIV. It briefly discusses strategies for delivering STI and HIV screening/testing results and providing treatment for individuals and their partners but does not include detailed STI diagnostic management and treatment regimens. Providers can find comprehensive information—including guidance on providing treatment for individuals with STI symptoms, exposure, or a positive test—in the CDC's STI Treatment Guidelines.[112] Providers can also download the CDC STI Treatment Guide app for mobile devices. In addition to streamlined STI prevention diagnosis and treatment recommendations, the app provides clinical care guidance, sexual history resources, patient materials, and other features to assist with patient management.

Risk Assessment

Understanding a person's risk for acquiring STIs or HIV can help guide appropriate counseling, testing, and

treatment. A risk assessment should be conducted for each individual person, and providers should not make assumptions about an individual's risk based on demographic factors alone. Risk assessment involves taking a comprehensive medical history, including a sexual history that covers the six Ps (partners, practices, protection, past history of STIs, pregnancy preferences and pleasure). (See guidance on taking a sexual history in Section 3, "Fundamentals of Sexual and Reproductive Health Care Delivery.")

Remaining aware of STI prevalence and trends in the populations and geographic areas they serve can help providers deliver appropriate care. This information can help a provider assess an individual's risk of HIV and STI acquisition when combined with demographic information and behavioral factors. The reported incidence of STIs in each state is available in the CDC's STI Surveillance Report, produced annually.[113] Providers can use the NCHHSTP AtlasPlus tool on the CDC website to search for state- and county-level STI data and generate tables, maps, and charts showing local STI prevalence.[114]

Prevention

Prevention counseling. Providers can engage patients in person-centered counseling to help them identify personal risk factors and strategies they can use to reduce their risk. Providers should tailor their counseling approach to each patient's individual risk factors while also aligning it with their specific needs and desires. Prevention counseling can include information about common STIs and their transmission and training in skills to reduce risk—including training in condom use and communication about safer sex. Providers should offer information about the risk of STI transmission associated with different sexual activities so the individual has the information they need to reduce their individual risk and communicate about safer sex with their partner(s).

Providers should strive to use patient-centered language that is specific and accessible rather than vague or jargony. For example:

Instead of. . .

- "Always use condoms"
- "Have fewer, safer partners"
- "Have safer sex"

Use. . .

- "What could you do that would make condoms more accessible to you (for example, putting condoms on the nightstand beside the bed)?"
- "Tell me about the last time you used a condom. What has worked for you in the past?"
- "What have you been doing to protect yourself?"
- "What conversations have you had with your partner (s) about protecting yourselves from STIs?"
- "What questions might come up for you when considering whether to have sex with someone who is also having sex with other people?"[47]

Wherever possible, condoms (external and internal) should be provided to all patients free of charge at clinical sites to increase access to condoms in the community.

Pre-exposure vaccination. Pre-exposure vaccination is the most effective method of preventing certain diseases caused by viruses that can be transmitted sexually—including hepatitis A virus (HAV), hepatitis B virus (HBV), human papillomavirus (HPV), and Mpox. Providers can discuss vaccination with all patients, give clear recommendations, and either provide vaccination or referral for vaccination in accordance with recommendations from the CDC[118] and medical professional organizations. Section 10, "Screening and Other Preventive Health Care Services," provides an overview of vaccination recommendations based on age and risk factors.

Pre-exposure prophylaxis for HIV. Pre-exposure prophylaxis (PrEP) is recommended for HIV prevention in adults who have had anal or vaginal sex in the last six months and have any of the following risk factors: an HIV-positive sexual partner; a bacterial STI in the past six months; history of inconsistent or no condom use with sexual partner(s); and (for persons who inject drugs) an HIV-positive injecting partner or sharing injection equipment. However, providers should not limit discussion of PrEP to only those deemed at risk of acquiring HIV; rather, information about PrEP can be provided to all sexually active individuals, including those without known risk factors.[115,116] When discussing STIs and strategies to prevent STIs, providers can ask, "*Are you aware of PrEP, there are medications that can prevent HIV? Have you ever used it or considered using it?*" Providers should attempt to assess each patient's risk of acquiring HIV before initiating PrEP. However, because people may not feel comfortable reporting sexual or injection behaviors that put them at risk for HIV, PrEP should be offered to any person who requests it. Providers can refer to the CDC Clinical Practice Guideline on Preexposure Prophylaxis for the Prevention of HIV Infection in the United States for detailed guidance on providing PrEP services.[117]

Post-exposure prophylaxis for HIV and STIs. Nonoccupational post-exposure prophylaxis (nPEP) consists

of a combination of antiretroviral medications administered after a potential exposure to HIV. CDC provides detailed guidance for offering nPEP, including timing, recommended testing, and medication regimens.[119] When considering nPEP, providers and patients can discuss whether the reported exposure presents a substantial risk of transmission (for example, having unprotected sex with, being sexually assaulted by, or sharing needles with someone who is known to be HIV-positive) or if the exposure was to someone with unknown HIV status. Sexually active patients who receive nPEP should be evaluated for PrEP after completing nPEP and testing negative for HIV.

Because of high rates of bacterial STI (syphilis, chlamydia, and gonorrhea) among cisgender men who have sex with men (MSM) and transgender women (TGW), CDC recommends all MSM and TGW who have been diagnosed in the past 12 months with a bacterial STI receive counseling about doxycycline postexposure prophylaxis (doxy PEP).[120] Doxy PEP involves taking doxycycline within 72 hours after having oral, vaginal, or anal sex. CDC recommendations offer detailed information about research, prescribing, and shared decision-making considerations. Although the pharmacokinetics of doxycycline and experience in treating bacterial STIs suggest that doxy PEP should be effective in other populations, clinical data to support doxy PEP in other populations (for example, cisgender women, cisgender heterosexual men, transgender men, and other queer and nonbinary persons assigned female at birth) are limited. As a result, providers can use clinical judgment and shared decision making to inform use of doxy PEP among those not currently included in CDC recommendations.[120–122]

Screening

Providers should offer screening for STIs in accordance with CDC treatment guidelines and USPSTF recommendations for STI and HIV screening that are summarized in Exhibit 11, which is not intended to be comprehensive.[123] Individuals should be engaged in decision making about STI testing and allowed access to the testing they want and the ability to opt out of testing they do not want to receive. Testing for specific STIs should be provided to all individuals upon request, regardless of risk factors. It is important to note, however, that the risk-benefit ratio of some types of screening requires careful consideration (for example, asymptomatic herpes screening).

Providers should clearly communicate all screening recommendations with patients, including the rationale for any recommended tests and the reasons why testing for some STIs may not be indicated. Opt-out screening can be implemented as a strategy to normalize testing, decrease stigma, and increase screening rates. When employing opt-out screening, the provider informs the patient that a test will be performed as routine unless the patient declines. Opt-out strategies are frequently used to support screening in adolescent populations or in geographic locations with a high prevalence of STIs.

Treatment

CDC STI Treatment Guidelines should guide treatment of all STIs.[126] In settings where same-day treatment is available, treatment for persons with STI symptoms and their partners can be offered while awaiting the results of diagnostic tests.[127] When possible, STI treatment should be provided on-site rather than called into a pharmacy to reduce barriers and ensure access to medication. To limit possible complications, pregnant people diagnosed with an STI should be treated immediately in accordance with CDC STI Treatment Guidelines; treatment does not need to be initiated by an obstetrician/gynecologist or other specialist.[127] The presence of an STI is a biological marker of risk for acquiring other STIs.[128] Therefore, people diagnosed with an STI should be offered testing for gonorrhea, chlamydia, HIV, and syphilis unless these tests were already done at the time of initial screening. Individuals with HIV infection should be linked to ongoing HIV care and treatment.[128,129]

Strategies to Increase Access to Care

A major barrier to STI and HIV testing and treatment services is stigma. Individuals may experience fear, shame, and discomfort that prevent them from seeking out STI and HIV services or from disclosing risk factors to providers. Strategies to increase access to STI and HIV care therefore include those that support confidentiality and enable people to exercise more autonomy in the care they receive and how they receive it. Modalities that emphasize and enable self-care are increasingly commonplace in the care of STIs and HIV. Some of these include self-swabbing for specimen collection, at-home testing, and telehealth. Providers may offer these strategies to patients when possible.

Express visits. STI express visits increase access to care by allowing people to receive walk-in STI testing and treatment without a full clinical exam. Research has found that express visits increase clinic capacity, reduce time to treatment, reduce visit time, decrease visit cost, and are associated with high patient satisfaction.[130,131] Express visits rely on a system of triage to quickly assess

Exhibit 11. STI Screening Recommendations for Asymptomatic Individuals

Type of STI	Age	Screening recommendations
Chlamydia and gonorrhea	<25 years	• At least annually for sexually active persons assigned female at birth (AFAB). Extragenital (pharyngeal and rectal) screening can be considered based on reported sexual behaviors and exposure. • All pregnant people. • Routine screening is not recommended for asymptomatic persons assigned male at birth (AMAB) who have sex with persons assigned female at birth (AFAB). However, screening for persons assigned male at birth (AMAB) and younger than age 25 should be offered in high-prevalence clinical settings (such as adolescent clinics, correctional facilities, and STI and sexual health clinics).
	≥25 years*	• At least annually for sexually active persons assigned female at birth (AFAB) who are at increased risk.* Extragenital (pharyngeal and rectal) screening can be considered based on reported symptoms, sexual behaviors, and exposure. • All pregnant people.
	All ages	• At least annually for sexually active persons assigned male at birth (AMAB) who have sex with persons assigned male at birth (AMAB); every 3 to 6 months if at increased risk.** • At least annually for persons with HIV.
Syphilis	All ages	• All pregnant individuals serologically for syphilis at the first prenatal care visit, followed by universal rescreening during the third trimester and again at birth.[124] • Asymptomatic persons assigned female at birth (AFAB) and at increased risk (geography, history of incarceration, and transactional sex work). • Asymptomatic persons assigned male at birth (AMAB) and at increased risk (history of incarceration, transactional sex work, geography, and younger than age 29). • At least annually for sexually active persons assigned male at birth (AMAB) who have sex with persons assigned male at birth (AMAB). • At least annually for sexually active individuals with HIV.
Herpes	All ages	• Evidence does not support routine serologic screening for adolescents and adults.^ • Type-specific HSV serologic testing can be offered for individuals presenting for an STI evaluation based on individual risk. • Type-specific HSV serologic testing can be offered for people with HIV presenting for an STI evaluation.
Trichomonas	All ages	• Screening should be offered for persons assigned female at birth (AFAB) receiving care in high-prevalence settings (for example, STI clinics and correctional facilities). • Screening should be offered for persons assigned female at birth (AFAB) at high risk for infection.****
HIV/AIDS	13–64 years	• At least once for all individuals.
	All ages	• At least annually for persons assigned male at birth (AMAB) who have sex with persons assigned male at birth (AMAB) if the patient and their sex partner(s) have had more than one partner since most recent HIV test. • All individuals who seek evaluation and treatment for STIs. • All pregnant people.
Hepatitis B	All ages	• All individuals at increased risk.***** • All persons assigned male at birth (AMAB) who have sex with persons assigned male at birth (AMAB) should be tested for HBsAg, anti-HBc, and anti-HBs. • Individuals with HIV should be tested for HBsAg, anti-HBc, and anti-HBs.

(*continued on next page*)

Exhibit 11. STI Screening Recommendations for Asymptomatic Individuals (*continued*)

Type of STI	Age	Screening recommendations
Hepatitis C	18–79 years	• All individuals except in areas where the hepatitis C infection (HCV) positivity is <0.1%.
	All ages	• Pregnant people except in settings where the hepatitis C infection (HCV) positivity is <0.1%. • Serologic testing at initial evaluation for persons with HIV. • Annual testing for persons assigned male at birth (AMAB) who have sex with persons assigned male at birth (AMAB) with HIV infection.
Mpox[125]		Recommended for all persons who had known or suspected exposure to someone with Mpox.Recommended for all persons who had a sex partner in the past two weeks who was diagnosed with Mpox.Recommended for gay, bisexual, or other MSM, and transgender and gender-diverse people (including adolescents) who had in the past six months, or anticipate having: - A new diagnosis of one or more STI - More than one sex partner People who had in the past six months, or anticipate having: - Sex at a commercial sex venue - Sex in association with a large public event in an area where Mpox transmission is occurring - Sex in exchange for money or other items People who are sexual partners of people with the above risks, People with HIV infection or other cause of immunosuppression who have recent or who anticipate potential Mpox exposure. • People who work in settings where they may be exposed to Mpox.

