

Department of Health and Human Services

Sexual and Reproductive Health, Education, and Services

This memo outlines key ways in which the Department of Health and Human Services (HHS) can establish and restore the principles of scientific integrity, as well as repair and rebuild its scientific capacity, during the next presidential term. Specific priorities and steps the agency can take to effectively act on these issues in 2021 are identified. This memo is complementary to, though not affiliated with, the broader [Blueprint for Sexual Health, Rights, and Justice](#) recommendations.

For decades, HHS has taken a science-based approach to family planning and reproductive health, but recent changes have reduced the role of evidence and complete information in several of its related activities. Improvements at the Office of Population Affairs (OPA), Food and Drug Administration (FDA), Office for Civil Rights (OCR), National Institutes of Health (NIH), and other agencies within HHS can ensure that future activities related to reproductive health, education, and services are science-driven and evidence-based.

The ability to determine whether, when, and under what circumstances to have children is an essential component of public health, and decades of research demonstrate the safety, efficacy, and benefits of voluntary, patient-centered family planning. However, FDA decisions on sexual and reproductive health products are too often made with apparent deference to political considerations rather than being driven by evidence, and conditions across HHS have grown dire over the past few years.

Many recent HHS appointees have advanced policies that reduce access to family planning education, services, and methods; cut off promising avenues of research for apparently ideological reasons; appear to put political considerations above patient access to care; and apply different standards to abortion medication than other drugs. They have often done so by ignoring and misrepresenting scientific and programmatic evidence. As a result, millions of people have lost access to reproductive health services and the reputation

of HHS has suffered. At the same time, HHS has fallen short on collecting data that would allow researchers to identify and study inequities in health care and develop solutions to improve sexual and reproductive health equity. Through specific policy actions and an agency-wide commitment to evidence, HHS can improve access while re-establishing an expectation that the agency will use, produce, and consider the best available evidence in its grantmaking, research, enforcement, and drug approval activities.

Top Priorities for the HHS Secretary

- **Use evidence to drive HHS-funded programs on sexual and reproductive health education and services.** Changes to sexual and reproductive health programs have ignored evidence and resulted in a loss of services to those who need them. HHS should rescind the domestic gag rule that prevents Title X grantees from providing high-quality, evidence-based family planning care, assess to what extent grantees are providing such care, and use existing enforcement authority to ensure compliance with evidence-based quality standards. It should restore the original evidence-based intent, structure, administration, and implementation of the Teen Pregnancy Prevention (TPP) Program and reactivate and fund the Teen Pregnancy Prevention Evidence Review.
- **Ensure OCR rulemaking and enforcement are based on evidence.** Recent structural changes and rulemaking at OCR were made based on specious rationale and without evidence that the issues they aimed to address warranted the actions taken. HHS should rescind the unwarranted rules and reallocate resources to ensure that enforcement priorities reflect the current definition of discrimination as well as evidence about the form and scope of civil rights problems.

- **Require that evidence rather than political considerations drive drug and device approval and guidance decisions.** Across administrations, FDA has appeared to make decisions on sexual and reproductive health–related drugs based on politics rather than evidence, and it has been too slow to respond to post-market surveillance information. The administration must ensure that the same rigorous, science-based standards and internal review processes applied to other drugs and devices are applied to reproductive health products. This should include taking immediate action to remove non-evidence-based restrictions for prescribing and dispensing the drug mifepristone, used in medication abortions.
- **Use evidence to advance equity.** HHS has committed to advancing health equity, but its data collection and analysis have not supported this goal as well as they should. HHS must ensure that it is collecting data that enable it to identify disparities in access to, and experiences with, reproductive health education and services, including evaluating maternal health data collection and reporting; that it routinely analyzes data to track progress on health equity; and that findings from these analyses reach policymakers who can make changes to advance equity.

