CONCERNED WOMEN for AMERICA

October 3, 2022

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
Washington, DC 20201

Dear Secretary Becerra,
Comment: RIN 0945-AA17, Docket ID # HHS-OS-2022-0012

On behalf of the hundreds of thousands of women I represent as CEO and President of Concerned Women for America (CWA), I am writing in strong opposition to the proposed rule (Rule) issued by the U.S. Department of Health and Human Services (the Department) titled "Nondiscrimination in Health Programs and Activities" (Docket ID # HHS-OS-2022-0012).

This Rule requires adherence to unethical medical practice, mandating health programs cover the destruction of innocent human life and maim children's healthy bodies in the name of "gender affirming care." It is a brazen attempt to exploit nondiscrimination law to deny rights of conscience and to strait-jacket America's health system to comply with extreme ideological goals that a majority of the American people oppose, including abortion on demand until birth and mutilating healthy bodies of youth struggling with an identity crisis.

Under your leadership, the Department and this Administration are losing in court on attempts to reinterpret nondiscrimination law, yet you seek to disregard those judgments against you in proposing this Rule. Women from both sides of the political spectrum beg you to reconsider your ill-advised attempts. Decisions such as *Religious Sisters of Mercy et al.* v. *Becerra et al., Franciscan All., Inc. v. Becerra, or Christian Employers Alliance* v. *U.S. Equal Employment Opportunity Commission et al*., should compel you to listen to most Americans and work to protect our unique identity as women instead of disregarding our concerns in order to appease some small, radical supporters.

Thumbing your nose at the court only underscores this Rule is nothing short of an executive power grab. Like the illegitimate 2016 Rule regarding Section 1557 of the Affordable Care Act (ACA), the Department is reading its preferred language into the meaning of "sex" that has never been authorized by Congress or approved by the Supreme Court. The Biden Administration's loss in *West Virginia v. EPA* should have caused you to reevaluate this illegal legislative rulemaking. It is reckless and irresponsible to disregard women's dignity and safety concerns, and the directive of courts, including the Supreme Court, merely because a decision does not fit your policy preferences.

The U.S. Department of Education's reinterpretation of Title IX, which was promulgated outside of the legal requirements of the Administrative Procedures Act, was thrown out in federal court. It cannot be relied upon to justify this Rule.

Proposing unprecedented changes to federal law through such an arbitrary and capricious process lacks any degree of legitimacy. The requirements of administrative rulemaking are meant to prevent this type

of abuses of power. This Rule hinges on an insular, circular "justification" created out of whole cloth imposing novel meanings and sweeping expansions never authorized by Congress and federal courts have acknowledged that.

Even worse, this Rule seeks to mandate an oppressive health care regime through Section 1557 of the ACA and other federal programs serving vulnerable women and children that rejects the humanity of babies in the womb, the human dignity of the female sex, and the human rights of children who have become pawns in an exploitative, for-profit enterprise of "gender affirming care" that deforms young bodies and sterilizes youth in Kafkaesque-style deception.

This Rule is not defensible

Nothing in congressional statute or statutory interpretation by the U.S. Supreme Court has changed the meaning of sex discrimination under Title IX, Title VI, or the ACA. The Department has no legitimate authority to rewrite federal civil rights law to redefine the immutable characteristic of sex to mean "gender identity."

Bostock established that "transgender status" was protected under Title VII in hiring and firing. "Transgender status" was based on the declared persona of an adult self-identifying as the opposite sex. The court went no further than recognizing this status under Title VII to extend certain workplace protections. It did not impose other social and financial obligations to an employer, other employees, or a health care plan. There was no "right" to accommodation beyond securing or retaining a job.

Using the "reasoning" of *Bostock* to create an undefined, unlimited, and ever evolving class of "gender identity" is an injection of political and policy desires, not adherence to settled law or statute. This is legislative rulemaking at its worst. HHS is trying to do exactly what the Department of Education is seeking to do under Title IX – creating an artificial, undefinable, and unenforceable right to demand accommodation for a self-declared identity. This is a seismic change to the objective classifications of civil rights laws.