^ https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/genital-herpes-serologic-screening.
*Per USPSTF, women age 25 years or older are at increased risk for chlamydial and gonococcal infections if they have a new partner, more than one sex partner, a sex partner with concurrent partners, or a sex partner who has an STI; practice inconsistent condom use when not in a mutually monogamous relationship; have a previous or coexisting STI; have a history of exchanging sex for money or drugs; or have a history of incarceration.
**Adapted from CDC Guidelines. Per the CDC, men who have sex with men are at increased risk for chlamydial and gonococcal infections if they are on PrEP, with HIV infection, or if they or their sex partners have multiple partners.
***Per USPSTF, risk of syphilis infection is increased among men who have sex with men; persons with HIV infection or other sexually transmitted infections; persons who use drugs; and persons with a history of incarceration, sex work, or military service. Clinicians should be aware of the prevalence of syphilis infections in their community and assess each person's individual risk.
****Per the CDC, individuals at risk for trichomonas include women with multiple sex partners and those with a history of transactional sex, drug misuse, STI, or incarceration.
*****Per USPSTF, individuals at increased risk for hepatitis B include individuals born in countries or regions with an HBsAg prevalence of 2 percent or greater (regardless of vaccination history in their country of origin) and adolescents and adults born in the United States who did not receive the HBV vaccine as infants and whose parents were born in regions with an HBsAg prevalence of 8 percent or greater (regardless of their biological mother's HBsAg status); persons who have injected drugs in the past or are injecting drugs currently; men who have sex with men; persons with HIV; and sex partners, needle-sharing contacts, and household contacts of persons known to be HBsAg positive.
Sources: https://www.cdc.gov/std/treatment-guidelines/screening-recommendations.htm
https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/chlamydia-and-gonorrhea-screening
https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/syphilis-infection-nonpregnant-adults-adolescents-screening
https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/hepatitis-b-virus-infection-screening.

which patients are eligible for express services; they can be implemented alongside comprehensive services. Clinical settings interested in starting or scaling up STI express visits can find adaptable resources in a toolkit developed by the National Association of County and City Health Officials in collaboration with the CDC.[131]

Self-testing. Self-testing is another option that can benefit individuals who do not want to or are not able to come into a facility for testing and may help reach people who would not otherwise get tested. An FDA-approved home tests for HIV and syphilis allow people to test and find out their result in a location of their choosing. Other STI test kits produced by various private and public entities enable people to collect their own specimens, which they then mail in for testing. Providers should support all people who want to access testing through self-tests. Clinic protocols and workflows should be adapted to facilitate timely access to follow-up care and treatment for persons selecting self-testing.

Performing self-swab for specimen. Many people who receive in-clinic testing prefer to collect their own specimens for STI testing. Specimens obtained through self-swabbing have the same sensitivity as clinician-obtained samples. Providers can offer people the option to

perform their own swabs with FDA-authorized self-collection kits during in-clinic testing as part of a trauma-informed and person-centered approach. Visual aids—which can be posted in restrooms or other areas where self-swabbing occurs—can help explain how to effectively collect a specimen. Diagrams in English and Spanish show how to self-collect vaginal, anal, and oral swabs.[132]

Partner services, including expedited partner therapy. Patients should also be counseled about the need to communicate with, evaluate, and treat partner(s) to avoid reinfection. Clinical staff can offer to assist those notifying partners of STI exposure through coaching on partner notification, providing written information to share with partners, or reaching out to partners directly with the person's consent and authorization. In some cases, state health departments may provide partner notification for some STIs as part of a broader range of public health services; if this is the case, patients can be informed of these services and that their partners may be notified of their exposure. People may also use online anonymous partner notification services, though the effectiveness of these services is unknown.

It is important to encourage all partners to seek timely evaluation and treatment. If a person did not receive same-day testing and treatment, providers can encourage them to bring their partner(s) with them when returning for treatment and treat everyone concurrently. Expedited partner therapy (EPT)—which involves treating the sex partners of persons diagnosed with chlamydia or gonorrhea by providing prescriptions or medications to the person to give to their partner(s) without the health care provider first examining the partner(s)—is a strategy to increase access to treatment for individuals who might not otherwise receive timely treatment.[133] EPT is legal in most states.[134] Providers should routinely offer EPT to people with chlamydia as a way to support patients to ensure all their partners will be able to receive timely treatment regardless of the partner's ability to seek and obtain treatment on their own. For partners exposed to gonorrhea, every effort should be made to provide treatment using the recommended intramuscular treatment regimen; however, if an exposed partner is unable or unlikely to access intramuscular treatment, EPT can be provided using the oral treatment regimen recommended by the CDC.[135]

SECTION 7: FAMILY BUILDING

People build their families in various ways, including through pregnancy, adoption, fostering, and surrogacy. The provider's role is to offer personalized, non-biased, nonjudgmental, medically appropriate care to meet the needs and desires of individual patients. For persons who wish to carry a pregnancy and give birth, providers can help enable healthy pregnancy by providing pre-pregnancy care and offering basic fertility services as needed. For persons in need of infertility services and for people with sperm, providers can help safeguard their health and optimize fertility. Depending on the scope of practice and clinical setting, providers may offer or refer patients to medically assisted reproduction services—including comprehensive infertility evaluations, medications to increase fertility, therapeutic donor insemination (TDI), and intrauterine insemination (IUI). Providers should understand the importance of timely referrals for patients requiring more specialized care, such as donor gametes or embryos, in vitro fertilization (IVF), or gestational surrogacy. Providers should also offer resources for adoption services for patients who want to explore building their family through adoption.

It is important to recognize that family building can present social, economic, and systems-level challenges. The services that enable many LGBTQI+ people, unpartnered people, and people experiencing infertility to achieve their reproductive goals and build families are often expensive, not covered by insurance, and inaccessible, especially to people from groups that are marginalized and in many geographic regions of the country. In addition, people from these groups may face stigma or discrimination in the process of family building. Some people also may wish to focus on building families at an early stage in their life, including but not limited to people with progressively debilitating disorders or heritable conditions that may result in early cessation of fertility. Providers can affirm an individual's family-building plans or goals, including whether, how, or with whom a person desires to build their family.

Enabling Healthy Pregnancy

Pregnancy is one way that people build families. Enabling healthy pregnancy by providing pre-pregnancy care is an essential component of quality SRH services. Providers should collect a thorough history and offer basic services and education about how to achieve a healthy pregnancy for all people who wish to become pregnant and those who would find pregnancy acceptable, including people who may become pregnant through penis-in-vagina sex and people who may use medically assisted reproduction. Information about healthy pregnancy can also be offered to those who are not immediately interested in pregnancy or would find pregnancy unacceptable at the present time. For those

with partners, evaluation of all partners occurs concurrently, if appropriate.

The history collected should focus on the patient's expressed reproductive goals and include only what is relevant to their circumstances. Elements of a comprehensive sexual and reproductive history in support of achieving pregnancy include:

- Medical history, including current health issues; review of systems, past illnesses, and surgeries, with special attention to endocrine (thyroid, hirsutism) and autoimmune disorders; and any illness, injuries, or medical conditions that may affect reproductive function.
- Fertility history as appropriate, including length of time patient has engaged in unprotected penis-in-vagina sex, level of fertility awareness, and previous infertility evaluation or treatment.
- Genitourinary and reproductive history, including history of STI or exposure, and sexual history. (See guidance on the 6 Ps in Section 3, "Fundamentals of Sexual and Reproductive Health Care Delivery.") For persons assigned female at birth (AFAB): sexual dysfunction, vaginismus, dyspareunia; menstrual history, including oligomenorrhea, dysmenorrhea, amenorrhea, obstetric/pregnancy history; gynecologic history, including endometriosis, fibroids, pelvic inflammatory disease (PID), abnormal cervical cytology, and procedures. For persons assigned male at birth (AMAB): erectile or ejaculatory dysfunction, trauma, infection, varicocele, and procedures.
- Past surgeries or hospitalizations specifically affecting reproductive organs or systems.
- Family history and genetic carrier screening.
- Current medications and ingested substances, including over-the-counter medications, vitamins or herbs, exogenous steroid hormones, and prescription medications, all to assess for compatibility with pregnancy or risk of infertility.
- Social and lifestyle history: relationship status, family structure, sexual partners, employment and recreational activities (with special attention to impact on reproductive function), nutrition, exercise, sleep, stress, and use of substances such as caffeine, alcohol, tobacco, and recreational drugs.
- Immunization status and titers infections associated with pregnancy complications but that are vaccine-preventable (varicella, measles, rubella).
- Mental health history, including current and past depression, anxiety, bipolar disorder, eating disorders, PTSD, substance use disorder, other psychiatric disorders, or physical, sexual or emotional abuse; screening for current domestic abuse and safety in the patient's home.

Professional organizations such as ACOG and the CDC[136] recommend that counseling to support achieving a healthy pregnancy include:

- Adequate nutritional intake and maintaining regular moderate physical exercise.
- Daily folic acid supplementation to decrease the risk of neural tube defects.
- Persons with chronic medical conditions (such as heart disease or autoimmune disorders) should discuss their desires for pregnancy with their providers to maximize control of the medical condition and avoid potentially teratogenic medications or those associated with pregnancy or fertility complications.
- Persons with diabetes aim for glucose levels as close to normal as is safely possible—ideally A1C <6.5 percent.
- Recommend that any individual contributing to pregnancy through gestation of pregnancy, egg, or sperm provision avoid alcohol, nicotine and other recreational drugs, and high caffeine intake, which may all negatively impact fertility and pregnancy outcomes.
- Recommending limiting exposures to toxins that may be harmful to a developing fetus, including lead, radiation, and chemical solvents.
- Fertility awareness education, including information about the fertile phase and tools such as ovulation predictor kits and cervical mucus monitoring that can be used to help identify ovulation.

Basic Infertility Services and Fertility Support

In alignment with ASRM guidelines, the pace and extent of the infertility evaluation should consider the patient's preferences, age, duration of infertility, relationship circumstances, medical history, and, in some cases, geographic location and access to higher levels of care.[137] This includes people who experience infertility while attempting to achieve pregnancy through penis-in-vagina sex with sperm involved as well as people who require donor gametes or medical assistance to build their family due to their gender, sexual orientation, and/or partner status. It is important that services are not only inclusive, but specifically oriented toward the needs of LGBTQI+ people when indicated.

Clinics can provide basic evaluation and counseling, share resources, and make referrals for people desiring to build a family through pregnancy—with or without the use of medically assisted reproduction (MAR)—or though foster care or adoption. Sites can also provide education about TDI, IUI, donor ova, donor sperm, donor embryo, and gestational carriers as well as MAR procedures such as IVF.[137] All MAR technology options available to heterosexual cisgender people are also

available to LGBTQI+ persons. Prompt referrals to specialty care should be made for people who want or would benefit from MAR. For patients pursuing TDI, avoid delays to treatment. TDI recipients using cryopreserved sperm have higher success rates with IUI over intracervical insemination and do not benefit from ovarian reserve testing or ovarian stimulation.[138] Age is the most predictive factor for IUI success,[138] although timing of the IUI procedure is also a vital factor.[139]

All persons attempting to achieve pregnancy should be screened for infertility, and sites are encouraged to follow the recommendations outlined in "Enabling Healthy Pregnancy." Evaluation of infertility should be performed for all persons attempting to conceive through penis-in-vagina sex with sperm after 12 months if younger than age 35 years and at 6 months if age 35 years or older. For people older than age 40 years or those with a medical history associated with infertility, consider immediate evaluation or referral for MAR.

For persons AFAB, a physical examination that includes vital signs; thyroid examination to identify any enlargement, nodule, or tenderness; and integumentary examination for signs of androgen excess should be performed. Genital exams, including pelvic exam, are not required for basic infertility evaluation. Assessment of ovulatory function for people AFAB is often best determined by a thorough menstrual history, and in many cases, this is all that is required. Menstrual cycles should be 21–35 days, regular, predictable, and consistent in terms of symptoms and flow. If a patient has a history of oligomenorrhea or amenorrhea, this is sufficient to establish anovulation and warrants further investigation to identify underlying etiology.[137]

For individuals AMAB, the semen analysis is the first and most simple screen for infertility. Abnormal results should be followed up with a physical exam to assess for infection, varicocele, or other causes of impaired sperm production.