Key Appointment Positions

- Assistant Secretary for Health
 - Principal Deputy Assistant Secretary
 - Deputy Assistant Secretary for Population Affairs
- Assistant Secretary for Planning and Evaluation
- Assistant Secretary for the Administration on Children and Families
- Assistant Secretary for Public Affairs
- Director of the Office for Civil Rights
- FDA Commissioner and Deputy Commissioner
- Administrator, Centers for Medicare and Medicaid Services (CMS)
- Director, Indian Health Service (IHS)
- HHS Office of General Counsel, Associate General Counsel for Civil Rights Division
- HHS Inspector General

Day-One Actions

- Announce intention of rulemaking to rescind the Title X gag rule. *(See Priority 1 below for more detail.)*
- Direct FDA to affirmatively suspend the Risk Evaluation and Mitigation Strategy (REMS) in-person dispensing requirement on mifepristone that endangers pregnant people by requiring them to travel during the COVID-19 public health emergency, and drop any pending legal challenges to uphold those restrictions. The suspension should remain in effect until FDA can undertake a comprehensive review. *(Priority 3)*

Actions for the First 30 Days

- Take initial rulemaking actions to rescind the Title X gag rule. *(Priority 1)*
- Issue sub-regulatory guidance to reinforce the expectation that all Title X–funded programs follow Quality Family Planning (QFP) guidelines. *(Priority 1)*
- Take initial steps to reactivate the Teen Pregnancy Prevention Evidence Review. *(Priority 1)*
- Restore the Office of Adolescent Health and appoint a well-qualified Director of Adolescent Health. *(Priority 1)*
- Begin the process of rescinding the refusal-of-care rule. *(Priority 2)*
- Abandon the HHS/Department of Justice (DOJ) appeal of decisions vacating the refusal-of-care rule. *(Priority 2)*
- Dissolve the Conscience and Religious Freedom Division within OCR. *(Priority 2)*
- Direct FDA to conduct a comprehensive review of the REMS imposed on mifepristone to eliminate medically unnecessary barriers to access based on well-established evidence, both clinical and real-world, of mifepristone’s effectiveness and safety. *(Priority 3)*
- Declare the administration’s commitment to reproductive health drug and device approvals based on scientific evidence free from political interference. *(Priority 3)*
- Direct departments to appoint leadership within 60 days to demonstrate the administration’s commitment to addressing disparities in minority health, women’s health, health equity, and LGBTQ+ health. *(Priority 4)*

Actions for the First 100 Days

- Begin to undo the damage of the domestic gag rule by allowing qualified entities that left the program as a result of the rule a way to rejoin it, and ensure the grant application and award process for Title X supports high-quality, science-based services. *(Priority 1)*
- Commission a rigorous review to assess the impact on clients' access to high-quality family planning care (including the full range of contraceptive methods) as a result of recent changes in the Title X regulatory framework, the effects of COVID-19 on service delivery, and the support needed to fully meet the goals of the Title X program going forward. *(Priority 1)*
- Ensure the grant application and award process for the TPP Program supports high-quality, evidence-based projects. *(Priority 1)*
- Assess the extent and status of TPP Program funding that remains unallocated, and direct that funding to evidence-based purposes consistent with the intent of the program. *(Priority 1)*
- If any decisions vacating the refusal-of-care rule are overturned, HHS should rescind the regulation. *(Priority 2)*
- Rescind the regulation narrowing Affordable Care Act (ACA) Section 1557 and engage in rulemaking using a broad definition of discrimination that aligns with the *Bostock* decision. *(Priority 2)*
- Direct divisions that directly address minority health, women's health, LGBTQ+ health, adolescent health, rural health, immigrant health, and health equity to announce plans within one year to enhance data collection and analysis to address health disparities. *(Priority 4)*

Priority 1: Use Evidence to Drive HHS-Funded Programs on Sexual and Reproductive Health Education and Services

Over five decades, the Title X program has funded a network of centers that provided high-quality, evidence-based *family planning care*, primarily to adolescents and clients with low incomes. However, the *Compliance With Statutory Program Integrity Requirements* rule issued in 2019—often called the domestic gag rule—requires providers receiving Title X funds to care for pregnant patients in a manner at odds with evidence-based standards of care, as well as

medical ethics. Among other things, it prohibits providers from making abortion referrals for patients who desire them, and requires referrals for prenatal care regardless of whether patients want to continue their pregnancies.