"Gender identity" imposes a new form of discrimination on the basis of immutable male/female sex. It is a personally-defined, subjective identity, not an objective biological reality. "Sexual orientation" creates a class based on emotional attraction, also not an objective biological trait. If subjective categories of identity are to be protected under federal nondiscrimination law, why only limit it to sex and not apply it to age or race? Accepting self-declared identity, versus immutable objective reality, as the basis for civil rights law is indefensible.

The only conclusion is that this Rule embodies the same illegitimacy in policy and practice that the Biden Administration is currently pursuing under all titles of civil rights law, but only for the personal preference of self-identified sexual attraction and identity, not for any other category of discrimination.

Resting "authority" for this Rule on a unilateral interpretation of *Bostock*, specifically rejected by the court, is untenable. Nowhere did the U.S. Supreme Court say its decision could or should be extended to require destructive medical surgeries and treatments for any "gender transition" claim, especially if requested by youth or caretakers who have been persuaded by reckless "gender specialists" and "professional" organizations peddling harmful "standards of care" protocols that are experimental and contrary to improving physical health. *Bostock* gives no legitimate claim to justify such a Rule.

Mandating "gender identity" to redefine "sex" imposes a new form of discrimination on the basis of sex

Sections 92.10, 92.101, 92.206, 147.104, 155.120, and 156.200 of this Rule establish a new category of sex as "gender identity" that is entirely subjective, personally determined, and evolving. By overriding

the meaning of sex as the scientific and undeniable presence of XX or XY chromosomes in every cell of the human body, this Rule imposes a new form of discrimination against individuals based on their actual sex.

The Rule cherry picks a Title IX court decision to justify a fabricated standard of "more than *de minimus* harm" as the basis for adjudicating "gender identity" claims:

> "However, the Department may still find that a covered entity violates Section 1557 if it implements the sex-based distinction in a way that constitutes discrimination, by imposing more than *de minimis* harm upon a particular individual. This is what Title IX requires."

This is false. By statue or regulation, Title IX has never required sex to be recognized as anything but objectively, biologically based. Covered entities should never be in violation of Section 1557 for recognizing or providing care to men and women on the basis of their sex as male and female. In fact, effective health care demands treatment according to sex.

The Department must answer these questions: How can the Rule threaten with violations a covered entity for providing health care based on sex, male and female, when sex is an integral part of appropriate care? How can you threaten covered entities with violations using a standard that lacks any basis in law and admittedly cannot be defined? Have you calculated the costs to covered entities for such claims?

The Rule sets up a direct attack on the status and dignity of women and our female sex by specifically mandating: "For example, a hospital that assigns patients to dual-occupancy rooms based on sex would be prohibited from requiring a transgender woman to share a room with a cisgender man, regardless of how her sex is recorded in her insurance or medical records."

Make no mistake, any male who declares he is a woman should NOT be admitted to a dual room where a vulnerable woman could be sexually assaulted. This is just another example of how this Administration and this Rule literally erases the assurance of protections for women on the basis of sex. This is more than an insult to women; it imposes a regime of harm.

What the Department has established, virtually the only point of clarity in this Rule, is this: any male who identifies as a woman is a superior protected class and granted superior protections over any human female.

<u>Imposes radical, sweeping, unlimited requirements for "gender affirming care"</u>

The Rule admits that no limitation on the definition of "gender identity" is possible, which makes it impossible to even define the limits of "gender affirming care."

> Relevant clinical guidelines acknowledge that not all individuals for whom such care is clinically appropriate will specifically identify as transgender, nor will all gender-affirming care specifically be related to transition from one binary gender to another. For example, people seeking gender-affirming care may refer to their gender identity using terms other than "transgender," such as "nonbinary," "gender nonconforming," "genderqueer," or "genderfluid."

The Rule places all these so-called "identities" in quotes - there is no attempt to isolate the meaning of any of these terms. What is the definition of transgender or queer or nonbinary or genderqueer? What is the difference between them? How is any covered entity expected to understand clinically appropriate care for a fabricated and evolving class of identities for which this Rule requires coverage as a matter of sex discrimination?