Few laboratory tests are needed in the initial infertility evaluation and should be limited to findings of the history and physical exam. The following tests should not be ordered routinely unless specifically indicated: prolactin (galactorrhea), estradiol, follicle-stimulating hormone (FSH), luteinizing hormone (LH), progesterone, endometrial biopsy, thrombophilia testing, karyotype, immunologic testing, advance sperm function testing, and laparoscopy for unexplained fertility.[137]

SECTION 8: PREGNANCY TESTING AND COUNSELING

This section provides guidance on pregnancy testing and person-centered counseling, including options counseling, and clinical guidance on individualized care that is responsive to each person's needs and desires (see Section 3, "Approaches to Care").

Pregnancy testing relies on measurement of human chorionic gonadotropin (hCG) in serum or urine. Urine testing is available as an over-the-counter or "at-home" test or as a point-of-care test and delivers a qualitative result of "positive" or "negative." Unless otherwise specified, the following information refers to point-of-care urine testing.

A positive or negative pregnancy test result may have different significance for different people. Some people will be happy with the results; others may express mixed emotions; and some may be surprised, disappointed, or upset. The provider or clinic staff's role in delivering pregnancy test results is to create an open, inclusive and nonjudgemental environment; validate and normalize multiple, complex and varied fieelings around pregnancy; actively listen and clarify facts; reassure the patient of their support. It is important that staff who are giving the results of positive pregnancy tests are prepared to discuss all pregnancy options with the patient. Confidentiality must be ensured, but if a patient asks to include a partner or other support person in the discussion, this should be honored.

Pregnancy Testing and Results

Individuals present to a health care facility for urine pregnancy testing for many reasons, some of which are listed below:

- Some will have already taken home tests and are seeking confirmation of negative or positive results.
- For others, it may be the first evaluation for pregnancy after a missed menstrual period or with symptoms of early pregnancy, such as breast tenderness or nausea.
- Pre-procedural pregnancy tests may be done before procedures such as IUD placement or uterine or endometrial biopsies to prevent the pregnancy from inadvertent impacts caused by cervical or uterine manipulation.

In general, a history and physical exam are not required for patients who present for pregnancy testing. However, collecting a brief, focused history, including the first day of the last menstrual period (LMP), use of a contraceptive method, date(s) of unprotected penis-in-vagina sex or family-building attempts via MAR, and a brief review of systems, can be useful in the diagnosis and in assessing gestational duration, patient decision making, and clinical management, including the need for further care.

Pregnancy test results should be presented in a neutral tone that is simple and straightforward, for example:

"Your pregnancy test today is negative. *This means that you are not pregnant."* When conveying the test result, allow time for the person to reflect on the result and to ask any questions they may have. Exhibit 12 outlines detailed steps to provide person-centered delivery of pregnancy test results.

All patients should be provided or referred for any additional health care needs, including STI screening; fertility/infertility assessment; prenatal, abortion, or adoption care; and related social services, such as housing or nutritional support. Many of these additional services can be offered to the patient at the facility where the pregnancy test was performed to facilitate continuity of care.

Negative Pregnancy Test

Persons with a negative pregnancy test who do not want to become pregnant can be offered contraceptive services. Person-centered contraceptive counseling should only be provided as desired by the patient. If desired, contraceptive services should be offered at the same visit. Persons with a negative pregnancy test who indicate that they have had penis-in-vagina sex within the last five days should be counseled about and offered EC, if desired. A urine pregnancy test result may be negative in the setting of recent intercourse (for example, pregnancy not yet established) and early pregnancy (for example, hCG levels in urine are not yet detectable). For additional details about contraception and EC, see Section 5, "Person-Centered Contraceptive Care Delivery and Strategies to Increase Access to Care."

Persons with a negative pregnancy test who wish to become pregnant should be offered services to help achieve pregnancy and engaged in a conversation about being prepared for a healthy pregnancy. For details, refer to Section 7, "Enabling a Healthy Pregnancy and Basic Infertility Services and Fertility Support."

Positive Pregnancy Test

If the pregnancy test is positive, the provider should assist the patient in estimating gestational duration (age) so that appropriate care and counseling can be provided. Pregnancy dating can be more difficult if the patient does not know their LMP or if they have irregular cycles. Any hormonal contraceptive use or gender-affirming hormones in the last cycle, including emergency contraception, make the LMP unreliable. If the person is unsure of the timing of their last normal menstrual period, a pelvic examination or pelvic ultrasound (more accurate) can help assess gestational age.

Pregnancy Options Counseling and Referral

Patients should be fully informed about all pregnancy options: parenting, adoption, and abortion.[e] An All Options Model is defined as "creating space and using active listening to explore someone's pregnancy decisions, feelings, and experiences, with curiosity and empathy, and without an agenda."[140,141] The goal of pregnancy options counseling is to equip people with information and resources.

Providers must offer nondirective counseling and be equipped to offer factual, neutral, nonjudgmental information about each option. Providers working in communities that are in states with restrictive abortion laws may consider using third-person language to share information. Options counseling should be provided in accordance with recommendations from professional medical associations, such as AAP.[142]

- For persons desiring to continue the pregnancy, affirm their decision and offer prenatal care and/or referrals. Talk with the person to learn of any other referrals or resources that may be helpful to them.
- For persons interested in pursuing adoption, affirm and offer resources to support this decision, including prenatal care and/or referrals. Providers may share appropriate community and/or national resources and referrals.
- For persons desiring to end the pregnancy, affirm this decision, and offer resource information. Based on gestational age and setting, explain to the patient what options may be available (such as medication abortion or uterine aspiration). When considering providing abortion care on-site or referring for abortion care, providers should be aware of factors affecting abortion access—including proximity of abortion care facilities—and legal restrictions on abortion care, including state-based legal restrictions impacting individuals seeking abortion services.

A person receiving options counseling does not need to declare or come to a decision by the end of the counseling session. It is important to remember that

[e]Federal conscience laws protect health care providers that refuse to participate in certain health care services on religious or moral grounds. These laws include the Church Amendments, codified at 42 U.S.C. § 300a-7; the Coats-Snowe Amendment, contained in 42 U.S.C. § 238n, et seq.; the Weldon Amendment, contained in Consolidated Appropriations Act, 2024, Public Law 118–47, div. H, tit. V, sec. 507(d)(1), 138 Stat. 460, 703 (Mar. 23, 2024); and others. The Department complies with all applicable federal conscience laws. More information about conscience laws is available here: Conscience Protections | HHS.gov. As noted in footnote b, the Title X statute (42 U.S.C. §300 et seq.), legislative mandates included in annual HHS appropriations, and the Title X implementing regulations at 42 CFR Part 59, Subpart A (86 Fed. Reg. 56144) prohibit providers from using Title X funds for abortion and certain related activities. For additional information about Title X restrictions, see OPA guidance at https://opa.hhs.gov/grant-programs/title-x-service-grants/about-title-x-service-grants/program-policy-notices.

patients have the right to receive, request, and refuse referrals and resources or information about all pregnancy options. They also have the right to defer making any decisions about their pregnancy during the visit. If a patient chooses to defer making a decision, discuss a timetable with the patient to help them understand their options at different gestational ages.

SECTION 9: EARLY PREGNANCY MANAGEMENT

This section offers guidance on early pregnancy management, including initial prenatal counseling and care as well as management of miscarriage and abortion. Even providers who do not offer full-scope prenatal care can and should offer basic early pregnancy care, encompassing management of urgent complications (such as early pregnancy loss), screening for medication use and other relevant conditions, and education on folic acid use and other time-sensitive topics. Providers should initiate referrals, ideally with a warm handoff, for any needed services not provided on-site, including prenatal care and planning for birth. High-quality, person-centered care in the earliest phases of pregnancy is crucial for improving maternal and infant health outcomes, and significant disparities in access to this care currently exist.[141]

Prenatal Counseling and Care

For persons considering or planning to continue a pregnancy, provide initial counseling (including offering education on healthy prenatal practices, prescribing folic acid and reviewing urgent warning signs and symptoms). It is expected that all pregnant people should be offered screening for STIs (including gonorrhea, chlamydia, syphilis, and HIV) and counseled about risk reduction strategies and potential risks to newborns. If needed, treatment should be provided in accordance with the most current CDC STI Treatment Guidelines.[128]

Early Pregnancy Loss

Early pregnancy loss during the first trimester is commonly known as miscarriage or spontaneous abortion.[143] Given how common early pregnancy loss is and that many people are unable to establish prenatal care until after the first trimester, providers of SRH care should be able to identify signs and symptoms of early pregnancy loss and be equipped to provide appropriate treatment or referrals. All pregnant persons should receive information about the signs and symptoms of early pregnancy loss and given instructions to report any concerns to a provider for further evaluation.

Providers can confirm early pregnancy loss by reviewing a patient's medical history; identifying the signs and symptoms, including vaginal spotting or bleeding with or without pain, and bleeding and/or passage of tissue from the vagina; and/or by conducting a physical exam that may include a pelvic ultrasound and quantitative β-hCG testing, depending on the resources available on-site.

Pregnancy loss can be managed in several ways: (1) expectantly, (2) with medications, and (3) uterine aspiration. Patient preference is paramount in determining the course of action. Expectant management is essentially "wait and watch" to assess whether the pregnancy resolves itself with no medical interventions. Decision aid tools have been shown to improve knowledge of treatment options and can be helpful to both providers and patients.[144]

Providers should also be prepared to identify and provide treatment or referral in the event of a suspected ectopic pregnancy. An ectopic pregnancy, or pregnancy occurring outside of the uterus, requires immediate medical care. Ectopic pregnancy occurs in about two out of every 100 pregnancies.[145] Providers should be aware of the signs of ectopic pregnancy: (1) abnormal vaginal bleeding, (2) low back pain, (3) mild pain in the abdomen or pelvis, and (4) mild cramping on one side of the pelvis.[146] Ectopic pregnancy can be dangerous if not treated and can cause internal bleeding, infection—and, in some cases, death—to the pregnant person.

Persons experiencing pregnancy loss may benefit from additional social support. The provider can assess the patient's need and desire for social support and refer them to appropriate counseling or supportive services. For additional information about management of early pregnancy loss, please refer to ACOG.[143]

Abortion[f]

Medical termination of intrauterine pregnancy can be managed with medication or through a procedure

[f]As noted in footnote e, federal conscience laws protect health care providers that refuse to participate in certain health care services on religious or moral grounds. These laws include the Church Amendments, codified at 42 U.S.C. § 300a-7; the Coats-Snowe Amendment, contained in 42 U.S.C. § 238n, et seq.; the Weldon Amendment, contained in Consolidated Appropriations Act, 2024, Public Law 118–47, div. H, tit. V, sec. 507(d)(1), 138 Stat. 460, 703 (Mar. 23, 2024); and others. The Department complies with all applicable federal conscience laws. More information about conscience laws is available here: Conscience Protections | HHS.gov. As noted in footnote b, the Title X statute (42 U.S.C. §300 et seq.), legislative mandates included in annual HHS appropriations, and the Title X implementing regulations at 42 CFR Part 59, Subpart A (86 Fed. Reg. 56144) prohibit providers from using Title X funds for abortion and certain related activities. For additional information about Title X restrictions, see OPA guidance at https://opa.hhs.gov/grant-programs/title-x-service-grants/about-title-x-service-grants/program-policy-notices.

Exhibit 12. Practical Tips for Discussing a Pregnancy Test Result

Before delivering the result
Understand that some people may not wish to process or even talk with health care providers about their pregnancy test result, and this is completely acceptable.
Although people will often want partners, loved ones, family members, or others to be part of the subsequent discussion, it is good practice to relay this information to the person alone first, giving them an opportunity to share any sensitive information and inform the clinician about preferences regarding sharing.
Be clear and use a neutral tone.
"Your urine pregnancy test today is positive. That means you are pregnant."
Pause for patient response
"Would you like a few minutes alone, or would you like me to stay here with you?"
Seek understanding, and pay attention to verbal and nonverbal responses.
Ask open-ended questions: "What thoughts or feelings are coming up for you right now?"
Validate and normalize
"It's normal to experience and go through several emotions as you are processing this information."
For positive pregnancy tests, offer to share pregnancy options
"Let me know how I can be most helpful to you. We can discuss any options you are interested in hearing about, including options for continuing or ending your pregnancy, or you can take time to think things over on your own."