When HHS proposed this rule, thousands of commenters warned, citing evidence from a similar action in Texas, that it would drive experienced providers out of the program, and that it would be impossible to replace those providers quickly with others who could provide the high-quality family planning care that the program has long required. HHS responded that it believed new providers who could meet clients' needs would enter the program, but it did not offer compelling evidence. Initial research found that within months of the rule taking effect, there was **a 47 percent drop in the program's capacity to serve female patients** and reduced access to services for women in at least **390 counties** spanning 30 states. Forcing high-quality providers out of Title X exacerbates disparities in access to family planning care, falling hardest on people of color, people living in rural areas, and people struggling to make ends meet. The administration should rescind this harmful rule and restore the integrity of the program, including by assessing whether new grantees are providing high-quality, evidence-based care and meeting the terms of their grants.

Beginning in 2010, the *TPP Program* funded high-quality, evidence-based teen pregnancy prevention grants. A **diverse group of grantees** across the nation replicated a variety of models that have demonstrated a positive effect on teen sexual behavior. Grants also support high-quality innovation and evaluation to continue expanding the evidence base. The first two five-year cycles of grants made vital contributions to the growing body of knowledge of what works to prevent teen pregnancy. This included high-quality implementation, rigorous evaluation, and learning from results. The TPP Program was recognized by *evidence experts* as a leading example of a tiered-evidence approach to evidence-based policymaking.

Since 2017, HHS repeatedly sought to eliminate or undermine the TPP Program by attempting to terminate grants, weakening evidence standards in grant announcements, and diverting funds supporting high-quality evaluation. While **courts blocked** most of these egregious actions, they harmed ongoing research and the scientific enterprise under way. HHS also stopped funding and updating the *Teen Pregnancy Prevention Evidence Review*, an independent, systematic, rigorous review of evaluation studies that informed TPP grantmaking and provided a clearinghouse of evidence-based programs for other federal, state, and community initiatives.

From 2010 through 2019, the TPP Program was administered by the Office of Adolescent Health (OAH) under the assistant secretary of health. This office, with a well-qualified director and expert staff, was *lauded for high-quality implementation*, including generating unprecedented amounts of research and transparency. In 2019, OAH was merged into OPA, the director position was subsumed into the deputy assistant secretary for population affairs, and significant staff time and technical assistance were diverted to other efforts.

Divisions across HHS—including the Administration for Children and Families (ACF), the Office of the Assistant Secretary for Planning and Evaluation (ASPE), the Agency for Healthcare Research and Quality (AHRQ), the Centers for Disease Control and Prevention (CDC), CMS, FDA, the Health Resources and Services Administration (HRSA), IHS, NIH, and the Substance Abuse and Mental Health Services Administration (SAMHSA)—should ensure that their work on sexual and reproductive health is driven by evidence, and this approach should apply to international as well as domestic work. In particular, CDC should recommit to advancing sexual and reproductive health and making contraceptive access a priority, including by serving as an active partner in revisions to *Providing Quality Family Planning Services* (QFP).