The only logical conclusion is that anything goes for a claim and entities are expected to comply. It's simply a matter of claiming "gender fill in the blank." This mandate is preposterous as a matter of health care and federal rulemaking, especially in a rulemaking intended to clarify the meaning and obligations under the nondiscrimination provisions of federal health care programs, not make them entirely arbitrary and capricious with unbounded obligations that cannot be equally or consistently enforced.

What is the specific definition of "gender affirming care"? The Rule cites additional concepts of "gender-affirming health services" or "transition-related care" but these do not define with any clarity the meaning or scope of this mandate. Does such incorporate behavioral health care services and mental health counseling that assist in realigning an individual's gender perception with his/her biological sex? If so, why is this not clearly stated in the Rule? If not, why not, knowing that this alignment will reduce costs and negate the required life-long medical treatment and documented long-term health detriments of drugs and surgeries required to refashion one's body to resemble one's personal perception of gender?

What medical diagnosis is required in order to qualify for procedures deemed "gender affirming care"? Is it gender dysphoria? This must be explained fully. What specific treatments and for what ages are these treatments and procedures warranted? What scientific method-based research is the basis for these determinations? What long-term evidence that includes desistance justifies the mandate for "gender affirming care"? The Department must answer all the above questions. Without clear, definitive, objective criteria, no recipient or provider can be expected to operate under the regime mandated by this Rule, and it is, therefore, arbitrary and capricious.

Section 92.206 and 92.207 of the Rule require that a covered entity must not deny, or limit services based on "gender identity." Is there any claim for service that could be denied? At any age? The Department must answer whether "gender affirming care" is for any claim related to one's identity and if not, provide the specific, objective criteria that defines the limits of such treatments. If the Department is unable to clearly delineate the provision of services required, it is further proof that this Rule is arbitrary and capricious.

The Department must answer these questions: What specific, exclusive list of treatments and procedures constitute "gender affirming care?" Does it cover any cosmetic, plastic surgery for any individual to change body appearance, refashion body parts, and alter sexual function? Does it include coverage for breast binders for youth, mastectomies and hysterectomies for teenage girls, cosmetic surgeries for feminizing or masculinizing characteristics, prosthetic penises, or breast augmentation for male bodies and female bodies? Without an exhaustive list of procedures and the objective, enforceable criteria for when these procedures are indicated under the Rule's "gender affirming care" mandate, this Rule is arbitrary and capricious.

Because the Rule is entirely vague, it is necessary for the Department to establish clearly whether "gender affirming care" includes all manner of health care treatments, behavioral, mental, and physical, that might affirm an individual's actual sex including realigning with that sex, in addition to any desired features, functions, thoughts, and appearance of sex. To deny coverage, services and procedures designed to assist an individual to align with his or her bodily sex and function would be sex discrimination.

The requirement for nondiscrimination-based care cannot go one way. This Rule must obligate covered entities for any health service or procedure that helps an individual conform to his or her natural sex and sexual function. To be nondiscriminatory it must also include any desired appearance that is

consistent with a person's sex. Nothing can be denied, including all cosmetic surgeries and elective procedures that refashion a body to desired appearances or it would be discriminatory.

Herein lies the trap the Department has laid for itself and every affected entity by expanding the meaning of sex without defining what it actually means. The massive, uncalculated costs and liabilities of this wrongheaded Rule to entities, providers, individuals, and the American taxpayer must be calculated. The Department must be able to fully account for the broad and deep impact and consequence of the mandate it prescribes.

Is gender dysphoria a disability under this Rule?

Does the Department agree or disagree that "gender dysphoria" constitutes a disability under the Americans with Disabilities Act as a Fourth Circuit Court of Appeals panel recently concluded in *Williams v. Kincaid*? If so, how does that assertion impact obligation and liability under this Rule? This question cannot be ignored as it is central to the responsibilities of recipients and providers of services required under this Rule.