Source: Adapted from Reproductive Health Access Project at https://www.reproductiveaccess.org/resource/pregnancy-options-counseling-model/ and Provide at https://providecare.org/practice-guide-all-options-pregnancy-counseling/#1664484177056-1f1809fd-ac61.

involving uterine aspiration.[2] Management with medication typically involves a combination of mifepristone and misoprostol. Mifepristone 200 mg is approved by FDA, in a regimen with misoprostol, for the medical termination of pregnancy through 70 days of gestation. The Mifepristone Risk Evaluation and Mitigation Strategy (REMS) Program sets out requirements that must be followed for the use of mifepristone for medical termination of early intrauterine pregnancy.[147] In some circumstances, uterine aspiration may be appropriate for termination of an intrauterine pregnancy, including for reasons of patient preference or when medically indicated (such as for those patients with contraindications to mifepristone or misoprostol). Persons desiring medication or procedural services for termination of pregnancy should receive referrals to timely care. The provider should assess each person's need and desire for social support and refer them to appropriate counseling or supportive services upon request (Exhibit 12).

Some patients may utilize telehealth services for medical abortion, using FDA-approved mifepristone, dispensed consistent with the Mifepristone REMS Program, which includes dispensing through a certified pharmacy either in person or via mail order. Providers should be prepared to provide post-abortion care, including management of side effects or complications.[148] Post-abortion care includes an assessment of signs and symptoms of ongoing pregnancy and/or incomplete abortion; the need for contraceptive, fertility, or STI services; and, if needed, a focused physical examination to assess any complaints.[148] Providers can refer to WHO guidelines for comprehensive recommendations.

SECTION 10: SCREENING AND OTHER PREVENTIVE HEALTH CARE SERVICES

For many people of reproductive age, a clinic or health center offering SRH services may be their only source of health care; therefore, visits can include provision of or referral to other preventive health services to improve the overall health of individuals and communities. This section provides guidance on the following preventive health services related to SRH: screening for chronic medical conditions (for example, diabetes and hypertension) that can impact fertility and family building; providing immunizations; cancer screening; providing gender-affirming care; and discussing topics such as perimenopause, mental health, use of alcohol and other substances, sexual assault, intimate partner violence, and human trafficking. The Women's Preventive Services Initiative (WPSI) also provides detailed guidance on these topics.[149]

SRH clinics that do not have the capacity to offer primary care services should have strong linkages to community providers to facilitate referrals for needs identified during SRH visits. In addition to the specific recommendations regarding the preventive health services below, it is useful if providers and clinic staff understand how social determinants of health influence health outcomes and how to provide support. At the patient level, providers can look for clinical flags, ask patients about social needs in a compassionate way, and help them access support services.[150] Clinics can use tools to help identify social needs, including:

- The Accountable Health Communities Health-Related Social Needs Screening Tool[151]
- HealthBegins Upstream Risks Screening Tool[152]
- WellRx[153]
- Your Current Life Situation Survey[154]
- Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE)[155]

Clinics should provide culturally sensitive services by using interpreters and patient navigators where possible and ensuring care is accessible to those most in need (for

example, by offering bus fare and child care, extending clinic hours, etc.).[150] When patients do not have access to a primary care provider, SRH providers should aim to offer the following suite of services: counseling about healthy weight, screening for chronic medical conditions, screening for and administration of immunizations, screening for cancer, gender-affirming care, perimenopausal care, screening for mental health, alcohol and other substance abuse, sexual violence and intimate partner violence, and human trafficking. These services should be provided in accordance with federal and professional medical recommendations that recognize the essential role of primary care services for all people and the impact that social factors, including economic stability, social and community context, and health care access, have on health and well-being.

Moving Beyond "Preconception Health"

The 2014 edition of the QFP recommended a suite of primary care services to promote the health of individuals before conception. This document aims to move beyond the notion of primary care solely for the promotion of healthy pregnancy and birth by recommending all individuals, regardless of pregnancy intention, be offered primary care services in accordance with the SRHE framework.

Source: Dehlendorf C, Akers AY, Borrero S, Callegari LS, Cadena D, Gomez AM, Hart J, Jimenez L, Kuppermann M, Levy B, Lu MC, Malin K, Simpson M, Verbiest S, Yeung M, Crear-Perry J. Evolving the Preconception Health Framework: A Call for Reproductive and Sexual Health Equity. *Obstet Gynecol*. 2021 Feb 1;137(2):234–239. 10.1097/AOG.0000000000004255. PMID: 33416289; PMCID: PMC7813442.

Healthy Weight

Preventive health services include patient-centered conversations about healthy behaviors with people (at any weight) and may include discussions about the relationship of weight to one's overall reproductive health and fertility. People with a higher body weight or those in larger bodies may encounter weight stigma and discrimination in health care settings, which can negatively affect health outcomes. Providers can reduce this stigma and improve outcomes by moving away from a focus on weighing patients and counseling about weight loss and toward healthy behaviors for people at any weight. If obtaining an individual's weight is required for continuity of care, ask for the patient's permission to discuss the topic before addressing weight-related issues, and become aware of strategies to guard against weight-related stress some might have in health care settings.

When applicable, patients should be provided the information that body size (both high and low weight) can affect their fertility.

Screening for Chronic Medical Conditions

Hypertension. Providers should screen for hypertension with office blood pressure measurement in accordance with USPSTF recommendations.[156] Ambulatory blood pressure monitoring and home blood pressure monitoring with validated and accurate devices can be used outside of a clinical setting to confirm a diagnosis of hypertension before starting treatment. Annual screening for hypertension in adults at increased risk for hypertension is recommended. Less frequent screening, every three to five years, is appropriate for adults ages 18 to 39 who are not at increased risk for hypertension and with a prior normal blood pressure reading. Providers should inform patients that hypertension in pregnancy can impact pregnancy outcomes, and close monitoring is critical.

Diabetes. Providers should screen adults ages 35 years and older with BMI ≥25 kg/m^2 for prediabetes and Type 2 diabetes in accordance with USPSTF recommendations.[157] Providers should offer or refer individuals with prediabetes and diabetes to effective prevention and treatment interventions. People with Type 1 or Type 2 diabetes should be encouraged to see a provider before trying to get pregnant, because diabetes increases risk of cesarean birth, large-for-gestational age babies, and children developing obesity or Type 2 diabetes in the future. Importantly, blood sugar goals are lower in pregnancy, so education and adjustments to medical management may be required. People with a history of gestational diabetes should be screened for Type 2 diabetes ideally within the first year postpartum, and every three years afterwards, for a minimum of 10 years after pregnancy.[158]

Immunizations

Providers should screen for immunization status and provide vaccinations as indicated in the CDC's immunization schedules.[159] Vaccines related to SRH care include HPV, Mpox, Hepatitis A and Hepatitis B. A full list of immunizations and schedules can be viewed on the CDC website or through the CDC's Vaccine Schedules App for Providers. Additional information and recommendations related to specific vaccines are published and regularly updated by the Advisory Committee on Immunization Practices.[160] Clinics that are unable to offer vaccines should make appropriate referrals to community providers for immunization.

Providers should be aware of state laws that regulate the ability of adolescent patients to consent to

Exhibit 13. Cancer Screening Recommendations by Type of Cancer, for People of Reproductive Age

Type of cancer	Age, years	Screening recommendations	Source
Breast[163]	<40	No screening	USPSTF
	40–74	Mammography biennially	USPSTF
Persons with BRCA mutations or increased risk of breast cancer[164]	25	Persons with BRCA1 or BRCA2 mutations should receive a clinical breast exam every six to 12 months and annual breast imaging starting at age 25.	ACOG
Cervix[165]	<21	No screening	USPSTF
	21–29	Screen every three years with cytology alone.	USPSTF
	>30	Screen with a co-test (cytology and hrHPV testing) every five years, hrHPV testing alone every five years, or cytology every three years.	USPSTF
Anus[166]	>35	Screen adults at higher risk who are age 35 and older, with screening initiated no later than age 45, with digital anal rectal examination (DARE) or anal cytology and/or hrHPV testing with DARE: • People living with HIV • Non-HIV immunosuppressed • Men who have sex with men • Transgender women • History of vulvar high-grade squamous intraepithelial lesion (HSIL) or cancer • Other groups with high incidence	Evidence Review
Oropharynx[167]		Screen annually with dental examination.	USPSTF
Penis and scrotum[166]		Screen individuals with a history of anogenital HSIL or cancer by visually inspecting the penis and scrotum.	Evidence Review
Testicular[168,169]	15–55	Testicular self-exam is not currently recommended by USPSTF. Testicular exam at routine physicals can be a decision between patient and provider. Providers can encourage patients to be familiar with their testicles.	USPSTF

vaccines. Organizations such as Teens for Vaccines[161] and VaxTeen[162] track consent laws for minors by state and offer resources for providers and patients to help adolescents access vaccines. Providers can also refer to state immunization registries/Immunization Information Systems to determine which vaccines patients have received.

Screening for Cancer

Providers should screen individuals for cancer in body parts that are part of sexual and reproductive anatomy. Screening recommendations by type of cancer can be found in Exhibit 13.

Gender-Affirming Care

Providers should support the sexual and reproductive health care needs of all people regardless of their gender identity by providing gender-inclusive and affirming care as well as information on gender-affirming hormone therapy and preventive care. ACOG, SFP, and WPATH make the following recommendations regarding health care for transgender and gender-diverse (TGD) individuals:[170]

- Create inclusive and inviting clinical environments. Providers should take steps to educate themselves and their medical teams about appropriate language and the health care needs of transgender patients.
- Clinics should ensure that gender identity and sex assigned at birth are clearly documented in the medical record as well as the patient's legal name, their chosen name(s), and pronouns.
- Fertility and parenting desires should be discussed early in the process of transition before the initiation of hormone therapy or gender affirmation surgery.
- Gender-affirming hormone therapy has not been studied as contraception. Individuals who do not wish to become pregnant or cause pregnancy in others should be counseled about the possibility of pregnancy if they are having penis-in-vagina sex. All currently available contraceptive methods can be offered for use in TGD patients, including those currently or previously on gender-affirming testosterone therapy, with consideration for commonly accepted medical contraindications in cisgender women.
- Hysterectomy with or without bilateral salpingo-oophorectomy is medically necessary for patients with gender dysphoria who desire this procedure.

- To guide preventive medical care, screening should be based on the organs that a person currently has, regardless of the person's gender identity, sexual orientation, or sexual activity.

In addition, providers can ask TGD patients about perceived levels of social support and social connectedness and refer them to available community support systems. Clinics should have a list of LGBTQI+ groups in the community available to share with patients; a list of national resources is available below:

- Lesbian, Gay, Bisexual, and Transgender (LGBT) National Help Center provides multiple hotlines for peer counseling; online peer chat options; and local resource searches for gay, lesbian, bisexual, transgender, and questioning people.
- PFLAG (Formerly Known as Parents, Families, and Friends of Lesbians and Gays) provides peer-to-peer support through in-person and virtual meetings, online outreach, and a variety of additional resources and programs. Hundreds of local PFLAG chapters are in operation across the country.
- Trans Lifeline provides a hotline—staffed by transgender people, for transgender people—to provide individual support for the needs of members of the community.
- The Trevor Project provides phone, instant messaging, and text services for LGBTQ individuals to communicate with a trained specialist; an online social networking space for youth and their friends and allies in the LGBTQ community; and an online resource center.

Finally, providers should be aware of policies and laws that protect youth and adults who identify as transgender and gender diverse from discrimination and violence.[171]

For sample language providers can use to deliver gender-affirming care, see a job aid created by the Reproductive Health National Training Center.[172]

Perimenopausal Care

Providers should be able to offer basic guidance about what to expect during perimenopause, counsel on lifestyle changes to help mitigate symptoms, and therapeutic options, either directly or by referral. Providers should also advise patients that pregnancy can still occur during perimenopause; patients wishing to avoid pregnancy should be offered contraceptive counseling.[94,173] Laboratory testing, including testing for follicle-stimulating hormone (FSH) levels, is not helpful in diagnosing menopause or determining fertility and should be avoided. The North American Menopause Society (NAMS) offers position statements, questionnaires, and clinical guidance on this topic.[174]

Perimenopause lasts four years on average and is often associated with irregular menses, vaginal dryness, vasomotor instability, sleep disturbances, mood changes, and other symptoms.[175] Symptom management includes lifestyle changes, hormone therapy, and other nontraditional treatment options.[176] A shared decision-making approach to menopause therapy includes discussion of symptoms and a review of treatment options including the risks and benefits, and a discussion of the patient's beliefs, preferences, and goals.