Administrative Actions

- Rescind the Compliance With Statutory Program Integrity Requirements rule (i.e., the domestic gag rule) on the basis of its failure to respond appropriately to evidence-based concerns about its impacts, and replace it with the former regulations until new ones can be created through the standard notice-and-comment process.
 - Begin to undo the damage of the domestic gag rule by allowing qualified entities that left the program as a result of the rule a way to rejoin it.
 - Assess the rule’s impact on clients’ access to high-quality family planning care (including the full range of contraceptive methods) and use existing enforcement authority to ensure compliance with evidence-based quality standards, including the QFP guidelines.
 - Ensure the TPP Program adheres to rigorous standards of evidence and to complete, unbiased, science-based information in its grant announcements, grant awards, evaluations, and implementation.
 - Assess the extent and status of TPP Program funding that remains *unspent*, and direct that funding to evidence-based purposes consistent with the intent of the program.
- Reactivate and dedicate funding for the Teen Pregnancy Prevention Evidence Review.
 - Restore OAH as a separate entity, appoint a well-qualified director of adolescent health, and ensure the office has sufficient funding to address the broad scope of adolescent health issues.

Budgetary Action

- The budget request for the TPP Program should provide adequate funding to support restoration of evidence-based implementation of grants that replicate effective programs and continue to expand evidence. This includes sufficient funding for technical assistance and high-quality evaluation, as well as funding for the Teen Pregnancy Prevention Evidence Review.

Priority 2: Ensure OCR Rulemaking and Enforcement Are Based on Evidence

OCR has an important role to play in safeguarding civil rights related to health care, but recent OCR actions based on specious rationales have diverted limited resources from appropriate priorities while employing a narrow version of discrimination that invites abuse. OCR must rescind rules that allow for discrimination based on gender identity and sex stereotyping and reverse damaging and inappropriate changes to its structure and approach.

Created in January 2018, the Conscience and Religious Freedom Division (CRFD) was established in part to investigate health-care workers’ claims of discrimination on the basis of religious and moral objections to providing patient care such as abortion or sex reassignment. HHS claimed that an increase in “conscience” complaints (where health-care providers or even those associated with the provision of a health-care service feel they are forced to provide care that violates their beliefs) merited the creation of CRFD, but that claim is false. In *federal court*, HHS attorneys admitted that prior to January 2018 “there was approximately one complaint per year” that would fall under CRFD’s purview. CRFD claimed an increase in “conscience” complaints in FY 2018—however, they still constituted only a microscopic percentage of the 33,194 total complaints OCR received that year. A federal court found that fewer than 10 complaints are fairly characterized as relating to the federal refusal laws that CRFD is charged with enforcing. HHS devoted additional resources and staff to focus on an imaginary “problem” for which there

is no evidence. OCR always had the responsibility and authority to investigate and enforce federal laws that allow health-care providers to refuse to perform certain services, so absent evidence that OCR was unable to do so, the creation of CRFD and disproportionate allocation of staff to it¹ was unwarranted.

The newly created CRFD drove HHS policies, including a refusal-of-care rule that dramatically expands the reach of existing federal refusal laws that enable doctors, hospitals, and other health-care entities to deny people care on the basis of the entities' own beliefs. Another rule that precedes CRFD's creation but uses similar rationale exempts employers and universities that have religious or moral objections to birth control from complying with the provision of the ACA's preventive care mandate that requires insurance plans to cover the full range of approved contraceptive methods. With no evidence to back its claims, HHS made the *sweeping statement* that the rule "will not affect over 99.9 percent of the 165 million women in the United States." *Experts vehemently disagreed, arguing* that the rule puts services like contraception, abortion, and HIV treatment at risk—catastrophic human costs that *HHS failed to assess*.

The Health Care Rights Law (Section 1557 of the ACA) is a groundbreaking civil rights law that prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in all health programs and activities receiving federal financial assistance. The Obama administration issued a regulation interpreting Section 1557 to define discrimination on the basis of sex as inclusive of abortion, sex stereotyping, and gender identity. On June 12, 2020, the Trump administration's HHS removed this definition in a *final rule* amending and superseding the rule issued under the Obama administration. Three days after the Trump administration rule was released, the US Supreme Court affirmed workplace protections for LGBTQ+ people in its *Bostock v. Clayton County decision*, which solidified the interpretation of sex discrimination as including discrimination based on sexual orientation and gender identity. The Trump administration's 1557 rule change was already problematic; the *Bostock* decision also makes it clear that its definition of discrimination violates federal civil rights law.