Peddles "gender affirmation" ideology and is a direct threat to youth struggling with identity

Section 92.207 mandates a broad class of new health care coverage obligations based on a person's "gender identity" with no identification or reporting of documented associated risks and no limitation regarding age. So-called "standards of care" in this field are based on non-empirical self-reporting surveys and are highly controversial. Calls for review have been silenced by complicit medical associations like in the American Academy of Pediatrics. International trans-promoting organizations, specifically WPATH, are defining "standards of care" that have no objective verification.

The Food and Drug Administration (FDA) has documented adverse event reports from the off-label use of puberty blockers – powerful drugs that remain unapproved to this day (see, https://www.fda.gov/drugs/questions-and-answers-fdasadverse-event-reporting-system-faers/january-march-2017-potential-signals-serious-risksnew-safetyinformation-identified-fda-adverse). Recently, the FDA added warnings about the potential harmful effects of puberty blocking drugs, including brain swelling and vision loss (see https://www.formularywatch.com/view/study-jak-inhibitors-may-have-different-side-effects).

A new review in the Journal of Sex and Marital Therapy evaluating the "Dutch protocol," which has been used to defend the use of puberty-blocking drugs and more severe forms of treatment on youth, cannot be ignored (see https://www.tandfonline.com/doi/full/10.1080/0092623X.2022.2121238). The Department must be able to answer these questions: What evidence underlies the requirements for treating minors under "gender affirming care"? Are there any age limitations on treatment? Who determines this?

The Rule cannot ignore the evidence of bodily and psychological harm that use of unapproved drugs cause, especially for young people, yet that is what the Rule requires by defining any withholding of "gender affirming" treatment an act of discrimination. Gender transition regret is only growing which will substantially add to costs of repairing physical and mental health. What long-term scientific research and objective evidence exists to fully justify the safety and use of puberty blockers for purpose of gender exploration? What proof that these interventions "do no harm" exists to justify mandating coverage as a matter of "nondiscrimination"?

Here's what Garrett from Baton Rouge told Lesley Stahl on *60 Minutes* (May 22, 2021): "I didn't get enough pushback on transition. I went for two appointments, and after the second one I had my letter

to go get on cross-sex hormones." In just 3 months, Garrett went from taking hormones to getting his testicles removed. He later got a breast augmentation but instead of feeling better he felt worse. "I had never really been suicidal before until I had my breast augmentation and about a week afterwards I wanted to, like, actually kill myself. I had a plan and I was actually going to do it but I just kept thinking about my family to stop myself."

Where is the Regulatory Impact Analysis for declaring a class of treatment based on "presumptive nondiscrimination" and the costs required to undergo treatment to reverse a regretted transition or to treat associated bodily damage from sex reassignment treatment? Chemical and surgical interventions for gender transition have become big business lacking any oversight or associated liability. Why should an insurer be required to cover the removal of a young man's testicles within three months of him declaring a decision to change "genders"? This would be required as "gender affirming care" under this Rule. Any determination to "discriminate" against elective treatment that mutilates the body, even if it increases serious health risks, could be challenged as discriminatory.

Tying the hands of America's health care system and any ethically-minded health provider with a sweeping mandate that anything less than accommodating self-defined gender identity could violate "more than *de minimus* harm" proves this Rule is the work of bureaucratic activists, not an objective, accountable agency that has an obligation to protect public health and the public trust. This Rule is nothing short of weaponizing ideology for the purposes of promoting a gender orthodoxy that is confusing the minds and destroying the bodies of our children.

What exactly is the requirement for fully informed consent for a minor age 18 and under for specific types of "gender affirming care"? Use of puberty blockers and cross sex hormones are entirely experimental on youth. The FDA has not approved drugs for these purposes. The FDA warnings for puberty blockers include the potential of increased suicide for children taking these potent drugs. A study in *The New Bioethics*, "Puberty Blockers for Children – Can They Consent?" concludes that minors are not able to give informed consent required by law (see https://www.tandfonline.com/doi/full/10.1080/20502877.2022.2088048).

Parents should never be allowed to consent on behalf of a child to medical treatment that compromises the normal development of a healthy body that erodes mental, physical, and sexual capacities, including lowering IQ, compromised bone structure and sterilization. This is where "gender affirming care" has become Frankenstein medicine. How does the Department justify medical surgeries that experiment on children to fashion fake vaginas or penises, that remove healthy reproductive organs, and casually give double mastectomies to teen girls distressed by their appearance?

Transition regret is real (see for example the documentary Detransition Diaries, https://vimeo.com/ondemand/detransitiondiaries). This will only increase as more young girls seek to remove their healthy breasts under the insidious marketing of "top surgery" to "relieve distress". A study by University of Chicago researchers admits to recruiting girls ages 13-24 for "gender confirming" breast removal. News headlines reporting on the study published in *JAMA Pediatrics* boast that participants feel "less distress" three months after double mastectomies as proof benefit (https://jamanetwork.com/journals/jamapediatrics/fullarticle/2796426). Only three months? What about three years? This is the kind of junk science that your department is using to defend heinous, unthinkable practices like "gender confirming" mastectomies on teen girls and mandating without limitation under this Rule. It is among the reasons this Rule should be stopped in its tracks.

The Department must calculate the cost of irreversible damage to young people, as well as the future obligations to taxpayers and medical providers, including associated malpractice liability, when

procedures like breast removal at one age could result in reconstructive surgery at another as profiled recently in *The New York Times* (9-26-22):

> "Jamie, a 24-year-old college student in Maryland, was raised as a girl and began identifying as a transgender boy in the eighth grade. After being sexually assaulted and dropping out in her junior year of high school, she said she started taking testosterone. Three months later, just after she turned 18, she underwent top surgery at a private practice in Massachusetts.
>
> For the next few years, Jamie said, she thrived. Testosterone made her feel energetic, and her anxiety dissipated. She went back to school and got certified as an emergency medical technician.
>
> But when she was 21, her father, who was dying of Alzheimer's, no longer recognized her. She fixated on her wide hips, which she worried stood out next to her facial hair and deep voice. After a date where she had sex with a straight man, she said, she realized she had made a mistake.
>
> "I realized I lost something about myself that I could have loved, I could have enjoyed, I could have used to feed children," Jamie said. She said she grieved for months and contemplated suicide.
>
> This spring, after a year of fighting her insurance company to cover the procedure, she had surgery to reconstruct her breasts. She never told her original surgeon that she had changed her mind, partly because she also blamed herself. Sometimes, she said, "I still don't like being a woman."
>
> Many surgeons say that they rarely hear about patients with regret. But it's unclear how many, like Jamie, never inform them."

This real account should not be dismissed. What long-term research justifies the costs over the benefits of this Rule, including the related risks and actual harm to physical and mental health that are a direct result of taking puberty blockers, cross sex hormones, and surgeries? Without this analysis, these so-called nondiscrimination mandates on providers of health programs and activities cannot be justified, especially for minors.

Again, this Rule cannot ignore the growing evidence of bodily and psychological harm that use of these unapproved drugs cause, yet that is what the Rule requires of covered entities by defining any withholding of "treatment" an act of "discrimination" on the basis of "gender identity." Transition regret will only increase as a lucrative and unregulated market for "gender affirming care" increases, especially under threat of federal civil rights violation. This will force employers, health insurers, and every person enrolled in their plans to pay for the fallout of this destructive medical practice.

What long-term scientific research and objective evidence is available that justifies the use and safety of puberty blockers, cross sex hormones, and "gender confirming" surgeries for the purpose of gender transition of minors? What proof that these interventions "do no harm" exists to justify mandating coverage as a matter of "non-discrimination"?

Mandating coverage for "gender affirming care" for a teen girl wanting to remove her breasts is tantamount to requiring liposuction for an anorexic. Cosmetic reconstruction and hormone treatments will never make a female/woman a male/man. The idea that children could be "born in the wrong body" is unscientific - as scientifically preposterous as saying the earth is flat. To affirm a child's view of himself as "her" and call irreversible sex reassignment "health care" is insidious deception. Mutilating a youth's body for "gender exploration," causing long-term health risks, including loss of IQ, decrease in bone density, increased risk of cancer, vision impairment, and sterilization, is nothing short of child abuse. No ethical medical practice should be engaged in such practice, and no insurer forced to cover

the evolving "queer" and "gender fluid" ideology that would give anyone a claim to such medical services and fuel an insatiable market diverting scarce medical resources for cosmetic claims to "affirm" a person's physical appearance.

Does the Rule's nondiscrimination requirement allow for health services and insurance coverage related to sexual attraction fluidity exploration in therapy (SAFE-T) and other sexual orientation change efforts? Does the Rule's nondiscrimination requirement forbid discriminating against SAFE-T health care? Is SAFE-T part of the full spectrum of health care options related to a person's sexual orientation? If not, why not, especially in light of the empirical research cited in this study of sexuality attraction fluidity and well-being in the *Journal of Human Sexuality*: https://www.journalofhumansexuality.com/_files/ugd/ec16e9_d0708a0dc82e4da78e0258eb96dc1467.pdf?

The Rule's expanded definition of federal financial assistance could impact any tax-exempt entity

Section 92.4 of the Rule expands the application of what constitutes federal financial assistance. Who exactly is covered as a "recipient of federal financial assistance?" The broad interpretation of this definition could have very far-reaching impacts. Recent Title IX district court rulings in Maryland and California classify tax-exempt status as federal financial assistance. It is imperative that the Department answer these questions as this will determine the scope of entities covered by the Rule: Does the Department agree with the interpretation in these cases that federal financial assistance includes tax-exempt status? Does that interpretation apply directly to this Rule? What entities are covered who previously have not been covered through the proposed changes to the definition?

Weaponizes abortion and gender ideology against small businesses, families, and faith-based providers and empowers government actors to overrule conscience protections

The Department claims that the economic impact to small business will not be significant. How can you adequately calculate this when the obligations for care under this Rule are limitless in scope because they are self-determined and without objective definition as described above? Asserting that the Rule clears the 3% "significant impact" and 5% "substantial number" thresholds for small entities is unjustifiable by the scant, incomplete analysis provided.

Where is the Family Policymaking Assessment required under Public Law 105-277?

Finally, this Rule is an affront to rights of conscience and religious freedom. The Constitution is clear about this even if federal law has not considered all contexts. The Rule makes it impossible for any faith-based entity or medical provider to operate independently under this Rule, without government intrusion or threat. Section 92.302 of the Rule makes the blatant admission that the Department can grant or overrule rights of conscience or religious belief at its own discretion:

> "OCR may determine at any time whether a recipient is exempt from the application of certain provisions of this part, or whether modified application of the provision is required as applied to specific contexts, procedures, or health care services, based on a Federal conscience or religious freedom law."

Further, if an exemption is available in one case, that doesn't provide a shield in other contexts:

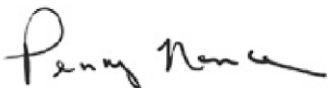
> "If OCR determines that a recipient is exempt from the application of certain provisions of this part or modified application of certain provisions is required as applied to specific contexts, procedures, or health care services, based on a Federal conscience or religious freedom law,

that determination does not otherwise limit the application of any other provision of this part to the recipient or to other contexts, procedures, or health care services."

Clearly, this Rule wants the Department to rule, not the Constitution or federal laws aimed at protecting our fundamental liberties. There is no doubt that this Rule intends to tie the hands of many health care entities and limit the free practice of providers acting with faith and conscience. The monumental chilling effect of the proposed practice stands in clear violation of this country's First Amendment jurisprudence. Under this rule, health care providers are required to beg on their knees with "mother may I" requests to the Department for permission to be ethical doctors and act according to the dictates of their professional judgments, their conscience and/or their deeply held religious convictions. Government actors should never be allowed to weaponize an ideology of abortion and "gender affirming care" against the moral practice of medicine by any covered entity who objects to killing unborn babies or maiming vulnerable children.

In conclusion, the hundreds of thousands of women supporters of CWA stands firmly opposed to this Rule which weaponizes the health care system to advance the Biden Administration's reckless and destructive pro-abortion and transactivist agenda. This Rule unilaterally overrules Congress, the courts, and the conscience of the American people. We urge in the strongest of terms against its implementation.

Sincerely,



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