Providers should be able to offer basic guidance about what to expect during perimenopause, counsel on lifestyle changes to help mitigate symptoms, and therapeutic options, either directly or by referral.

- Lifestyle changes include smoking cessation, sleep hygiene, maintaining a lower ambient temperature, and using non-estrogen water- or silicone-based vaginal lubricants.[177]
- Systemic hormone therapy with estrogen, with or without progestin, has been shown to be the most effective treatment for hot flashes and night sweats, as well as protecting against bone loss.[178,179]
- Local estrogen is the most effective treatment for genitourinary symptoms of menopause, including vaginal dryness, pain with sex, and dysuria.[177,179]
- Any patient with a uterus who uses systemic estrogen therapy should also use progestin to reduce the risk of endometrial hyperplasia and cancer.[177,180] Progestin can be administered continuously or intermittently through a variety of delivery systems, including orally or via intrauterine device.[180]
- Consider non-hormonal medical management of vasomotor symptoms with medications like paroxetine and fezolinetant for patients who prefer non-hormonal management or those ineligible for hormone therapy.[178]

Both NAMS and ACOG also offer fact sheets and other information for patients.[166,181]

Mental Health

USPSTF recommends screening for depression and anxiety in all adults from ages 18 to 64 years, including people who are pregnant and postpartum.[182,183] Pregnant persons should be screened for perinatal depression.[184] USPSTF and AAP recommend screening adolescents annually for major depressive disorder and anxiety.[185–189] Though the optimal screening

interval is unknown, repeated screening may be most productive in adolescents with risk factors for anxiety, and opportunistic screening may be appropriate for adolescents with infrequent health care visits. Pregnant persons should be screened for perinatal depression.[184]

Providers should discuss the limits of their confidentiality and be aware of the age of consent for mental health services in their states and reporting requirements for adolescents.

Commonly used screening tools can be found in Exhibit 14.

Exhibit 14. Commonly Used Screening Tools for Mental Health Conditions

Screening Tool Name	Mental Health Condition	Patient Age	
		Adults	Adolescents
Generalized Anxiety Disorder scale-7 (GAD-7)	**Anxiety**	**X**	**X**
Screen for Child Anxiety Related Disorders (SCARED)	**Anxiety**		**X**
Center for Epidemiologic Studies Depression			
Scale (CES-D)	**Depression**	**X**	
Patient Health Questionnaire-2 (PHQ2)	**Depression**	**X**	
Patient Health Questionnaire-9 (PHQ9)	**Depression**	**X**	
Patient Health Questionnaire-9 Modified for Adolescents (PHQ9M)	**Depression**		**X**

Sources: https://adaa.org/sites/default/files/GAD-7_Anxiety-updated_0.pdf, https://www.aacap.org/App_Themes/AACAP/docs/member_resources/toolbox_for_clinical_practice_and_outcomes/symptoms/Scared-Child.pdf, https://www.apa.org/depression-guideline/epidemiologic-studies-scale.pdf, https://cde.nida.nih.gov/sites/nida_cde/files/PatientHealthQuestionnaire-2_v1.0_2014Jul2.pdf, https://www.apa.org/depression-guideline/patient-health-questionnaire.pdf, https://www.aacap.org/App_Themes/AACAP/docs/member_resources/toolbox_for_clinical_practice_and_outcomes/symptoms/GLAD-PC_PHQ-9.pdf

Alcohol and Other Substance Use

Providers should routinely discuss use of alcohol, tobacco, and other substances with patients and provide brief behavioral counseling interventions and referrals to appropriate care.[190,191] The CDC and USPSTF recommend regular screening of adults, including pregnant people, and adolescents for use of tobacco, alcohol, and other substances.[93,191–195]

Exhibit 15 lists commonly used tools to screen for unhealthy use of alcohol and other substances. In addition to selecting an appropriate screening tool, providers should be prepared to support patients with a substance use disorder in a person-centered way, regardless of their desire to seek treatment. A person's alcohol or substance use is not a barrier to receiving the SRH services, including pre-pregnancy care, they desire.

For discussions on the use of other substances, providers should be aware of the shifting nature of the opioid epidemic and the emergence of polysubstance use.[201] Providers can review data published online by the National Survey on Drug Use and Health to understand the extent of substance use in a particular area.[202] Clinical service sites should be aware of community resources for patients who express a desire to connect with substance use treatment programs.

Sexual Violence and Intimate Partner Violence

Providers should be prepared to use a trauma-informed approach to discuss sexual violence and intimate partner violence (IPV) during routine clinical visits.[203,204] ACOG and AAP recommend that universal education about IPV be offered to all patients at least annually.

Universal education is the clinical strategy used to educate all patients on healthy and unhealthy relationships and the health consequences of IPV. This approach differs from screening in that it advocates for all patients to be given information on the health impact of IPV regardless of whether or not they disclose current or past experiences of violence, thus reaching more people who may choose not to disclose. Universal education can be coupled with direct inquiry and an offer for a warm referral and available resources for IPV—as needed and when a patient discloses violence in response to use of CUES (description below) or other screening. Before discussing sexual violence and IPV, providers should understand their state reporting requirements, make a plan to see the patient alone, and disclose the limits of their confidentiality.[205] When a person discloses sexual violence or IPV, the provider should convey empathy, validation, and nonjudgmental care. It is important to connect patients to additional services they may need, including forensic nursing care, housing, legal advocacy, and support groups.

Exhibit 15. Commonly Used Screening Tools for Alcohol and Other Substance Use

Screening tool name	Substance Type		Age		How Tool Is Administered	
	Alcohol	Drugs	Adults	Adole-scents	Self-Led	Clinician-Led
Screening to Brief Intervention (S2BI)	X	X		X	X	X
Brief Screener for Alcohol, Tobacco, and Other Drugs (BSTAD)	X	X		X	X	X
Tobacco, Alcohol, Prescription Medication, and Other Substance Use (TAPS)	X	X	X		X	X
Alcohol Screening and Brief Intervention for Youth: A Practitioner's Guide (NIAAA)	X			X		X
Opioid Risk Tool — OUD (ORT-OUD) Chart		X	X		X	

Sources: https ://nida.nih.gov/s2bi/,[196] https ://nida.nih.gov/bstad/,[197] https ://nida.nih.gov/taps2/,[198] https ://www.niaaa.nih.gov/alcohols-effects-health/professional-education-materials/alcohol-screening-and-brief-intervention-youth-practitioners-guide,[199] https://nida.nih.gov/nidamed-medical-health-professionals/screening-tools-resources/opioid-risk-tool-oud-ort-oud.[200]

Futures Without Violence developed the CUES intervention to improve care for persons experiencing intimate partner violence.[206] This intervention focuses on a team-based approach to addressing IPV, with the following key elements:

- *C:* Confidentiality. Always see the patient alone for at least part of the visit, and disclose your limits of confidentiality before discussing IPV.
- *UE:* Universal Education + Empowerment. Use safety cards to talk with all patients about healthy and unhealthy relationships and the health effects of violence. Always give at least two cards to each patient so they can share with caregivers, loved ones, friends, and family.
- *S:* Support. Disclosure is not the goal, but it will happen. Discuss a person-centered care plan to encourage harm reduction. Make a warm referral to a domestic or sexual violence advocacy organization, and document the disclosure in order to follow up at the next visit.

RHNTC, in partnership with Futures Without Violence, developed a health-care-staff-facing video series illustrating how to apply different components of the CUES intervention in response to IPV.

Human Trafficking

Providers and other clinical staff should be trained to recognize the indicators of human trafficking, often called "red flags;" be prepared to complete an evidence-based human trafficking screening tool; and be equipped to assist victims of trafficking in receiving additional information, support, and referral to care. Signs of human tracking include:

- Scripted or inconsistent history
- Signs of physical or sexual abuse, medical neglect, or torture
- Unwilling or hesitant to answer questions about an injury or illness
- Accompanied by an individual who does not let the patient speak for themselves, refuses to allow for privacy, or insists on interpreting for them
- Evidence of controlling or dominating relationships (excessive concerns about pleasing a family member, romantic partner, or employer)
- Fearful or nervous behavior or avoiding eye contact
- Resistance to assistance
- Hostile behavior
- Unable to provide an address
- Unaware of the location, the current date, or the time
- Person is not being paid or wages are withheld
- Does not have identification or other documents
- Is not in control of own money

The National Human Trafficking Prevention Framework, developed by the HHS Office on Trafficking in Persons, hosts SOAR to Health and Wellness, an online training for health care and social service providers. The SOAR training equips professionals with skills to identify, treat, and respond appropriately to human trafficking.

Assisting victims of human trafficking or someone at risk of trafficking requires thoughtful planning using a trauma-informed approach. This may include working with the patient to complete a safety plan or referring them via a warm handoff to an organization that provides safety planning services.[207] Service sites should ensure they have a comprehensive human trafficking referral directory that includes anti-trafficking organizations and programs that offer emergency, transitional, and long-term services to victims and survivors.

Service sites should post the Federal Human Trafficking Hotline number in visible locations (Exhibit 16).

Exhibit 16. Commonly Used Screening Tools for Human Trafficking

Tool	Demographic	Environment
Commercial Sexual Exploitation-Identification Tool (CSE-IT)	Ages 10+; sex trafficking only	Multiple settings, including child welfare and juvenile justice systems, schools, homeless youth shelters, health care, and mental health settings
Human Trafficking Interview and Assessment Measure (HTIAM-14)	Homeless youth; sex and labor trafficking	Service provider setting
Human Trafficking Screening Tool (HTST/HTST-SF)	Ages 18–24; sex trafficking only	Runaway and homeless youth system settings
Quick Youth Indicators for Trafficking (QYIT)	Homeless youth; sex and labor trafficking	Service provider setting
Short Screen for Child Sex Trafficking	Ages 12–18; sex trafficking only	Health care setting
Vera Institute's Trafficking Victim Identification Tool (TVIT)	Ages 13+; sex and labor trafficking	Not specified

Source: Tools listed from the National Human Trafficking Prevention Framework, developed by the HHS Office on Trafficking in Persons, and endorsed by the EWG.

SECTION 11: USING PERFORMANCE MEASURES TO TRACK AND IMPROVE QUALITY OF CARE

Standardized performance measures within health care settings help to identify opportunities to improve patient care, reduce costs, and increase efficiency of care delivery while also allowing for monitoring of success in satisfying regulatory requirements and supporting public accountability.[208,209] These measures are increasingly emphasized as a means of promoting and ensuring quality in health systems.

This section describes the use of these measures to help identify weaknesses, prioritize opportunities, and identify what works and doesn't work to drive quality improvement (QI) efforts in the context of SRH. Quality improvement draws on a wide range of approaches and methods, most of which share underlying principles and steps to identify the quality issue(s), understand the problem from a range of perspectives, design and plan delivery of an improvement intervention, identify and test solutions, and implement the solution and ensure the intervention becomes standard practice.

Within the context of SRH, performance measures can be embedded in a health care system's QI process to help assess its capacity and effectiveness at meeting an individual's SRH needs and preferences—and to identify, track, and address inequities. Such QI processes should be based on the underlying principles shared above and focus on efforts to improve access and patient-centeredness.[210]

The following terminology is used to define performance measures for SRH services. A performance measure is a valid and reliable measure of a health care structure, process, or outcome that captures a component of quality SRH services consistent with the definition of quality family planning and SRH and aggregated at a provider, facility, plan, state, or regional level.[211]

- *Structure* refers to the context in which care is delivered, including the physical environment, staff, financing, and equipment.
- *Process* refers to the transactions between patients and providers throughout the delivery of health care.
- *Outcomes* refer to the effects of the structure and process of health care on the health status of patients and populations and on the patient experience of care.
- *Validity and Reliabilty:* Validity of a performance measure refers to whether it measures what it was intended to measure. Reliability refers to whether the same results can be produced consistently under the same conditions.