Administrative Actions

- Begin the process of rescinding the refusal-of-care rule.
- Rescind the regulation narrowing ACA Section 1557 and engage in rulemaking using a broad definition of discrimination that aligns with the *Bostock* decision.

- In recognition of the lack of evidence demonstrating its necessity and in accordance with Court findings, dissolve CRFD.

Budgetary Action

- Allocate rulemaking and enforcement resources based on evidence of problems.

Priority 3: Require that Evidence Rather than Political Considerations Drive Drug and Device Approval and Guidance Decisions

To fulfill its mission, FDA must make decisions about drugs and devices based on the best available evidence, and regularly update those decisions to ensure they continue to reflect evolving knowledge. Past agency failures in these areas warrant a renewed public commitment to making evidence-based decisions and prompt action to correct past errors.

FDA decisionmaking across a range of reproductive health drugs and devices is an area in which political appointees often make decisions counter to recommendations from scientific experts, with apparent political motivations. In two especially well-known cases, *Plan B* (levonorgestrel emergency contraception) and medication abortion (mifepristone), political appointees across multiple administrations overruled agency scientists and medical experts to restrict or delay access.

During the partial review of mifepristone's label and REMS in 2016, for example, agency officials publicly acknowledged that the commissioner *personally overruled* the recommendations of reviewers in at least one instance, with other instances of political interference known or suspected to have occurred. Although the label *approved in 2016* removed some restrictions on mifepristone, it did not reevaluate requirements that the drug be prescribed and dispensed only by a limited group of providers—despite an extensive *international record* demonstrating that medication abortion without such restrictions is safe and effective. Now, in the COVID-19 context, FDA has sought to continue to require patients seeking abortions to face unnecessary exposure by traveling to one of the limited sources of mifepristone, *despite lifting similar restrictions on other drugs*. In July, a federal court *found* that these requirements provide "no significant health-related benefit" and are "unnecessary regulations." FDA must act to eliminate medically unnecessary barriers to access based on well-established evidence, both clinical and real-world, of mifepristone's effectiveness and safety.

Furthermore, in all of its decisions, FDA should use a range of evidence as a complement to—not a replacement for—controlled clinical trials in the approval and post-market surveillance of drugs and medical devices. Rigorously evaluated data, including analysis of post-market safety reports and studies, electronic health records, and registries, can help us better understand a more complete safety and effectiveness profile for both drugs and devices than manufacturer-sponsored clinical trials alone. Preclinical and clinical trials typically have extensive exclusion criteria and controls, which make use in the research setting different from average use. Dismissing data collected in the “real world” means ignoring the voices and lived experience of patients who were not part of the sponsor’s studies and may not fit an industry narrative. Such evidence has played a key role in recent post-market regulatory actions challenging the safety of medical devices such as Essure and breast implants.

Administrative Actions

- Direct FDA to affirmatively suspend the REMS in-person dispensing requirement on mifepristone that endangers pregnant people by requiring them to travel during the COVID-19 public health emergency, and drop any pending legal challenges to uphold those restrictions; the suspension should remain in effect until FDA can undertake a comprehensive review of the REMS.
- Direct FDA to conduct a comprehensive review of the REMS imposed on mifepristone to eliminate medically unnecessary barriers to access based on well-established evidence, both clinical and real-world, of mifepristone’s effectiveness and safety.
- Declare the administration’s commitment to reproductive health drug and device approvals based on scientific evidence free from political interference.
- Ensure that the same rigorous, science-based standards and internal review processes applied to other drugs and devices are applied to reproductive health products. The secretary must direct FDA to reexamine previous decisions where routine agency processes were subverted in favor of political outcomes.