Importantly, performance measures can, in some cases, adversely impact outcomes and patient experience by incentivizing specific behaviors or processes inconsistent with quality care. For example, metrics for frequency of testing for sexually transmitted infections can contribute to patients being tested without their knowledge or consent.[212,213] To protect against these effects, measures that reflect experience of care and people's lived experience are critical. This is particularly important in SRH due to the personal nature of decisions related to reproduction, the historical and contemporary reproductive oppression and coercion in the United States, and the well-documented inequities in care by race and ethnicity.[214,215] To ensure appropriate use, performance measurement and QI processes should emphasize people's experiences and preferences, avoid creating harm by monitoring and protecting against

adverse impacts of performance measures, allow for evaluation of inequities through appropriate data stratification, and disseminate results intentionally to promote implementation of evidence-based practices and help ensure measures are being interpreted and applied in a meaningful way.[215]

Determining Which Performance Measures Are Needed

Sites that offer SRH services should select, measure, and assess at least one intermediate- or outcome-based performance measure on an ongoing basis. Structure- and process-based performance measures can also be used to better determine how to improve quality. For core components of SRH care for which there are no validated performance measures, teams may use quality measures (for example, unvalidated indicators) to support local QI activities, but not public reporting. When evaluating the need, quality, acceptability, and priority of a specific performance measure, clinical service sites can consider three key factors:[216]

- *Importance.* Is the focus of the measure supported by evidence that it is an important component of quality? Is the topic important to measure and report—for example, does it address a priority aspect of health care? Is there an opportunity for improvement?
- *Scientific Acceptability.* What is the level of evidence for the measure (for example, that a change in the measure is likely to represent a true change in health outcomes)? Does the measure produce consistent (reliable) and credible (valid) results about the quality of care?
- *Feasibility.* Are the results meaningful, understandable, and useful information for QI? Can the measure be implemented without undue burden (for example, captured with electronic data or electronic health records)?

Using the list in Exhibit 17, service delivery sites can select at least one intermediate- or outcome-based performance measure. This non-exhaustive list of measures aligns with the QFP recommendations, the Centers for Medicare and Medicaid Services (CMS) core set of Adult and Child Health Care Quality Measures,* and the approved and HRSA-supported WPSI recommendations.+ The measures on the list have been developed by a variety of entities such as the National Committee for Quality Assurance (NCQA), Partnership for Quality Measurement (PQM), Quality Payment Program, and HRSA's National Performance Measures. These measures are used to assess quality in many federal and nonfederal programs. The exhibit highlights measures that are ready to implement and actionable, such as the Person-Centered Contraceptive Counseling (PCCC) measure, and other valid and reliable measures, such as those for STI screening rates and access to appointments. It also includes a range of structure-, process-, and outcome-based measures.

Additional resources for selecting and understanding the best ways to use reporting measures include the following:

- Medicaid Adult Core Set Reporting Resources
- Medicaid Child Core Set Reporting Resources
- PQM Submission Tool and Repository Measure Database
- WPSI aligned performance measures

Implementing Measures and Interpreting the Data

Although the measures each service site uses may vary, all sites should address the following cross-cutting considerations when implementing the measures and interpreting the data.[217]

- *Understand that performance measures cannot address or solve every problem.* They can signal that there is an issue, but teams should be prepared to dedicate additional effort to dig deeper and understand what really needs to be fixed.
- *Be aware of the ways that "improving" performance may inadvertently lead to coercive practices.* In one example, a service site identified measures for increasing sexual risk assessment and chlamydia screening for tracking improvement during a QI project. The team also developed balancing measures to provide a marker of potential unintended consequences of improvement activities or gaps in improvement. These measures included unnecessary screening of patients who were not documented as sexually active, and no screening for sexually active patients. Another possibility is for service sites to use the PCCC measure and contraceptive provision measure in tandem to ensure contraceptive provision is not accompanied by bias, reproductive coercion, and/or an otherwise negative patient experience (Exhibit 18).
- *Whenever possible, stratify by demographics* (for example, race, ethnicity, preferred language, age, sex, sexual orientation and gender identity, disability status, payment used for visit, federal poverty level, and/or other socioeconomic indicators) and *visit characteristics* (for example, visit type, provider). Service sites can monitor differences to determine what service delivery processes, systems, and policies may be

Exhibit 17. Examples of Performance Measures for SRH and Related Services

Sample Measures	Type of Measure	Steward and/or Endorsing Entity
Access measures not specific to SRH care		
Getting timely appointments, care, and information	PRO-PM	Consumer Assessment of Healthcare Providers and Systems (CAHPS); PQM 0005
How well providers communicate with patients	PRO-PM	CAHPS; PQM 0005
Helpful, courteous, and respectful office staff	PRO-PM	CAHPS; PQM 0005
Contraception		
Contraceptive Care — Most & Moderately Effective Methods*±	Intermediate outcome	OPA MME; PQM 2903
Contraceptive Care — Access to LARC*±	Structure	OPA LARC; PQM 2904
Contraceptive Care — Postpartum Access to LARC*±	Structure	OPA Postpartum LARC; PQM 2902
SINC-Based Contraceptive Care — Non-Postpartum	Intermediate Outcome	University of California — San Francisco (UCSF) eCQM; PQM 3699e
SINC-Based Contraceptive Care — Postpartum	Intermediate Outcome	UCSF eCQM; PQM 3699e
Person-Centered Contraceptive Counseling (PCCC) Measure	PRO-PM	UCSF PCCC; PQM 3543
Sexually Transmitted Infections and HIV		
Chlamydia screening and follow up*	Process	NCQA
Chlamydia screening in women*±	Process	NCQA; PCQM 0033
Human Papillomavirus Vaccine for Female Adolescents (HPV)	Process	NCQA
HIV/AIDS: Sexually Transmitted Diseases-Screening for Chlamydia, Gonorrhea, and Syphilis*	Process	HRSA
HIV linkage to care	Process	HRSA
Language		
L1A: Screening for preferred spoken language for health care	Process	George Washington University
L2: Patients receiving language services supported by qualified language services providers	Process	George Washington University
Other Preventive Health Services		
Breast Cancer Screening for average risk women*±	Process	NCQA; PQM 2372
Cervical Cancer Screening*	Process	NCQA; PCQM 0032
Screening for Depression and Follow-Up Plan±	Process	CMS
Wellness Preventive Visit		
Well-Woman Visit*±	Process	HRSA
Adolescent Well-Visit*±	Process	HRSA

* Denotes inclusion in CMS Adult and Child Health Care Quality Measures.
+ Denotes measure is in the approved and HRSA-supported WPSI recommendations.
LARC = long-acting reversible contraceptive.

driving suboptimal performance and inequities, and where opportunities for improvement exist to advance SRHE. In one example, 75 percent of respondents to a service site's PCCC survey selected "excellent" in response to questions that addressed the domains of patient experience of counseling: interpersonal connection, adequate information, and decision support. After disaggregating scores by preferred language, data showed that respondents to surveys in Spanish were less likely to report a top score than respondents who completed surveys in English (60 percent vs. 78 percent).

- *If measurable differences are observed between different groups, service sites should engage with patients, community members, and community advisory boards.* Actionable feedback can be provided on experiences of care, perceived barriers, and interventions and supports that might help alleviate these barriers. In response to the disparate PCCC scores referenced above, the service site shadowed several Spanish-speaking patients throughout their visit to gain insight into how this group experienced care; and, at the end of the visit, they asked each patient what went well and what did not go well. The service site also sought feedback on potential barriers to an optimal patient experience from its community advisory board, which included patients, frontline community health and social service providers, and representatives from community-based organizations.

Exhibit 18. Spotlight on Contraceptive Performance Measures

Before 2016, there were no validated, standardized clinical performance measures for assessing the quality of contraceptive care. Stakeholders developed measures to address this gap, which were endorsed by the National Quality Forum.

- *Contraceptive provision and use measures* help ensure providers meet patients' contraceptive needs by providing them with access to methods to control their fertility as desired, including those, like long-acting reversible contraceptive methods, that have the most barriers to provision.
- *The Person-Centered Contraceptive Counseling (PCCC) measure* helps ensure that people receive contraceptive care focused on their preferences and desires, including being treated respectfully during contraceptive counseling, having the support to make informed choices concerning their contraceptive options, and not experiencing coercive or directive counseling toward choosing a particular method.
- *Use of the two types of measures in combination* is recommended to ensure patient preferences are respected in the context of efforts to increase access to contraception given fears that the provision measures may incentivize providers to inappropriately promote the more effective methods of contraception.

Sources: https://opa.hhs.gov/research-evaluation/title-x-services-research/contraceptive-care-measures; https://pcccmeasure.ucsf.edu.

- *Consider implementation-related and external factors.* Service sites can develop approaches that consider a range of factors, which are impacted by capacity (linked to setting type and funding source), community context, state and local requirements, and political climate. For example, some Title X multidisciplinary teams have come together with the shared goal of increasing chlamydia screening rates. Through learning sessions and action periods over six to 15 months, they learn from subject matter experts, engage with other teams to learn from each other, and apply and test improvements in their own clinical settings.[218] The evidence-based interventions they choose to implement (for example, integrating screening into routine care, adopting opt-out language in scripts and education materials, and utilizing diverse payment options to address cost barriers) will vary based on baseline performance, capacity, patient population, and community needs, but all focus on achieving the same overall goal.[219]

Using Data to Improve Quality

Performance data should be shared widely with clinic staff at all levels and across all disciplines. Dissemination strategies include adding data to existing quality reports or dashboards, reporting out during staff meetings or team huddles, sharing dashboards and tables via email, and posting dashboards and charts in staff areas. Staff at all levels can be offered opportunities to provide feedback about potential drivers of current performance and potential strategies for improvement.[220] Broad dissemination provides an opportunity for service sites to communicate with a larger audience about their vision for high-quality SRH care and foster buy-in for QI efforts.

Service sites can begin to identify opportunities for improving care quality once they have successfully incorporated the performance measures into their data review process. Similarly, as to the process of selecting measures, effective QI strategies are equity focused and person-centered, integrate consideration of historical and ongoing harms, and meaningfully address inequities. When selecting which intervention(s) to prioritize, service sites should solicit meaningful participation from internal partners about feasibility and potential impact. The broader the group of partners, the greater the likelihood of uncovering experiential knowledge that can complement or inform QI activities. Examples of steps that may improve quality of SRH care include developing job aids, providing equity-focused and task-specific training for providers, streamlining health center workflow, conducting more patient and community education, and strengthening relationships with referral sites through formal memoranda of understanding.[221]

Additional SRH-focused quality improvement resources are listed below:

- The New York Department of Health's guide for Engaging Primary Care Providers in Chlamydia Screening Quality Improvement, details the approach and highlights key successes of a quality improvement framework for the delivery of sexual health services by pediatric primary care providers.[222]
- The Texas Department of State Health Services website highlights a range of Ryan White Program clinical quality management resources, including tools and a leadership training toolkit.[223]
- The RHNTC has several resources available to support performance improvement on the contraceptive care measures, including a change package outlining the rationale, improvement strategies, and Title X success stories and a toolkit to support health care organizations in ensuring access to the full range of contraceptive methods for patients.

Moving Forward

Existing performance measures do not allow for assessment of all aspects of quality in comprehensive SRH

services. Additional work is underway to develop new measures at both the population and individual levels, with the overarching goal being to support programs and policies that advance person-centeredness and reproductive autonomy and ensure that SRH services align with the broad experiences, desires, and needs of diverse people. A future, full "suite" of SRH measures could potentially assess (1) a person's desire for services, determining whether they access the care they wanted to receive; (2) service provision and patient satisfaction with services; and (3) patient SRH outcomes, such as pregnancy, fertility, and sexual and reproductive well-being.[216] Many new measure development efforts are focused on cultivating equitable collaborations and engaging communities throughout the measurement and QI processes, which has long been called for by reproductive justice advocates.[224] Looking forward, there will be an ongoing need to continuously assess the degree to which measurement and associated QI efforts are aligned with best practices for equity-focused, patient-centered sexual and reproductive health care.

CONCLUSION

During the past decade, several changes have taken place in the United States that have affected the delivery of SRH care, including family planning services, and the understanding of what constitutes quality. This broader context has been accounted for in designing these recommendations. This update of the QFP expands on previous recommendations on providing person-centered SRH care and expands the definition of quality to include individuals' needs, values, and preferences.