Priority 4: Use Evidence to Advance Equity

HHS has *committed to advancing health equity*, but its data collection and analysis have not supported this goal as well as they should. In order to address health inequities in a comprehensive and integrated way, HHS must develop and fund research to better understand the overall health status and the sexual and reproductive health needs and experiences of all communities. It should apply this approach across divisions—including ACF, ASPE, AHRQ, CDC, CMS, FDA, HRSA, IHS, NIH, and SAMHSA—and in both its domestic and international work.

HHS must ensure that it is collecting appropriate data, that it routinely analyzes data to track progress on health equity, and that findings from these analyses reach policy-makers who can make changes to advance equity, such as developing and implementing evidence-based interventions that can substantially improve outcomes for historically marginalized groups. Efforts must include those for whom research data are frequently lacking, such as racial and ethnic groups often combined into broad categories, LGBTQ+ people, immigrants, people with disabilities, rural residents, and young people. By improving data collection on abortion, contraception, maternal health, sexually transmitted infections, sexual orientation and gender identity, formal sex education, and social determinants of health for under-researched populations, HHS can meaningfully expand capacity to address sexual and reproductive health inequities. It is important to note that, given the particular personal and political sensitivities surrounding reproductive health in the United States, any moves to improve surveillance must safeguard the privacy, rights, and needs of patients and providers.

Sexual and reproductive health advocates have warned that several recent policy changes will exacerbate health disparities. Such policies include those discussed above (the Title X gag rule, exemptions from the ACA’s preventive care mandate, and the newly narrowed interpretation of the ACA’s prohibition on discrimination) as well as changes to the Medicaid program (e.g., *approval of waivers that let states make changes that limit access to family planning services*). Research should examine whether these policy changes have had the predicted detrimental impacts to health equity.

Administrative Actions

- Clinical and behavioral research studies and surveys sponsored across all relevant agencies must collect data about the sexual and reproductive health of all communities while soliciting specific data on race, ethnicity, immigration status, age, disability status, geographic location, sexual orientation, sex assigned at birth, and gender identity so that data may be stratified on multiple characteristics. Data on literacy and health literacy should also be collected so research and surveys are developed so they can be understood by all populations.
- Assign personnel to conduct analyses of how recent policy changes in sexual and reproductive health have affected disparities across the dimensions listed above.
- If the *Data to Save Moms Act (HR 6165)* has not passed, take the action described in Section 4 of the bill by creating a Task Force on Maternal Health Data and Quality Measures. As described in the act, the task force should consider Maternal Mortality Review Committee members' participation in trainings on bias, racism, or discrimination; the extent to which states have implemented systematic processes of listening to the stories of pregnant and postpartum women and their family members, with a particular focus on minority women and their families; legal barriers preventing the collation of state maternity care data; the extent to which data are sufficiently stratified by race and ethnicity in the context of maternity care quality measures; the extent to which quality measures consider subjective measures of patient-reported experience of care; and recommendations to

improve maternal health data collection and reporting processes, and maternity care quality measures.

- If the *Social Determinants for Moms Act (HR 6132)* has not passed, take the action described in Section 2 of the bill by establishing a task force that includes representatives of relevant HHS agencies, other federal departments, and community representatives to develop coordinated strategies to address social determinants of health influencing maternal health outcomes.
- Elevate and strengthen existing offices and divisions related to minority health, women's health, health equity, and LGBTQ+ health to ensure that they have the resources and authority to collect and analyze data and ensure that their findings inform policy discussions.

Budgetary Action

- Propose a budget that includes expanded funding for program evaluation and research to gather comprehensive data sets that can be disaggregated by race, ethnicity, immigration status, age, disability status, geographic location, sexual orientation, sex assigned at birth, and gender identity. Budgets for grant-funded programs should include sufficient resources to assist grantees with appropriate data collection.

Endnote

1. The Health Information Privacy Division has only 20 full-time equivalents to investigate 78 percent of the complaints OCR receives, while CRFD has 12 full-time equivalents to investigate 4 percent of the complaints OCR receives.

ENDORSED BY

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