In addition to incorporating new evidence, this update incorporates newer approaches to care, including adopting a health equity lens and recognizing the impact of structural and interpersonal racism, classism, ableism, and bias based on sexual orientation and/or gender identity on health and SRH care. The aim is to enable a broad range of health care providers to help ensure that all people, regardless of individual characteristics can have their SRH needs met. Specific updates include an expanded emphasis on person-centeredness and equity, an explicit gender-inclusive approach, and use of language throughout to recognize that people of all genders may need and access SRH care and center the needs of groups and individuals who experience SRH inequities in shaping the recommendations, rather than considering "special populations" separately. Additionally, the evidence supports a recommendation to discuss reproductive desires with a person-centered approach that focuses on open-ended communication and nonjudgmental counseling and does not endorse a single framework to achieve these discussions. Additional technical content includes (1) guiding principles and details on approaches to care to help providers carry out these guiding principles, (2) new care delivery strategies, like telehealth and over-the-counter (OTC) oral contraception, (3) a broader content on early pregnancy management and resources, (4) and expanded approach to family building, (5) new or expanded preventive health care services related to mental health, healthy weight, perimenopausal care, gender-affirming care, and human trafficking, (6) new STI and HIV prevention strategies, including self-care approaches and post- and pre-exposure prophylaxis (PEP and PrEP).

The new recommendations also include care for a broad range of provider specialties in varied settings both within and beyond the formal health care system, including patient-led and self-care options and intentionally incorporate published scientific evidence and existing guidelines, and include more expansive types of evidence. In sum, these recommendations intend to set the standard of SRH care and can be used by all current and future providers of SRH services in varied settings, including primary care, specialty care (for example, obstetrics/gynecology, neurology, and rheumatology), and community settings (for example, mobile clinics, schools, and pharmacies). These recommendations are specifically intended for all current or potential providers of SRH services, including those funded by the Title X program.

OPA will update the QFP recommendations periodically to reflect new findings in the scientific literature and revisions to the clinical guidelines referenced in this update of the QFP.

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EXHIBIT E

Priorities of Office of the Assistant Secretary for Health

The Office of the Assistant Secretary for Health (OASH) is tasked with improving the health and well-being of Americans by leading on policy, practices, and programs. To this end, OASH is committed to prioritizing gold-standard science and the mission outlined in the *Make America Healthy Again Commission Report* and the *Make Our Children Healthy Again Strategy* to deliver better health outcomes.

In close coordination with other operating divisions and agencies of the U.S. Department of Health and Human Services (HHS), OASH will advance rigorous science to address the nation's most pressing health challenges, including the chronic disease epidemic, the mental health crisis, obesity, nutritional deficiencies, exposure to chemical and environmental toxins, and an overreliance on medical interventions. As a steward of public health programs and taxpayer funding, OASH seeks to restore scientific integrity and transparency to rebuild public trust and advance the public good.

Priorities

Please note that this is not an exhaustive list of all OASH priorities. This document is intended to clarify specific issues that may require additional guidance.

Addressing the chronic disease epidemic:

HHS is leading a science-driven response to the nation's chronic disease epidemic, a priority of the administration, and HHS has received a mandate from the President to identify and address the root causes, especially among children. OASH's health programs and offices play a key role in developing solutions to eliminate chronic disease, including programs that address nutrition, physical activity, and exposure to harmful chemical and environmental toxins. For example, the Office on Women's Health is exploring opportunities to improve outcomes for women with conditions such as endometriosis, polycystic ovary syndrome, and uterine fibroids. OASH is advancing strategies that prioritize prevention, restore scientific integrity, and promote better health outcomes for all Americans. OASH will preference programs, partnerships, grants, cooperative agreements, contracts and other funding mechanisms (together, "OASH programs and funding") that prioritize these objectives.

Ending diversity, equity, and inclusion (DEI) policies and practices across OASH's programs:

The prior administration implemented radical DEI policies across HHS. OASH is committed to restoring merit-based opportunities and, to the extent permitted by law, removing discriminatory or otherwise illegal practices, such as providing benefits and advantages based on race or ethnicity

rather than need, severity of disease, or another legitimate basis. OASH will prioritize relationships that are in compliance with this priority and applicable nondiscrimination law.

OASH has previously invested in ideologically-laden concepts like health equity— mainly focused on identifying and documenting worse health outcomes for minority populations. This has not translated into measurable improved health for minority populations, and in many cases has undermined core American values.

OASH will prioritize efforts that go beyond the use of ideologically laden concepts and focus on solution-oriented approaches. This includes actively testing, advancing, scaling, and implementing innovative evidence-based interventions and treatments that address poor health outcomes, including the root causes of Americans' chronic disease epidemic.

Reducing overmedicalization in health care and increasing focus on optimal health and addressing underlying root causes:

OASH recognizes the pervasive overreliance on pharmaceutical and surgical interventions, which have failed to sufficiently address the chronic disease epidemic. OASH is committed to supporting programs and initiatives that will focus on the underlying causes of disease, including lifestyle modifications and other modalities that are shown to be effective in improving optimal health outcomes. OASH will prioritize OASH programs and funding that further these objectives.

Providing medically accurate and reliable information necessary for informed consent:

OASH will ensure that medically accurate materials or instructions with pharmaceutical or health-related recommendations include information on the full range of health risks, so that individuals, such as parents and guardians of minors, can make fully informed decisions. OASH is reviewing programs and initiatives to ensure that content and materials contain medically accurate information.

Ending support for gender ideology, including sex-rejecting procedures for children, and ensuring evidence-based care:

HHS released a comprehensive review of the evidence and best practices for promoting the health of children and adolescents with gender dysphoria. This review, informed by an evidence-based medicine approach, revealed serious concerns about medical interventions, such as puberty blockers, cross-sex hormones, and surgeries, that attempt to reject a child's sex. HHS also released guidance providing for sex-based definitions rooted in scientific biological reality.In alignment with this HHS review and guidance, it is a priority of OASH to protect children from such interventions and, to the extent permitted by applicable law, including any applicable court orders, OASH will deprioritize programs that engage in these practices. It is also an OASH priority to ensure OASH programs accurately reflect science, including the biological reality that a person's sex, as either male or female, is unchangeable and determined by objective biology. Accordingly, to the extent permitted by applicable law, including any applicable court orders, OASH will prioritize OASH programs and funding that accurately reflect the scientific biological reality of sex.

Enforcing the Hyde Amendment:

The Hyde Amendment protects taxpayer funds administered by HHS from paying for elective abortion. OASH will prioritize OASH programs and funding that respect the dignity of life and do not use taxpayer funding to promote elective abortion, consistent with applicable law.

Ensuring gold standard science, curtailing corporate capture and preventing conflicts of interest:

OASH is committed to promoting and funding programs based on gold standard science and radical transparency. The public must know that unbiased science—evaluated through a transparent process and insulated from conflicts of interest—guides the recommendations of our health agencies, and OASH-funded programs and activities carried out by OASH's partners. OASH will deprioritize those that present conflicts of interest or otherwise compromise their objectivity in carrying out OASH-funded programs.

As part of this commitment, OASH will evaluate its existing programs, federal advisory committees, partnerships, grants, cooperatives agreements, contracts, and other funding mechanisms for any conflicts of interest (whether actual, potential or perceived) and terminate such relationships where OASH determines it appropriate and to the extent permitted by law. Open scientific discussion and inquiry is vital to the advancement of science and sound medicine, and OASH is dedicated to ensuring that scientists and medical professionals who conduct or discuss nuanced risk-benefit analyses that deviate from official guidelines do not experience retaliation in the form of professional repercussions, scrutiny from licensing boards or potential disciplinary action. OASH will prioritize OASH programs and funding that support critical discussion, encourage the development of and reporting to safety systems, and foster an open dialogue.

Ensuring OASH funds benefit eligible individuals and not illegal aliens:

Pursuant to the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA), OASH will review its programs and funding to ensure they are used to benefit eligible individuals and not used to encourage or support illegal immigration. OASH will prioritize programs that further the agency's priority to end illegal immigration.

Ensuring adolescent program materials are age-appropriate:

OASH has an obligation to ensure that its programs are age appropriate for minors and do not promote harmful ideologies, such as gender ideology and discriminatory equity ideology. OASH will focus on programs that do not promote material that depicts, describes, exposes or presents obscene, indecent, or sexually explicit content, including content that encourages, normalizes or promotes sexual activity for minors. OASH will prioritize OASH programs and funding that are in compliance with these priorities and applicable law.

Protecting parental rights to direct the religious upbringing of their children:

OASH is committed to ensuring parental rights in religious education and school choice. To the fullest extent of its authority under the law, OASH programs will defend the constitutional rights of parents to direct the religious upbringing of their children, including parents' right to protect their children from exposure to content that burdens the exercise of their religious beliefs.

OASH will implement the above priorities consistent with applicable laws, regulations, court orders, and any required procedures.

Office of the Assistant Secretary for Health

EXHIBIT F

HHS Priorities | HHS.gov

akaprod-www.hhs.gov/about/priorities/index.html

Assistant Secretary for Public Affairs (ASPA) September 30, 2025

As stewards of taxpayer funds, HHS must deliver real results for the American people. Today, I am announcing that HHS is adopting a unified strategy that aligns our priorities and funding to fulfill that promise. We will prioritize gold-standard science and carry forward the mission set out in the Make America Healthy Again Commission Report [PDF, 4.03 MB], links to an external website, opens in a new tab and the Make Our Children Healthy Again Strategy, links to an external website to achieve better health outcomes for all Americans, especially our kids.

HHS will further empower its Operating and Staff Divisions to make funding decisions that reflect our priorities, advance scientific opportunity, strengthen the workforce, and ensure balance across programs—always consistent with the law and with court orders.

Taxpayer dollars are finite and sacred. They are entrusted to us to prudently invest in America's health and future. By setting clear priorities and aligning our goals, we will show the American people that we honor their trust—and that we will not rest until every dollar advances their health, independence, and dignity.

Robert F. Kennedy, Jr.

Secretary

Address the chronic disease epidemic

Curing the nation's chronic disease epidemic is the principal direction to Make America Healthy Again. HHS will prioritize programs that identify and address potential dietary, behavioral, medical, and environmental drivers of chronic disease, especially those that affect America's children, tribal communities and vulnerable populations.

Empower patients to make informed decisions about health care

Restoring transparency and trust to the public is crucial for patients to make the best decisions about health care for themselves and for their families. HHS will ensure that medically accurate materials or instructions with pharmaceutical or health-related recommendations include information on the full range of health risks, so that individuals, such as parents and guardians of minors, can make fully informed decisions about their health.

Prevent conflicts of interest

The public must know that unbiased science—evaluated through a transparent process and insulated from conflicts of interest—guides the recommendations and programs of our health agencies. HHS will deprioritize partnerships with organizations that present conflicts of interest, politicize science, or otherwise compromise their objectivity or integrity in carrying out HHS-funded programs.

Achieve gold standard science

HHS has a robust plan, opens in a new tab [PDF, 1.58 MB] to implement Gold Standard Science. To the extent permitted by law, HHS programs will prioritize programs and organizations that exhibit strategies to promote the tenets of Gold Standard Science, like

innovative program designs to promote constructive skepticism, replicability studies, and research on how to make every dollar of science funding go further.

Explore alternative testing models

HHS is committed to developing, validating, and scaling the use of human-biology-based new approach methodologies (NAMs) to complement animal models and enhance investigations. HHS will prioritize funding opportunities and infrastructure for non-animal approaches to improve human health.

Further our understanding of autism

HHS will prioritize initiatives to understand the etiology and the treatment and care needs of the broad spectrum of people with autism to improve their health outcomes. To the extent permitted by law, HHS will prioritize programs and partnerships with organizations that move beyond studying genetic risk factors for autism towards prevention.

Toxins

HHS will prioritize protecting children and families from harmful chemical exposures by addressing the impact of toxic substances in food, water, air, and consumer products. Many harmful substances accumulate and persist in people over time, magnifying their risks during vulnerable developmental windows. We will work with federal partners to strengthen oversight of plastics, PFAS, and other high-risk substances, and ensure that guidance and safety standards reflect independent, gold-standard science. Protecting children's health across their lifespan will be the guiding principle of this effort.

HHS will improve transparency in food and product safety reviews, close loopholes that may allow unsafe chemicals into the marketplace, and expand surveillance of chemicals found in blood, breastmilk, and other human tissues to guide stronger protections.

Investigate and care for those with Long COVID

While the COVID-19 pandemic is over, many Americans are still struggling with its aftermath through a range of ongoing symptoms sometimes called Long COVID. HHS will prioritize studying the demography, features, and care of Long COVID patients, as well as funding programs to address Long COVID symptoms, severity, duration or etiology.

Advance the scientific understanding of the aging process

Aging is a leading risk factor for most chronic diseases that affect older Americans. HHS will prioritize research that advances our understanding of the biological mechanisms of aging and develops interventions that target aging processes to improve health span and reduce disease burden.

Use digital tools and artificial intelligence to improve health

Technological breakthroughs in areas like artificial intelligence provide exciting new possibilities for science and medicine. HHS will prioritize programs that research or implement the best uses of digital health tools for prevention of disease and to improve health status and health outcomes.

Data Privacy

Americans own and should have control over their personal data. HHS will assure the privacy and individual stewardship of Americans' data–that held by HHS and that regulated by HHS policies. HHS will maintain federated data architectures and strong access controls, to give the highest levels of protection to individuals' personal information.

Usher in a deflationary era in healthcare costs

Achieving affordable healthcare for all Americans is essential to Make America Healthy Again. The Centers for Medicare & Medicaid Services (CMS) will lead efforts to drive system-wide deflation in healthcare costs through value-based care models that prioritize efficiency, transparency, enhanced competition, and other innovative reforms. These initiatives will simultaneously advance patient health outcomes by emphasizing preventive care, personalized treatments, and access to high-quality services for underserved communities.

Strengthen the health care workforce

The backbone of a strong health care system equipped to Make America Healthy Again is a strong and sustainable health care workforce. HHS will prioritize programs and policies that promote the development of a resilient health care workforce equipped to meet the needs of all American patients, including those in rural, tribal, and underserved areas, while respecting their conscience rights.

Promote patient safety

HHS is committed to making health care delivery safer and more effective for all Americans. HHS will prioritize programs that uncover and implement changes that can benefit large numbers of patients in significant ways or profoundly and substantially benefit smaller patient groups.

Promote work and self-sufficiency

Work is not just a means of income; it instills dignity, responsibility, and opportunity. To the extent permitted by law, HHS will prioritize programs and policies that promote work as the primary pathway to self-sufficiency and economic independence.

Foster marriage and family formation

Strong families are the cornerstone of a healthy society. HHS will support programs that encourage marriage, recognizing its importance in fostering economic and social well-being. To the extent permitted by law, HHS will also prioritize programs that encourage the formation and stability of two-parent families, valuing the unique and critical roles of both mothers and fathers. Further, HHS is committed to pursuing policies that make it possible for American families to own a home and raise their children on a single income, as was possible for generations of Americans before.

End illegal race discrimination

So-called "diversity, equity, and inclusion" (DEI) programs, which are based on ideologies that promote differential treatment of people based on race or ethnicity and rely on poorly defined concepts or on unfalsifiable theories, are fundamentally anti-American.

HHS will not tolerate unlawful discrimination. Our civil rights laws prohibit funding recipients from conducting DEI programs in ways that distribute burdens or benefits on the basis of race.

Rather than supporting DEI programs, HHS will end race-based special preferences in grant making and instead direct resources to programs that advance the health and longevity of all Americans. Specifically, HHS training programs will focus on training future medical providers and scientists to lead American preeminence in health for the 21st century. These programs should be based on merit, follow civil rights law, and not unlawfully discriminate against anyone.

Combat gender ideology and protect children

It is an HHS priority to ensure our programs accurately reflect science, including the biological reality that a person's sex as either male or female is unchangeable and determined by objective biology, as reflected in HHS's guidance promulgating sex-based definitions.

HHS released a comprehensive review, opens in a new tab [PDF] of the evidence and best practices for promoting the health of children and adolescents with gender dysphoria. This review, informed by an evidence-based medicine approach, found medical interventions, such as puberty blockers, cross-sex hormones, and surgeries, that seek to reject a minor's sex are unsupported by the evidence and have an unfavorable risk/benefit profile.

HHS will work to protect children from these practices, and, to the extent allowable by applicable federal law and any relevant court orders, HHS will deprioritize programs that engage in these practices where permissible. HHS funds will also not support the costs of such practices where not required by the law or court order.

End taxpayer subsidies for illegal immigration

Illegal immigration presents significant threats to our nation. HHS programs will not encourage or support illegal immigration. Consistent with the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA) and other applicable law, HHS will ensure its programs benefit Americans first by not supporting unqualified aliens.

Reaffirm parental authority and protect religious liberty and conscience rights

"In God We Trust" is the national motto (36 U.S.C. § 302), faith in God is the cornerstone of the American Republic, and the Founding Fathers enshrined the free exercise of religion in the First Amendment. It is an HHS priority to ensure that all programs respect religious liberty and rights of conscience, including by complying with Federal conscience laws, such as those protecting against forced participation in abortion.

HHS programs will defend the constitutional rights of parents to direct the upbringing of their children by ensuring that the programs it conducts or funds protect children's innocence and respect parents' right to protect their children from exposure to content that burdens the exercise of their religious beliefs.

End crime and disorder on America's streets

HHS is committed to making America's streets and communities safe again and ending the vagrancy, disorderly behavior, and violent attacks that have made our nation's cities unsafe. HHS grants will prioritize evidence-based programs and deprioritize programs that fail to achieve adequate outcomes, including so-called "harm reduction" or "safe consumption" efforts, which only facilitate illegal drug use and its attendant harm. HHS will deprioritize support for "housing first" policies that fail to ensure accountability and fail to promote treatment, recovery, and self-sufficiency.

HHS does not support drug injection sites for illegal drugs, or so-called "safe consumption sites," or the use or distribution of illegal drugs and associated paraphernalia. HHS will ensure that its funds reduce rather than promote homelessness by supporting, to the maximum extent permitted by applicable federal law, comprehensive services for individuals with serious mental illness and substance use disorder, including crisis intervention services.

Enforce the Hyde Amendment

The Hyde Amendment protects taxpayer funds administered by the HHS from being used for elective abortion. HHS will prioritize programs and funding mechanisms that respect the dignity of human life at all stages of development, improve maternal health care, strengthen the family, and do not use taxpayer funding for elective abortion, consistent with the Hyde Amendment.

Improve oversight of foreign funded institutions

All HHS offices should consider whether there is a justification for conducting a program at a foreign site rather than a domestic one. HHS will prioritize the latter over the former when justified and consider whether each project involving foreign collaboration will likely lead to better health for Americans. When such projects are appropriate, HHS will take proactive steps to monitor and oversee the foreign collaborators and collaboration sites to ensure that they comply with the applicable U.S. laws governing the receipt of HHS funds and the programs in which the collaboration occurs.

Ending dangerous gain-of-function research

Dangerous gain-of-function research creates unacceptable risks to public health and national security. HHS will prioritize programs and policies that strengthen independent oversight, enforce strict biosafety and biosecurity standards, and close potential loopholes in both federally and non-federally funded research. NIH has already terminated foreign projects in

countries of concern, suspended remaining covered research pending new policy, and directed all awardees to immediately review and report ongoing work. HHS will ensure taxpayer dollars do not currently support high-risk gain-of-function projects abroad or at home, while also working to establish more robust safeguards and to maintain America's global leadership in biotechnology, biodefense, and health research.

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

State of New York, et al.

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

(see attachment)

DEFENDANTS

U.S. Department of Health and Human Services, et al.

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☉ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

INTELLECTUAL PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit (15 USC 1681 or 1692)
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☉ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

- ☉ 1 Original Proceeding
- ☐ 2 Removed from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from Another District *(specify)*
- ☐ 6 Multidistrict Litigation - Transfer
- ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
5 U.S.C. § 706

Brief description of cause:
violations of federal law and arbitrary and capricious agency action

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:

JURY DEMAND: ☐ Yes ☉ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
August 27, 2026

SIGNATURE OF ATTORNEY OF RECORD
/s/ Virginia A. Williamson

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. Origin. Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service.

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related cases, if any. If there are related cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

Civil Cover Sheet—Plaintiffs—Attorneys

Virginia A. Williamson (D. Md. Bar No. 31472)
Assistant Attorney General
Office of the Attorney General
200 Saint Paul Place, 20th Floor
Baltimore, Maryland 21202
410-576-6584
vwilliamson@oag.maryland.gov

Adam Kirschner (D. Md. Bar No. 31767)
Senior Assistant Attorney General
Office of the Attorney General
200 Saint Paul Place, 20th Floor
Baltimore, Maryland 21202
410-576-6424
akirschner@oag.maryland.gov

James C. Luh (D. Md. Bar No. 31776)
Senior Assistant Attorney General
Office of the Attorney General
200 Saint Paul Place, 20th Floor
Baltimore, Maryland 21202
410-576-6411
jluh@oag.maryland.gov

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Maryland

State of New York, et al.

Plaintiff(s)

v.

U.S. Department of Health and Human Services, et al.

Defendant(s)

Civil Action No. 1:26-cv-03405

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Kelly O. Hayes
U.S. Attorney, District of Maryland
36 S. Charles Street 4th Fl.
Baltimore, MD 21201

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Virginia A. Williamson
Office of the Attorney General
Civil Division, Federal Accountability Unit
200 Saint Paul Pl
Baltimore, MD 21202

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 1:26-cv-03405

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Maryland

State of New York, et al.

Plaintiff(s)

v.

U.S. Department of Health and Human Services, et al.

Defendant(s)

Civil Action No. 1:26-cv-03405

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Todd Blanche
Attorney General
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington DC 20530

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Virginia A. Williamson
Office of the Attorney General
Civil Division, Federal Accountability Unit
200 Saint Paul Pl
Baltimore, MD 21202

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 1:26-cv-03405

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Maryland

State of New York, et al.

Plaintiff(s)

v.

U.S. Department of Health and Human Services, et al.

Defendant(s)

Civil Action No. 1:26-cv-03405

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Virginia A. Williamson
Office of the Attorney General
Civil Division, Federal Accountability Unit
200 Saint Paul Pl
Baltimore, MD 21202

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 1:26-cv-03405

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Maryland

State of New York, et al.

Plaintiff(s)

v.

U.S. Department of Health and Human Services, et al.

Defendant(s)

Civil Action No. 1:26-cv-03405

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Robert F. Kennedy, Jr.
Secretary of Health and Human Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Virginia A. Williamson
Office of the Attorney General
Civil Division, Federal Accountability Unit
200 Saint Paul Pl
Baltimore, MD 21202

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 1:26-cv-03405

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

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❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Maryland

State of New York, et al.

Plaintiff(s)

v.

U.S. Department of Health and Human Services, et al.

Defendant(s)

Civil Action No. 1:26-cv-03405

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* U.S. Department of Health and Human Services
Office of the Secretary, Office of Assistant Secretary for Health
200 Independence Avenue, S.W.
Washington, D.C. 20201

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Virginia A. Williamson
Office of the Attorney General
Civil Division, Federal Accountability Unit
200 Saint Paul Pl
Baltimore, MD 21202

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 1:26-cv-03405

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Maryland

State of New York, et al.

Plaintiff(s)

v.

U.S. Department of Health and Human Services, et al.

Defendant(s)

Civil Action No. 1:26-cv-03405

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Brian Christine
Assistant Secretary for Health
U.S. Department of Health and Human Services
Office of the Secretary, Office of Assistant Secretary for Health
200 Independence Avenue, S.W.
Washington, D.C. 20201

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Virginia A. Williamson
Office of the Attorney General
Civil Division, Federal Accountability Unit
200 Saint Paul Pl
Baltimore, MD 21202

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 1:26-cv-03405

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Maryland

State of New York, et al.

Plaintiff(s)

v.

U.S. Department of Health and Human Services, et al.

Defendant(s)

Civil Action No. 1:26-cv-03405

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* U.S. Department of Health and Human Services
Office of the Secretary, Office of Assistant Secretary for Health
Office of Population Affairs
200 Independence Avenue, S.W.
Washington, D.C. 20201

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Virginia A. Williamson
Office of the Attorney General
Civil Division, Federal Accountability Unit
200 Saint Paul Pl
Baltimore, MD 21202

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 1:26-cv-03405

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Maryland

State of New York, et al.

Plaintiff(s)

v.

U.S. Department of Health and Human Services, et al.

Defendant(s)

Civil Action No. 1:26-cv-03405

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Amy L. Margolis
Deputy Director of the Office of Population Affairs
U.S. Department of Health and Human Services
Office of the Secretary, Office of Assistant Secretary for Health
Office of Population Affairs
200 Independence Avenue, S.W.
Washington, D.C. 20201

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Virginia A. Williamson
Office of the Attorney General
Civil Division, Federal Accountability Unit
200 Saint Paul Pl
Baltimore, MD 21202

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 1:26-cv-03405

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc: