No. 24-12826

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

STATE OF FLORIDA,
FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION,
FLORIDA DEPARTMENT OF MANAGEMENT SERVICES,

Plaintiffs-Appellees,

and

CATHOLIC MEDICAL ASSOCIATION,

Plaintiff-Appellee-Cross-Appellant,

v.

DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al*,

Defendants-Appellants-Cross-Appellees.

On Appeal from the United States District Court
for the Middle District of Florida

APPENDIX

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TABLE OF CONTENTS

ADMCLOSED,APPEAL,STAYED

U.S. District Court
Middle District of Florida (Tampa)
CIVIL DOCKET FOR CASE #: 8:24-cv-01080-WFJ-TGW

State of Florida et al v. Department of Health and Human Services et al
Assigned to: Judge William F. Jung
Referred to: Magistrate Judge Thomas G. Wilson
Case in other court: Eleventh Circuit, 24-12826-J
Cause: 05:0702 Administrative Procedure Act

Date Filed: 05/06/2024
Date Terminated: 12/13/2024
Jury Demand: None
Nature of Suit: 899 Other Statutes: Administrative Procedures Act/Review or Appeal of Agency Decision
Jurisdiction: Federal Question

Plaintiff

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in his official capacity

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Date Filed	#	Docket Text
05/06/2024	1	COMPLAINT against All Defendants (Filing fee $405 receipt number AFLMDC-22063290) filed by All Plaintiffs. (Attachments: # 1 Exhibit 1, # 2 Exhibit 2, # 3 Exhibit 3, # 4 Exhibit 4, # 5 Exhibit 5, # 6 Civil Cover Sheet, # 7 Proposed Summons)(McCotter, R.) (Entered: 05/06/2024)
05/06/2024	2	CORPORATE Disclosure Statement by Catholic Medical Association, Florida Agency for Health Care Administration, Florida Department of Management Services, State of Florida. (McCotter, R.) (Entered: 05/06/2024)
05/07/2024	3	NEW CASE ASSIGNED to Judge William F. Jung and Magistrate Judge Thomas G. Wilson. New case number: 8:24-cv-1080-WFJ-TGW. (AJS) (Entered: 05/07/2024)
05/07/2024	4	NOTICE TO COUNSEL James R. Conde, Julie Marie Blake and Matthew S. Bowman Local Rule 2.01(c), Special Admission - File a Motion to Appear Pro Hac Vice. Co-counsel with filing rights may electronically file the motion on behalf of the lawyer seeking Special Admission or the motion may be filed in paper format; Pay the Special Admission Fee; Submit a Pro Hac Vice E-File Registration through PACER. Visit www.flmd.uscourts.gov/for-lawyers for details (Signed by Deputy Clerk). (AJS) (Entered: 05/07/2024)
05/07/2024	5	NOTICE TO COUNSEL R. Trent McCotter Local Rule 2.01(c), Special Admission - File a Motion to Appear Pro Hac Vice. Co-counsel with filing rights may electronically file the motion on behalf of the lawyer seeking Special Admission or the motion may be filed in paper format; Pay the Special Admission Fee; Submit a Pro Hac Vice E-File Registration through PACER. Visit www.flmd.uscourts.gov/for-lawyers for details (Signed by Deputy Clerk). (AJS) (Entered: 05/07/2024)
05/07/2024	6	SUMMONS issued as to Administrator, Centers for Medicare and Medicaid Services, Centers for Medicare and Medicaid Services, Department of Health and Human Services, Director, Office for Civil Rights, Secretary, Department of Health and Human Services, U.S. Attorney and U.S. Attorney General. (AJS) (Entered: 05/07/2024)
05/07/2024	7	PROOF of service by Catholic Medical Association, Florida Agency for Health Care Administration, Florida Department of Management Services, State of Florida (McCotter, R.) (Entered: 05/07/2024)
05/07/2024	16	**STANDING ORDER regarding Discovery Motions. Signed by Magistrate Judge Thomas G. Wilson on 5/7/2024. (KMN)** (Entered: 05/20/2024)
05/08/2024	8	NOTICE of Local Rule 1.07(c), Local Rule 3.02(a)(2), and Local Rule 3.03. **-Local Rule 1.07(c)** requires lead counsel to file *promptly* a **Notice of a Related Action** identifying and describing any related action either pending or closed in the Middle District or elsewhere.

		-Local Rule 3.02(a)(2) requires the parties in every civil proceeding, except those described in subsection (d), to file a case management report (CMR) using the uniform form at www.flmd.uscourts.gov. The CMR must be filed (1) within forty days after any defendant appears in an action originating in this court, (2) within forty days after the docketing of an action removed or transferred to this court, or (3) within seventy days after service on the United States attorney in an action against the United States, its agencies or employees. Judges may have a special CMR form for certain types of cases. These forms can be found at www.flmd.uscourts.gov under the Forms tab for each judge. **-Local Rule 3.03** requires each party to file a disclosure statement. Counsel must make their disclosures using the standard court form. The Disclosure Statement form can be found at www.flmd.uscourts.gov. (Signed by Deputy Clerk). (JCG) (Entered: 05/08/2024)
05/08/2024	9	NOTICE informing the parties that they may consent to the jurisdiction of a United States magistrate judge by filing Form AO 85 Notice, Consent, and Reference of a Civil Action to a Magistrate Judge using the event **Consent to Jurisdiction of US Magistrate Judge**. (Signed by Deputy Clerk). (JCG) (Entered: 05/08/2024)
05/14/2024	10	Unopposed MOTION for R. Trent McCotter to appear pro hac vice, Special Admission fee paid, Receipt No. AFLMDC-22090184 for $150 by Florida Agency for Health Care Administration, Florida Department of Management Services. (McCotter, R.) Motions referred to Magistrate Judge Thomas G. Wilson. (Entered: 05/14/2024)
05/14/2024	11	Unopposed MOTION for James R. Conde to appear pro hac vice, Special Admission fee paid, Receipt No. AFLMDC-22090231 for $150 by Florida Agency for Health Care Administration, Florida Department of Management Services. (McCotter, R.) Motions referred to Magistrate Judge Thomas G. Wilson. (Entered: 05/14/2024)
05/15/2024	12	MOTION for Preliminary Injunction *or Stay of Rule Under the APA* by all Plaintiffs. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C, # 4 Exhibit D, # 5 Text of Proposed Order)(McCotter, R.) Modified on 5/16/2024 to edit docket text; Chambers notified. (LD). (Entered: 05/15/2024)
05/15/2024	13	**ORDER granting 10 Motion to Appear Pro Hac Vice; granting 11 Motion to Appear Pro Hac Vice. R. Trent McCotter and James R. Conde are authorized to appear in this matter pro hac vice. Signed by Magistrate Judge Thomas G. Wilson on 5/15/2024. (KMN)** (Entered: 05/16/2024)
05/17/2024	14	NOTICE of Lead Counsel Designation by James R. Conde on behalf of Florida Agency for Health Care Administration, Florida Department of Management Services. Lead Counsel: James R. Conde. (Conde, James) (Entered: 05/17/2024)
05/20/2024	15	NOTICE of Lead Counsel Designation by Natalie Christmas on behalf of State of Florida. Lead Counsel: Natalie Christmas. (Christmas, Natalie) (Entered: 05/20/2024)
05/20/2024	17	Unopposed MOTION for Julie Marie Blake to appear pro hac vice, Special Admission fee paid, Receipt No. AFLMDC-22112080 for $150 by Catholic Medical Association. (McCotter, R.) Motions referred to Magistrate Judge Thomas G. Wilson. (Entered: 05/20/2024)
05/20/2024	18	Unopposed MOTION for Matthew S. Bowman to appear pro hac vice, Special Admission fee paid, Receipt No. AFLMDC-22112094 for $150 by Catholic Medical Association. (McCotter, R.) Motions referred to Magistrate Judge Thomas G. Wilson. (Entered: 05/20/2024)
05/21/2024	19	**ORDER granting 17 Motion to Appear Pro Hac Vice; granting 18 Motion to Appear Pro Hac Vice. Accordingly, Attorney Julie Marie Blake and Matthew S. Bowman are**

		authorized to appear pro hac vice. Signed by Magistrate Judge Thomas G. Wilson on 5/21/2024. (KMN) (Entered: 05/23/2024)
05/24/2024	20	MOTION for Extension of Time to File Response/Reply as to 12 MOTION for Preliminary Injunction OR Stay of Rule Under the APA by All Defendants. (Holland, Liam). (Entered: 05/24/2024)
05/24/2024	21	RESPONSE in Opposition re 20 MOTION for Extension of Time to File Response/Reply as to 12 MOTION for Preliminary Injunction or Stay of Rule Under the APA filed by Catholic Medical Association, Florida Agency for Health Care Administration, Florida Department of Management Services, State of Florida. (McCotter, R.). (Entered: 05/24/2024)
05/28/2024	22	**ENDORSED ORDER granting 20 Motion for Extension of Time to File Response / Reply. Response due by 6/13/2024. If Plaintiffs desires to file a Reply, it is due on or before 6/18/2024 by close of business. Signed by Judge William F. Jung on 5/28/2024. (CCB)** (Entered: 05/28/2024)
05/28/2024	23	NOTICE of Telephonic Hearing on 12 MOTION for Preliminary Injunction or Stay. Motion Hearing set for 6/21/2024 at 01:30 PM before Judge William F. Jung. Counsel are directed to call the reserved conference toll free number at 1-888-557-8511. Enter the access code: 4744914 followed by the # (pound) key. You will be prompted to enter the security code: 1080 followed by the # (pound) key. Please call in at least 10 minutes before the scheduled hearing. (CCB) (Entered: 05/28/2024)
05/28/2024	24	NOTICE of Lead Counsel Designation by Julie Marie Blake on behalf of Catholic Medical Association. Lead Counsel: Julie Marie Blake. (Blake, Julie) (Entered: 05/28/2024)
06/03/2024	25	**ENDORSED ORDER: Additionally, on June 21 by 5 pm each party should copy chambers email and each other with MSWord draft Orders that they would wish the Court to enter. Signed by Judge William F. Jung on 6/3/2024. (Jung, William)** (Entered: 06/03/2024)
06/10/2024	26	NOTICE of Hearing (change as to in person and time only) on 12 MOTION for Preliminary Injunction or Stay. Motion Hearing set for 6/21/2024 in person at 02:30 PM in Tampa Courtroom 15 B before Judge William F. Jung. (CCB) (Entered: 06/10/2024)
06/11/2024	27	Unopposed MOTION to File Excess Pages by All Defendants. (Holland, Liam) (Entered: 06/11/2024)
06/11/2024	28	**ENDORSED ORDER granting unopposed 27 Motion to File Excess Pages. Signed by Judge William F. Jung on 6/11/2024. (CCB)** (Entered: 06/11/2024)
06/12/2024	29	Unopposed MOTION for Allison H. Pope to appear pro hac vice, Special Admission fee paid, Receipt No. AFLMDC-22191849 for $150 by Catholic Medical Association. (Blake, Julie) Motions referred to Magistrate Judge Thomas G. Wilson. (Entered: 06/12/2024)
06/13/2024	30	**ENDORSED ORDER granting 29 Motion to Appear Pro Hac Vice. Attorney Pope may appear pro hac vice as counsel for Plaintiff Christian Medical Association, subject to payment of the $150.00 special admission fee and submission of the Pro Hac Vice E-File Registration (see https://www.flmd.uscourts.gov/for-lawyers) within seven days of this order. Signed by Judge William F. Jung on 6/13/2024. (CCB)** (Entered: 06/13/2024)
06/13/2024	31	CORPORATE Disclosure Statement by Administrator, Centers for Medicare and Medicaid Services, Centers for Medicare and Medicaid Services, Department of Health and Human Services, Director, Office for Civil Rights, Secretary, Department of Health and Human Services. (Holland, Liam) (Entered: 06/13/2024)

06/13/2024	32	NOTICE of a related action per Local Rule 1.07(c) by Administrator, Centers for Medicare and Medicaid Services, Centers for Medicare and Medicaid Services, Department of Health and Human Services, Director, Office for Civil Rights, Secretary, Department of Health and Human Services. Related case(s): Yes (Attachments: # 1 Exhibit 1 Neese Class Certification Order, # 2 Exhibit 2 Neese Final Judgment, # 3 Exhibit 3 ACP Amended Complaint, # 4 Exhibit 4 ACP Memorandum Opinion and Order, # 5 Exhibit 5 ACP Supplemental Briefing, # 6 Exhibit 6 Dekker Judgment, # 7 Exhibit 7 Dekker Opposition to Motion to Enforce the Court's Judgment or, Alternatively, to Clarify the Court's Judgment, # 8 Exhibit 8 McComb Complaint, # 9 Exhibit 9 Catholic Benefits Ass'n Amended Complaint, # 10 Exhibit 10 Tennessee Complaint, # 11 Exhibit 11 Texas Complaint)(Holland, Liam) (Entered: 06/13/2024)
06/13/2024	33	RESPONSE in Opposition re 12 MOTION for Preliminary Injunction or Stay of Rule Under the APA filed by Administrator, Centers for Medicare and Medicaid Services, Centers for Medicare and Medicaid Services, Department of Health and Human Services, Director, Office for Civil Rights, Secretary, Department of Health and Human Services. (Holland, Liam). (Entered: 06/13/2024)
06/18/2024	34	RESPONSE re 32 Notice of a Related Action filed by Florida Agency for Health Care Administration, Florida Department of Management Services. (Conde, James) (Entered: 06/18/2024)
06/18/2024	35	REPLY to Response to Motion re 12 MOTION for Preliminary Injunction *OR STAY OF RULE UNDER THE APA* filed by Florida Agency for Health Care Administration, Florida Department of Management Services. (Conde, James) (Entered: 06/18/2024)
06/21/2024	36	**ORDER permitting electronics for hearing of 6/21/2024 as to Counsel Allison Pope. Signed by Judge William F. Jung on 6/21/2024. (CCB)** (Entered: 06/21/2024)
06/21/2024	37	Minute Entry. In Person Proceedings held before Judge William F. Jung: MOTION HEARING held on 6/21/2024 re 12 MOTION for Preliminary Injunction *OR STAY OF RULE UNDER THE APA* filed by Florida Department of Management Services, Florida Agency for Health Care Administration, Catholic Medical Association, State of Florida. Court Reporter: Susan Cayler (JCG) (Entered: 06/21/2024)
06/21/2024	38	The court's Exhibit referenced at the Motion Hearing held on 6/21/2024.(JCG) (Entered: 06/21/2024)
06/26/2024	39	RESPONSE re 38 Exhibit list - court *Defendants' Response to the Court's Exhibit* filed by Administrator, Centers for Medicare and Medicaid Services, Centers for Medicare and Medicaid Services, Department of Health and Human Services, Director, Office for Civil Rights, Secretary, Department of Health and Human Services. (Attachments: # 1 Exhibit 1 -- Transcript of Preliminary Injunction Proceedings, Doe v. Noggle, No. 1:23-cv-02904-SEG (N.D. Ga. Aug. 10, 2023))(Holland, Liam) (Entered: 06/26/2024)
06/28/2024	40	NOTICE of supplemental authority re 34 Response by Catholic Medical Association. (Pope, Allison) (Entered: 06/28/2024)
07/03/2024	41	**ORDER granting in part and denying in part 12 Motion for Preliminary Injunction. Signed by Judge William F. Jung on 7/3/2024. (Jung, William)** (Entered: 07/03/2024)
07/08/2024	42	Consent MOTION for Extension of Time to File Answer re 1 Complaint by All Defendants. (Holland, Liam) (Entered: 07/08/2024)
07/08/2024	43	**ENDORSED ORDER granting 42 Consent Motion for Extension of Time to Answer. All Defendants' answer or response to the complaint is due 9/9/2024. Signed by Judge William F. Jung on 7/8/2024. (CCB)** (Entered: 07/08/2024)

07/24/2024	44	TRANSCRIPT of Motion Hearing held on 6.21.24 before Judge William F. Jung. Court Reporter/Transcriber: Susie Cayler. Email address: reportercayler@gmail.com. Telephone number: 15157785008. NOTICE TO THE PARTIES - The parties have seven (7) calendar days to file with the court a Notice of Intent to Request Redaction of this transcript. If no such notice is filed, the transcript may be made remotely available to the public without redaction after ninety (90) calendar days. Transcript may be viewed at the court public terminal or purchased through the Court Reporter/Transcriber before the deadline for Release of Transcript Restriction. After that date it may be obtained through PACER or purchased through the Court Reporter. Redaction Request due 8/14/2024. Redacted Transcript Deadline set for 8/26/2024. Release of Transcript Restriction set for 10/22/2024. (Cayler, Susan) (Entered: 07/24/2024)
08/29/2024	45	NOTICE of Appearance by Zachary Sherwood on behalf of Administrator, Centers for Medicare and Medicaid Services, Centers for Medicare and Medicaid Services, Department of Health and Human Services, Director, Office for Civil Rights, Secretary, Department of Health and Human Services (Sherwood, Zachary) (Entered: 08/29/2024)
08/30/2024	46	NOTICE OF APPEAL as to 41 Order on Motion for Preliminary Injunction by Administrator, Centers for Medicare and Medicaid Services, Centers for Medicare and Medicaid Services, Department of Health and Human Services, Director, Office for Civil Rights, Secretary, Department of Health and Human Services. Filing fee not paid. (Sherwood, Zachary) (Entered: 08/30/2024)
09/03/2024	47	MOTION to Stay *Proceedings* by Administrator, Centers for Medicare and Medicaid Services, Centers for Medicare and Medicaid Services, Department of Health and Human Services, Director, Office for Civil Rights, Secretary, Department of Health and Human Services. (Sherwood, Zachary) (Entered: 09/03/2024)
09/03/2024	48	RESPONSE in Opposition re 47 MOTION to Stay *Proceedings* filed by Florida Agency for Health Care Administration, Florida Department of Management Services. (Conde, James) (Entered: 09/03/2024)
09/04/2024	49	TRANSMITTAL of initial appeal package to USCA consisting of copies of notice of appeal, docket sheet, order/judgment being appealed, and motion, if applicable to USCA re 46 Notice of Appeal. Eleventh Circuit Transcript information form forwarded to pro se litigants and available to counsel at www.flmd.uscourts.gov under Forms and Publications/General. (LNR) (Entered: 09/04/2024)
09/05/2024	50	**ENDORSED ORDER granting in part and denying in part 47 Motion to Stay. This case is stayed pending a telephonic status conference that will be set by the Court. Signed by Judge William F. Jung on 9/5/2024. (CCB)** (Entered: 09/05/2024)
09/05/2024		Case Stayed. (Case inadvertently lifted on 12/13/2024) (BD) (Entered: 12/13/2024)
09/10/2024	51	NOTICE of Telephonic Hearing: Status Conference set for 11/13/2024 at 9:00 AM before Judge William F. Jung. Counsel are directed to call the reserved conference toll free number at 1-888-557-8511. Enter the access code: 4744914 followed by the # (pound) key. You will be prompted to enter the security code: 1080 followed by the # (pound) key. Please call in at least 10 minutes before the scheduled hearing. (CCB) (Entered: 09/10/2024)
09/11/2024	52	NOTICE OF CROSS APPEAL as to 41 Order on Motion for Preliminary Injunction by Catholic Medical Association. (Blake, Julie) (Entered: 09/11/2024)
09/12/2024	53	TRANSMITTAL of initial appeal package to USCA consisting of copies of notice of appeal, docket sheet, order/judgment being appealed, and motion, if applicable to USCA re

		52 Notice of Cross Appeal. Eleventh Circuit Transcript information form forwarded to pro se litigants and available to counsel at www.flmd.uscourts.gov under Forms and Publications/General. (KME) (Entered: 09/12/2024)
09/12/2024		FEE PAID. Appeal fee, Receipt No. AFLMDC-22513165 for $605 paid Notice for appeal to the Eleventh Circuit Court of Appeals. (Blake, Julie) (Entered: 09/12/2024)
09/18/2024	54	TRANSCRIPT information form filed by Administrator, Centers for Medicare and Medicaid Services, Centers for Medicare and Medicaid Services, Department of Health and Human Services, Director, Office for Civil Rights, Secretary, Department of Health and Human Services for proceedings held on 06/21/2024 before Judge Jung re 46 Notice of Appeal USCA number: 24-12826. Electronic notification sent to Court Reporter Susan Caylor (Holland, Liam) (Entered: 09/18/2024)
09/19/2024	55	COURT REPORTER ACKNOWLEDGMENT by Susie Cayler re 46 Notice of Appeal,. Estimated transcript filing date: 9.20.24. USCA number: 24-12826. (Cayler, Susan) (Entered: 09/19/2024)
09/19/2024	56	NOTIFICATION that transcript has been filed by Susie Cayler re: 46 Notice of Appeal,. USCA number: 24-12826. (Cayler, Susan) (Entered: 09/19/2024)
10/10/2024	57	TRANSCRIPT information form filed by Catholic Medical Association re 52 Notice of Cross Appeal. USCA number: 24-12826. No transcript(s) requested. (Bowman, Matthew) (Entered: 10/10/2024)
11/12/2024	58	**ENDORSED ORDER: Counsel, there is no need for a status conference tomorrow and it is canceled. Please file a one-page update no later than November 15, informing the Court your view of the present status before this District Court. Consider in this short discussion the pending appeals as well as the likelihood of mootness given a pending change in administration. Signed by Judge William F. Jung on 11/12/2024. (Jung, William)** (Entered: 11/12/2024)
11/12/2024	59	NOTICE canceling status conference hearing scheduled for 11/13/2024. (CCB) (Entered: 11/12/2024)
11/15/2024	60	RESPONSE re 58 Order filed by Catholic Medical Association, Florida Agency for Health Care Administration, Florida Department of Management Services, State of Florida. (Conde, James) (Entered: 11/15/2024)
11/15/2024	61	STATUS report by Secretary, Department of Health and Human Services, Director, Office for Civil Rights, Administrator, Centers for Medicare and Medicaid Services, Centers for Medicare and Medicaid Services, Department of Health and Human Services. (Holland, Liam) (Entered: 11/15/2024)
12/13/2024	62	**ENDORSED ORDER directing the Clerk to administratively close this case. Any party may reopen at any time by filing a motion. Signed by Judge William F. Jung on 12/13/2024. (CCB)** (Entered: 12/13/2024)

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Transaction Receipt

12/30/2024 16:51:26

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Description:	Docket Report	**Search Criteria:**	8:24-cv-01080-WFJ-TGW

IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

STATE OF FLORIDA; FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION; FLORIDA DEPARTMENT OF MANAGEMENT SERVICES; CATHOLIC MEDICAL ASSOCIATION, on behalf of its current and future members,

Plaintiffs,

No. 8:24-cv-1080

DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, in his official capacity as Secretary of the Department of Health and Human Services; MELANIE FONTES RAINER, in her official capacity as the Director of the Office for Civil Rights; CENTERS FOR MEDICARE AND MEDICAID SERVICES; CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of the Centers for Medicare and Medicaid,

Defendants.

COMPLAINT FOR DECLARATORY RELIEF AND PRELIMINARY AND PERMANENT INJUNCTIVE RELIEF

INTRODUCTION

1. Under the guise of federal non-discrimination rules, the Department of Health and Human Services ("HHS") seeks to redefine the practice of medicine. HHS's rules threaten the livelihood of doctors who refuse to provide experimental, sterilizing, "gender-change" interventions to persons suffering from psychological distress—including minor children. To do so, HHS purports to override the State of

Florida's laws and regulations protecting the health and safety of its residents. HHS further threatens the loss of federal funds for States and insurance issuers that refuse to cover these interventions. Plaintiffs bring this action to stop HHS's interference with the ethical practice of medicine and state police powers.

2. Section 1557 of the Affordable Care Act ("ACA") forbids covered entities, including States, from discriminating in health programs or activities "on the ground prohibited under … title IX of the Education Amendments of 1972." 42 U.S.C. § 18116(a). Title IX, in turn, prohibits discriminating "on the basis of sex." 20 U.S.C. § 1681(a).

3. On May 6, 2024, HHS and the Centers for Medicare and Medicaid Services ("CMS") promulgated rules purporting to implement Section 1557 (collectively, the "2024 Rules"). 89 Fed. Reg. 37,522 (May 6, 2024).

4. But the 2024 Rules go far beyond the limits of Section 1557 and Title IX. The 2024 Rules require Florida to allow and even fund drugs and surgeries for "gender-transition." The 2024 Rules do this through a series of missteps that are foreclosed by logic and Eleventh Circuit precedent.

5. First, the 2024 Rules define "[d]iscrimination on the basis of sex" to include discriminating based on "(i) Sex characteristics, including intersex traits; (ii) Pregnancy or related conditions; (iii) Sexual orientation; (iv) Gender identity; and (v) Sex stereotypes." 89 Fed. Reg. at 37,699, *to be codified at* 45 C.F.R. § 92.101(a)(2). Despite this, HHS claims "it is not necessary to define 'sex' in this rule." 89 Fed. Reg. at 37,575.

6. Second, the 2024 Rules make it presumptively discriminatory for covered hospitals, clinics, residential treatment centers, medical practices, and pharmacies to "[d]eny or limit" puberty blockers, cross-sex hormones, or surgeries "sought for purpose of gender transition," if covered entities provide those services for "other purposes." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.206(b)(4). For example, under the final rule, a gynecological surgeon who performs a hysterectomy to treat endometrial cancer is presumptively required to remove a healthy uterus for a "gender transition." *Id.*; *see also* Notice of Proposed Rulemaking ("NPRM"), 87 Fed. Reg. 47,824, 47,867 (Aug. 4, 2022).

7. A medical practice that refuses to assist a gender transition may avoid sanctions if HHS's Office for Civil Rights ("OCR") deems a refusal "clinically appropriate *for a particular individual*." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.206(c) (emphasis added). OCR will review "medical necessity standards or guidelines" to ensure a clinical or ethical judgment is "bona fide" in a particular case, and not pretextual. 89 Fed. Reg. at 37,613.

8. Repeatedly, however, HHS emphasizes that covered entities must make an "*individualized* clinical judgment" for gender-change interventions. *Id.* at 37,575, 37,595–97 (emphasis added). OCR will review a "non-categorical denial[]" of a gender-change intervention "on a case-by-case basis." *Id.* at 37,607. The implied threat is clear: Any medical provider that categorically refuses to follow OCR's preferred "standards or guidelines" of care—*i.e.*, gender transition—risks crippling enforcement proceedings and punishment.

9. Third, on top of this, the 2024 Rules force States and insurance issuers to subsidize gender transitions. The 2024 Rules make it presumptively illegal for covered insurance providers and other entities—including States administering HHS programs such as ACA health-insurance exchanges, Medicaid, and a Childrens Health Insurance Program ("CHIP")—to set "limitations or restrictions" on claims "for specific health services related to gender transition" if doing so "results in discrimination on the basis of sex." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.207(b)(5). Again, under the 2024 Rules, sex discrimination includes discriminating based on "gender identity," and does not distinguish between providing a service for one purpose as opposed to another. *Id.* at 37,699, 37,701. An insurer that covers a hysterectomy to treat endometrial cancer is presumptively required to cover the removal of a healthy uterus for a "gender transition."

10. An insurance issuer or a State may avoid sanctions by showing no "medical necessity" for a gender-transition intervention in a particular case. But the 2024 Rules prohibit a "categorical coverage exclusion … for all health services related to gender transition." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.207(b)(4), (c). In other words, HHS has already determined that "gender transition" is medically necessary and that disagreeing with HHS is a pretext for discriminating on the basis of sex. Indeed, according to HHS, merely referring to gender-change interventions as "experimental or cosmetic would be considered evidence of pretext because this characterization is not based on current standards of medical care." NPRM, 87 Fed. Reg. at 47,874.

11. HHS's attempt to mandate gender-transition interventions and force States to subsidize the cost is unlawful under binding Eleventh Circuit precedent. To begin, the meaning of "sex" under Section 1557 extends no further than "sex" in Title IX. *See* 89 Fed. Reg. at 37,638 (admitting that "Section 1557 is best read to incorporate existing interpretations of what constitutes sex discrimination under title IX, including regulatory interpretations and case law"). In *Adams v. School Board of St. Johns County*, the Eleventh Circuit held that "sex" in Title IX *unambiguously* means "biological sex," *not* "sexual orientation" or "gender identity," 57 F.4th 791, 812–15 (11th Cir. 2022) (en banc).

12. Moreover, under *Adams*, the prohibition against discriminating "on the basis of sex" in Title IX must be read to permit some sex-based differences—including separate living facilities and bathrooms. *Id.* at 814 (citing 28 U.S.C. § 1686; 34 C.F.R. § 106.33). But reading Title IX to protect "'gender identity,' as [HHS does], would result in situations where an entity would be prohibited from" separating living facilities such as dual-occupancy hospital rooms based on sex whenever that comes "into conflict with a transgender person's gender identity." *Id.* That is wrong, and it is foreclosed by *Adams*. *Id.* "Whether [Section 1557] should be amended to equate 'gender identity' and 'transgender status' with 'sex'"—therefore—"should be left to Congress"—not an unelected administrative agency. *Id.* at 817. By purporting to do what may be done *only* by Congress, the 2024 Rules exceed HHS's statutory authority under Section 1557.

13. Further, a refusal to provide or subsidize these treatments is not "discrimination" anyway. 42 U.S.C. § 18116. *See Discriminate*, Webster's Third New International Dictionary 648 (1976) ("to make a difference in treatment or favor on a class or categorical basis in disregard of individual merit"); *Discrimination*, Black's Law Dictionary 534 (9th ed. 2009) ("failure to treat all persons equally when no reasonable distinction can be found between those favored and those not favored"). Refusing to provide interventions to anyone because of doubts about medical efficacy or ethical misgivings is not treating transgender individuals differently at all, much less on the basis of sex.

14. In medicine, therapeutic purpose matters. Removing organs with cancer is not "to [a doctor's mind], materially identical in all respects" to removing a healthy organ for a gender transition. *Bostock v. Clayton Cnty.*, 590 U.S. 644, 660 (2020). It is therefore not discriminatory for a State to prohibit interventions based on a clinical or ethical judgment that those interventions are not safe and effective or ethical to treat gender dysphoria, while allowing those interventions to treat materially *different* health conditions such as cancer.

15. HHS's false equivalency across treatments with different therapeutic purposes is foreclosed by logic and at odds with binding precedent. The Eleventh Circuit has held that a State does not discriminate or stereotype "on the basis of sex" (the exact same words used in Title IX) when it categorically forbids hormonal treatments or the removal of healthy organs for a gender transition. *Eknes-Tucker v. Governor of Ala.*, 80 F.4th 1205, 1227–30 (11th Cir. 2023) (Equal Protection Clause);

see id. at 1233–34 (Brasher, J., concurring). By ignoring material differences in therapeutic purpose, the 2024 Rules would fundamentally redefine the practice of medicine and place OCR lawyers in the strange position of overseeing—and second-guessing—the clinical and ethical judgments of health care professionals and state medical boards across the country.

16. Section 1557 is an ordinary non-discrimination law, not a Trojan horse empowering OCR to play doctor and decree gender-transition interventions as the federal standard of care through threats of enforcement. Because the 2024 Rules are unauthorized by law, violate the clear-notice requirements of the Spending Clause, raise major questions and usurp traditional police powers without clear authority, fail to grapple with contrary evidence showing gender-transition interventions are not safe and effective, and depart from prior agency positions without explaining or considering reliance interests, this Court must set aside the 2024 Rules as contrary to law and arbitrary and capricious.

PARTIES

17. Plaintiff State of Florida is a sovereign State and has the authority and responsibility to protect its public fisc and the health, safety, and welfare of its citizens. Florida has the sovereign authority to regulate the practice of medicine within the State, promulgate standards of care for licensed physicians, determine what medical procedures are reasonable for purposes of Medicaid coverage, and decide what services and procedures should be covered by its employee health insurance policies. Florida has agencies and healthcare facilities that receive federal financial assistance

and participate in HHS health-related programs subject to Section 1557 and the 2024 Rules.

18. Ashley Moody, the Attorney General of Florida, has authority to sue in the name of the State. *See* Fla. Stat. § 16.01(4)–(5). That power is incredibly broad, and includes the power to vindicate injuries to the State at any governmental level. *See, e.g.*, *Florida v. Nelson*, 576 F. Supp. 3d 1017, 1030 (M.D. Fla. 2021) (finding standing based on an injury to a state university); *Florida v. Becerra*, 544 F. Supp. 3d 1241, 1253–54 (M.D. Fla. 2021) (finding standing based on injuries to political subdivisions of the State).

19. Plaintiff Florida Agency for Health Care Administration ("AHCA") administers Florida's Medicaid and CHIP programs and assists CMS in regulating facilities that participate in Medicare. Exhibit 1, Kniepmann Decl. ¶¶ 1–2 ("Ex. 1").

20. Plaintiff Florida Department of Management Services ("DMS") is the business arm of Florida's government. DMS's primary mission is to support sister agencies as well as current and former state employees with workforce and business-related functions, including the provision of State Group Insurance. Exhibit 2, Sanders Decl. ¶ 3 ("Ex. 2").

21. Plaintiff Catholic Medical Association ("CMA") is the largest association of Catholic individuals in healthcare. CMA has 2,500 members nationwide in all fields of practice. CMA has a Florida statewide guild called the Florida Catholic Medical Association. CMA also has seven local Florida guilds, which are located in Gainesville, Miami, Orlando, Jacksonville, Palm Beach, Pensacola, and

St. Petersburg/Tampa Bay. CMA's 2024 national conference will be held in Orlando, Florida, as was CMA's 2021 national conference. CMA is organized as a Virginia nonprofit corporation.

22. Most CMA members provide medical care in health programs and activities that receive federal financial assistance and are subject to Section 1557. CMA seeks relief on behalf of its current and future members for all aspects of their practices.

23. CMA and its members hold the position that gender-transition procedures are unethical and dangerous. Providing, facilitating, referring for, or endorsing gender-transition efforts violates their medical views, their core religious beliefs, and their oath to "do no harm." CMA's members have medical and ethical positions contrary to the 2024 Rules' requirements, and they also have overlapping religious objections. It is within CMA's advocacy mission to advocate and litigate for its members' right to the conscientious and faithful practice of medicine.

24. The Executive Director of CMA is Mario Dickerson. Additional facts about CMA's membership are set forth in Mr. Dickerson's attached declaration ("Ex. 3") and in attached declarations from representative CMA members Dr. Michael S. Parker of Mansfield, Ohio ("Ex. 4"), and Dr. Quentin L. Van Meter of Atlanta, Georgia ("Ex. 5"). CMA's members are similarly situated to Drs. Parker and Van Meter.

25. Defendant Department of Health and Human Services is the agency of the United States that promulgated and now enforces the 2024 Rules.

26. Defendant Xavier Becerra is the Secretary of the Department of Health and Human Services. Plaintiffs sue Defendant Becerra in his official capacity only.

27. Defendant Melanie Fontes Rainer is the Director of the Office for Civil Rights within HHS and now enforces the 2024 Rules. Plaintiffs sue Defendant Fontes Rainer in her official capacity only.

28. Defendant Centers for Medicare and Medicaid Services is an agency within HHS.

29. Defendant Chiquita Brooks-LaSure is the Administrator of CMS. Plaintiffs sue Defendant Brooks-LaSure in her official capacity only.

JURISDICTION AND VENUE

30. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1346, and 1361.

31. Plaintiffs are "entitled to judicial review" under 5 U.S.C. § 702.

32. The Court is authorized to award the requested declaratory and injunctive relief against Defendants under 5 U.S.C. §§ 703, 706, 28 U.S.C. §§ 1361, 2201–02, the Constitution, and the Court's equitable powers.

33. This Court may award costs and attorneys' fees under the Equal Access to Justice Act, 28 U.S.C. § 2412, and the Religious Freedom Restoration Act ("RFRA"), 42 U.S.C. § 1988(b).

34. Venue is proper under 28 U.S.C. § 1391(e)(1) because an agency of the United States is a Defendant, and Plaintiff the State of Florida is a resident of every judicial district and division in its sovereign territory, including this judicial district

and division. *See Florida v. United States*, No. 3:21-cv-1066, 2022 WL 2431443, at *2 (N.D. Fla. Jan. 18, 2022) ("It is well established that a state 'resides at every point within its boundaries.'" (alteration omitted) (quoting *Atlanta & F.R. Co. v. W. Ry. Co. of Ala.*, 50 F. 790, 791 (5th Cir. 1892))); *see also California v. Azar*, 911 F.3d 558, 569–70 (9th Cir. 2018) ("[A] state with multiple judicial districts 'resides' in every district within its borders."); *Utah v. Walsh*, No. 2:23-cv-016-Z, 2023 WL 2663256, at *3 (N.D. Tex. Mar. 28, 2023) ("Texas resides everywhere in Texas."); *Alabama v. U.S. Army Corps of Eng'rs*, 382 F. Supp. 2d 1301, 1329 (N.D. Ala. 2005) ("[C]ommon sense dictates that a state resides throughout its sovereign borders.").

LEGAL BACKGROUND

I. The Affordable Care Act and Title IX

35. In March 2010, Congress passed, and President Obama signed, the ACA. Pub. L. No. 111-148, 124 Stat. 119.

36. Section 1557 of the ACA provides that "an individual shall not, on the ground prohibited under … title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.) … be excluded from participating in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving federal financial assistance, or under any program or activity that is administered by an Executive agency or any entity established under [the ACA]." 42 U.S.C. § 18116(a).

37. Section 1557 does not reference sexual orientation or gender identity. Its sole basis for prohibiting sex discrimination is a cross-reference to "the ground prohibited under … title IX (20 U.S.C. 1681 et seq.)."

38. Title IX states: "No person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance … ." 20 U.S.C. § 1681(a).

39. That general prohibition includes several sex-specific limitations and rules of construction. *Id.* Section 1686, for example, provides that nothing in Title IX "shall be construed to prohibit … maintaining separate living facilities for the different sexes." 20 U.S.C. § 1686.

40. Title IX furthermore does not apply to covered entities "controlled by a religious organization if the application of this subsection would not be consistent with the religious tenets of such organization." 20 U.S.C. § 1681(a)(3).

41. Section 1554 of the ACA provides that "notwithstanding any other provision of [the ACA, HHS] shall not promulgate any regulation that— … violates the principles of informed consent and the ethical standards of health care professionals." 42 U.S.C. § 18114(5).

42. Section 1557 applies to what HHS calls "covered entities," which includes recipients of federal financial assistance programs such as Medicaid and CHIP. Covered entities include hospitals, clinics, and doctors that accept patients

paying for services through these financial assistance programs, as well as pharmacies and insurance issuers.

43. An entity "any part of which" participates in HHS financial assistance programs is subject in all aspects of its health programs and activities to Section 1557. *Id.* § 18116(a). That means that any hospital or doctors' office that accepts a single Medicaid or CHIP patient must follow Section 1557 for *all* its patients, no matter how other patients pay for care.

44. The ACA incorporates Title IX's public and private enforcement mechanisms for Section 1557 and HHS's implementing regulations. 42 U.S.C. § 18116(a).

45. If OCR finds a covered entity in noncompliance, HHS may require providers to take remedial action or lose federal funding.

46. Section 1557 allows members of the public to sue covered entities to require compliance and seek damages. *See Cummings v. Premier Rehab Keller, P.L.L.C.*, 596 U.S. 212, 218 (2022).

II. Prior 1557 Rules, Guidance, and Related Litigation

A. The 2016 Rules

47. On May 18, 2016, HHS published rules purporting to implement Section 1557. Those rules defined discriminating "on the basis of sex" to include discriminating against an individual "on the basis of pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical

conditions, sex stereotyping, and gender identity." 81 Fed. Reg. 31,376, 31,467 (May 18, 2016). HHS defined the term "gender identity" in that rule as "an individual's internal sense of gender, which may be male, female, neither, or a combination of male and female, and which may be different from an individual's sex assigned at birth." *Id.* at 31,467.

48. On December 21, 2016, the U.S. District Court for the Northern District of Texas vacated the 2016 rules and enjoined HHS from "enforcing the [rules] prohibition against discrimination on the basis of gender identity or termination of pregnancy." *Franciscan All., Inc. v. Burwell*, 227 F. Supp. 3d 660, 696 (N.D. Tex. 2016). On gender identity, the Court reasoned that "the meaning of sex in Title IX unambiguously refers to 'the biological and anatomical difference between male and female students as determined at their birth.'" *Id.* at 687. It then held that "HHS's expanded definition of sex discrimination exceeds the grounds incorporated by Section 1557." *Id.* at 689.

49. The Court's vacatur of the 2016 rules remains "in effect." *Franciscan All., Inc. v. Becerra*, 47 F.4th 368, 377 (5th Cir. 2022) ("In short, Franciscan Alliance's APA claim is moot, its RFRA claim is not, and we leave the district court's vacatur of the 2016 Rule in effect."); *see also Religious Sisters of Mercy v. Becerra*, 55 F.4th 583, 609 (8th Cir. 2022) ("affirm[ing] the district court's grant of permanent injunctive relief against a requirement to provide 'gender-transition procedures' under Section 1557 on the ground that it violates the Religious Freedom Restoration Act").

B. The 2020 Rules

50. On June 12, 2020, HHS issued new rules rescinding the 2016 rules. 85 Fed. Reg. 37,160 (June 19, 2020) (the "2020 Rules").

51. The 2020 Rules repealed HHS's expansive definition of "on the basis of sex" and relied instead on the self-executing text of Section 1557, which speaks for itself. It also recognized the applicability of Title IX's religious exemption.

52. On June 15, 2020, three days after HHS issued its new rules, the U.S. Supreme Court decided *Bostock v. Clayton County*, 590 U.S. 644 (2020).

53. *Bostock* interpreted Title VII of the Civil Rights Act of 1964, which prohibits employers from discriminating "because of … sex." 42 U.S.C. § 2000e-2(a)(1). The Court in *Bostock* "proceed[ed] on the assumption that 'sex'" refers "only to biological distinctions between male and female." *Bostock*, 590 U.S. at 655. The Supreme Court then interpreted the text of Title VII to mean that "[a]n employer violates Title VII when it intentionally fires an individual employee based in part on sex." *Id.* at 659. "If the employer intentionally relies in part on an individual employee's sex when deciding to discharge the employee—put differently, if changing the employee's sex would have yielded a different choice by the employer—a statutory violation has occurred." *Id.* at 659–60.

54. Applying that rule to employers who fired their employees solely on the basis of the employee "being homosexual or transgender," the Supreme Court held the employers could be liable under Title VII. As the Court explained, when an employer fires a man who identifies as a woman solely for "traits or actions" it

tolerates in a female colleague, the employees "are, to the employer's mind, materially identical in all respects, except that one is a man and the other a woman." *Id.* at 660. The Court reasoned that biological sex is, therefore, a but-for cause of the employees' disparate treatment.

55. The Court, however, made clear its decision was limited to employment discrimination under Title VII. "The employers worry that our decision will sweep beyond Title VII to other federal or state laws that prohibit sex discrimination. … But none of these other laws are before us, we have not had the benefit of adversarial testing about the meaning of their terms, and we do not prejudge any such question today." *Id.* at 681.

56. After *Bostock*, "[t]wo courts entered nationwide injunctions preventing much of the 2020 Rule[s] from going into effect, effectively reinstating portions of the 2016 Rule[s]," even though the 2016 rules had already been vacated. *Franciscan All.*, 47 F.4th at 372 (citing *Whitman-Walker Clinic, Inc. v. HHS*, 485 F. Supp. 3d 1, 60 (D.D.C. 2020); *Walker v. Azar*, 480 F. Supp. 3d 417, 420 (E.D.N.Y. 2020)). These courts concluded that, "in light of *Bostock*, sex-stereotyping discrimination encompasses gender identity discrimination." *Id.* at 372–73.

C. The 2021 and 2022 Notices

57. The day he was sworn into office, President Biden issued an executive order asserting that "laws that prohibit sex discrimination … prohibit discrimination

on the basis of gender identity or sexual orientation." Exec. Order No. 13,988, 86 Fed. Reg. 7023, 7023 (Jan. 20, 2021).

58. On May 25, 2021, pursuant to this executive order, HHS published a document titled "Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972." 86 Fed. Reg. 27,984 (May 25, 2021). The May 2021 notice announced that "consistent with the Supreme Court's decision in *Bostock* and Title IX," HHS would "interpret and enforce section 1557 of the Affordable Care Act prohibition on discrimination on the basis of sex to include: Discrimination on the basis of sexual orientation; and discrimination on the basis of gender identity." *Id.* at 27,984.

59. Shortly thereafter a group of physicians challenged the notification on the grounds that it would force them to treat youth suffering from gender dysphoria in a manner that violated their clinical judgment and conscience. *Neese v. Becerra*, No. 2:21-cv-163-Z, 2022 WL 16902425, at *1–2 (N.D. Tex. Nov. 11, 2022). The U.S. District Court for the Northern District of Texas found the Notification to be "not in accordance with the law." *Id.* at 3. The Court entered a declaratory judgment declaring that "Section 1557 of the ACA does not prohibit discrimination on account of sexual orientation and gender identity, and the interpretation of 'sex' discrimination that the Supreme Court of the United States adopted in [*Bostock*] is inapplicable to the prohibitions on 'sex' discrimination in Title IX of the Education Amendments of 1972 and in Section 1557 of the ACA." Final Judgment, *Neese*, 2:21-cv-163-Z (N.D. Tex. Nov. 22, 2022), ECF No. 71.

60. In March of 2022, HHS published another document titled "Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy," https://perma.cc/LX26-59QR ("2022 Notice"). The 2022 Notice asserted that HHS "unequivocally" takes the position that restricting gender-change interventions even "for minors … is dangerous." HHS announced that its Office of Civil Rights would consider bringing enforcement actions against medical providers who comply with state laws that "restrict" the use of these interventions for minors. HHS also claimed that refusal to provide these interventions could be discriminating on the basis of disability. *Id.*

61. In *Texas v. Equal Employment Opportunity Commission*, the U.S. District Court for the Northern District of Texas vacated the 2022 Notice. 633 F. Supp. 3d 824, 847 (N.D. Tex. 2022). Among other things, the Court held that the 2022 Notice misread *Bostock*, and did not adequately explain how, despite the specific exclusion of gender identity disorders from the definition of disability in the Rehabilitation Act (and hence in Section 1557, *see* 42 U.S.C. § 18116(a) (including "section 794 of title 29"), failure to provide cross-sex hormones or surgeries to these individuals could be discriminating on the basis of a disability. *Id.* at 836–38.

FACTUAL BACKGROUND

I. Sex, Gender Dysphoria, and "Gender-Change" Interventions

A. Sex and Gender

62. As the Supreme Court and the Eleventh Circuit have observed, "sex … is an immutable characteristic." *Adams*, 57 F.4th at 807 (quoting *Frontiero v. Richardson*,

411 U.S. 677, 686 (1973) (plurality opinion)); *see also* Expert Report of Stephen B. Levine 8 (Feb. 23, 2022), *in* Attachments to Comments of Alliance Defending Freedom, *Factual Evidence*, HHS-OS-2022-0012-68192.

63. Sex, therefore, is not arbitrarily "assigned at birth," as HHS's terminology implies. Rather, an individual's sex is male or female "according to [the individual's] reproductive organs and functions assigned by the chromosomal complement." Inst. of Medicine, *Exploring the Biological Contributions to Human Health: Does Sex Matter* 13 n.2 (2001) (*Does Sex Matter*); Levine, *supra*, at 8–9 (same); *see also* Fla. Stat. § 456.001(8) ("'Sex' means the classification of a person as either male or female based on the organization of the human body of such person for a specific reproductive role, as indicated by the person's sex chromosomes, naturally occurring sex hormones, and internal and external genitalia present at birth."); *Sex*, American Heritage Dictionary 1605 (5th ed. 2011) ("Either of two divisions, designated female and male, by which most organisms are classified on the basis of their reproductive organs and functions.").

64. Sex should not be confused with "gender," which is increasingly understood by some to mean a person's "self-perception" as male, female, or perhaps something else. *Does Sex Matter*, *supra*, at 13 n.2. HHS, for example, claims that gender identity may be female, male, both, somewhere in between, or neither. 81 Fed. Reg. at 31,467. Unlike sex, gender cannot be reliably determined by inspecting reproductive organs or genetic testing. And unlike sex, gender is not an immutable characteristic. A person's gender identity may change over time.

65. Sex begins in the cells and the womb before anyone writes a birth certificate. "With some exceptions, individuals are either chromosomally XX and developmentally female or chromosomally XY and developmentally male." *Does Sex Matter*, *supra*, at 17. "It is the overriding presence of a gene on the Y chromosome (SRY) that results in development of the male gonadal pathway." *Id.* at 33. The testes start developing "by the 6th to 7th week of gestation." *Id.* at 55. By the 12th to 14th week, "male and female fetuses can be distinguished by inspection of the external genitalia." *Id.* at 61.

66. Physical differences between boys and girls become pronounced during puberty. This process of sexual maturation and growth is "primarily the consequence of testosterone secretion by the Leydig cells in boys and of estrogen secretion by the granulosa cells in girls." *Id.* at 66; *see also Adams*, 57 F.4th at 819–20 (Lagoa, J., specially concurring) (discussing some of the significant physical differences that develop during puberty).

67. Some individuals are born with disorders of sex development. These disorders may result in physiological traits that are inconsistent with chromosomal sex, and, in rare cases, a body that cannot be classified as male or female. These individuals are sometimes labeled "intersex." *See Adams*, 57 F.4th at 822–23 (Wilson, J., dissenting) (discussing "intersex people"). The prevalence of intersex individuals has been estimated at 1 in 5,000 per live birth. Leonard Sax, *How Common is Intersex? A Response to Anne Fausto-Sterling*, 39 J. Sex Res. 174 (2002). Intersex traits are caused

by congenital chromosomal, genetic, or hormonal abnormalities that prevent normal sexual development. *See* Levine, *supra*, at 9.

B. Gender Dysphoria

68. The American Psychological Association previously defined an incongruence between sex and gender as a "gender identity disorder." Am. Psych. Ass'n, *Diagnostic and Statistical Manual* 71 (3d ed. 1987).

69. In 2013, the American Psychological Association discontinued the term "gender identity disorder" and defined the psychological condition now known as "gender dysphoria" as a discomforting or distressing discordance between a person's biological sex and sense of "gender identity." Am. Psych. Ass'n, *Diagnostic and Statistical Manual* 451–53 (5th ed. 2013).

70. Not all transgender individuals experience "dysphoria." *Id.*

71. Gender dysphoria, like gender, is not necessarily permanent. In children, gender dysphoria usually resolves as the child undergoes puberty, as the child's gender identity may change. This is why "watchful waiting" became the standard approach for treating gender dysphoria in minors. Levine, *supra*, at 17–19.

C. The "Gender-Change" Protocol

72. "What the medical profession has come to call gender-affirming care was not available for minors until just before the millennium." *L.W. v. Skrmetti*, 83 F.4th 460, 467 (6th Cir. 2023). Over the past decade or so, influential interest groups in the United States have advocated for treating gender dysphoria by "affirming" a child or

adult's sense of incongruence with sex through a protocol of social, chemical, and surgical interventions aimed at changing a patient's physical characteristics and behavior to accord with his or her sense of "gender." *Id.* These groups claim these interventions, often labeled "gender-affirming care," are medically necessary for many, including minors undergoing puberty, even though the treatments may lead to infertility and other serious side effects.

73. One of these groups is the World Professional Association for Transgender Health ("WPATH"), which publishes what it styles as "standards of care" for treating gender dysphoria in both children and adults. *See* WPATH, *Standards of Care for the Health of Transgender and Gender Diverse People*, Version 8, 23 Int'l J. of Transgender Health S1 (2022) ("WPATH 8"); WPATH, *Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People*, Version 7 (2012), HHS-OS-2022-0012-4074 ("WPATH 7").

74. HHS has previously described WPATH as an "advocacy group." 85 Fed. Reg. at 37,186–87. For good reason. WPATH members must show a commitment to "transgender rights" and need not be medical professionals. Levine, *supra*, at 26. "Contrary viewpoints have been known to be shouted down and effectively silenced by the large numbers of nonprofessional adults who attend the organization's biennial meetings." *Id.*

75. According to WPATH, psychological treatment or counseling "aimed at trying to change a person's gender identity and expression to become more congruent with [biological sex] … is no longer considered ethical." WPATH 7, *supra*, at 16;

WPATH 8, *supra*, at S53 (same). WPATH's guidelines instead steer health care professionals into a gender-change regimen.

76. Another organization is the Endocrine Society, an association of endocrinologists that stand to benefit from an increase in the prevalence of hormone therapy. The Endocrine Society has published a guideline with recommendations for treating gender dysphoria in minors and adults. Although its recommendations "do not establish a standard of care" for gender dysphoria, the Endocrine Society claims hormonal and surgical interventions are medically necessary to treat many children as well as adults suffering from dysphoria. *See* Wyle C. Hembree, *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*, 10 J. Clin. Endocrinol Metab. 3869, 3896 (2017), HHS-OS-2022-0012-4060 ("Endocrine Society Guideline").

77. The gender-change protocol embraced by these groups proceeds in four escalating steps: (1) social transition and mental health treatment, (2) puberty blockers, (3) cross-sex hormones, and (4) sex-reassignment surgery. Jason Rafferty et al., *Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents*, 142 Pediatrics 1, 6–7 (2018) (Adults who have gone through puberty don't need puberty blockers.).

78. For pre-pubescent children, the protocol begins with "social transition"—that is, usually, encouraging a child to adopt the stereotypical behaviors, clothing, and hairstyle associated with members of the opposite sex, and allowing the child to adopt a name and pronouns used by the opposite sex. *Id.* at 6.

79. During the onset of puberty, the next step is administering a long-acting GnRH analogue, commonly known as a puberty blocker, to suppress the child's normal puberty, and hence the child's normal physical and sexual development. *Id.*

80. Most minors administered a puberty blocker for gender dysphoria are then prescribed supraphysiological levels of "cross-sex" hormones—hormones associated with the physiological development of the opposite sex: Estrogen for males, and testosterone for females. Levine, *supra*, at 48–49.

81. The last step is "gender-reassignment" surgery. That can include a double mastectomy to remove healthy breasts, "bottom surgery" to remove the healthy reproductive organs of either sex, and plastic surgery and cosmetic procedures to imitate the genitals and the physical appearance of the opposite sex. *See* WPATH 7, *supra*, at 57; WPATH 8, *supra*, at S258, App'x E (listing the procedures in a list that "is not intended to be exhaustive").

82. Gender-reassignment surgery cannot reassign sex. It does not change an individual's chromosomes or replace sexual organs with the functioning reproductive organs of the opposite sex. Rather, bottom-surgery renders an individual permanently infertile.

83. The medical guidelines of WPATH and the Endocrine Society have become more aggressive over time. "Today, these guidelines permit the use of puberty blockers or cross-sex hormones from the early stages of pubertal development. Therapy or time spent living as the desired gender is no longer required before or along with such treatments. Many surgical treatments initially restricted to adults have

become available to minors in the past six years, often without any prerequisites for therapy or cross-sex hormone treatments." *L.W.*, 83 F.4th at 467–68 (citations omitted).

84. Diagnoses for gender dysphoria have simultaneously increased. "In the last few years, the number of doctors prescribing sex-transition treatments and the number of children seeking them have grown." *Id.* at 468. At the same time, "[t]he percentage of youth identifying as transgender has doubled from 0.7% of the population to 1.4% in the past few years, while the percentage of adults (0.5% of the population) has remained constant." *Id.*

D. Health Risks of the Gender-Change Protocol

85. Although groups such as WPATH and the Endocrine Society claim these gender-change interventions have psychological benefits, "no one disputes that these treatments carry risks or that the evidence supporting their use is far from conclusive." *L.W.*, 83 F.4th at 489.

86. The FDA may approve the marketing of drugs as safe and effective to treat a condition based on "adequate and well-controlled investigations"—typically a double-blind, randomized, clinical trial. 21 U.S.C. § 355(d). The FDA has approved puberty blockers to rectify a hormonal imbalance in young children caused by precocious puberty, but it has not approved marketing these drugs as part of a regimen to treat gender dysphoria in minors or adults. The use of these drugs for that purpose is therefore "off-label."

87. As WPATH 7 acknowledged, "[t]o date, no controlled clinical trials of any feminizing/masculinizing hormone regimen have been conducted to evaluate safety or efficacy in producing physical transition." WPATH 7, *supra*, at 47. That remains true today.

88. Even supporters acknowledge that puberty blockers have health risks. The Endocrine Society, for example, acknowledges that the "primary risks of pubertal suppression" are "adverse effects on bone mineralization," "compromised fertility if the person subsequently is treated with sex hormones, and unknown effects on brain development." Endocrine Society Guideline, *supra*, at 3882.

89. Although little is known about the long-term effects of puberty blockers used for a gender transition on brain function and brain development, the FDA recently required drug manufacturers to warn that puberty blockers may cause "pseudotumor cerebri, including headache, papilledema, blurred or loss of vision, diplopia, pain behind the eye or pain with eye movement, tinnitus, dizziness and nausea." FDA, *Risk of Pseudotumor Cerebri Added to Labeling for Gonadotropin-Releasing Hormone Agonist* (July 1, 2022).

90. Cross-sex hormones such as testosterone and estrogen have not been approved by the FDA to treat gender dysphoria. (Testosterone is a Class III controlled substance because it "may lead to moderate or low physical dependence or high psychological dependence," so it is not available over the counter. 21 U.S.C. §§ 802(41), 812(b)(3)(C), (c), Schedule III(e)).

91. Cross-sex hormone interventions also have physical side effects and increase serious health risks. *See L.W.*, 83 F.4th at 489 (listing side effects and potential health risks in detail).

92. Giving adolescent girls the high doses of testosterone needed for a gender-change induces hyperandrogenism. According to WPATH 8, this causes "clitoral enlargement" (clitoromegaly), "vaginal atrophy" (atrophy of the vagina's lining), "deepening of the voice," "facial/body hair growth" (hirsutism), "acne," and "scalp hair loss." WPATH 8, *supra*, at S254, App'x C, Tbl. 1 (cleaned up); *see also* WPATH 7, *supra*, at 37 (similar).

93. According to WPATH 8, induced hyperandrogenism in adolescent girls also, at a minimum, increases the risk of "polycythemia" (bone marrow producing too many red blood cells, which increases the risk of blood clots and heart attacks), "infertility," "weight gain," "acne," "sleep apnea," "androgenic alopecia" (balding), "hypertension" (high blood pressure), "decreased HDL ['good'] cholesterol and increased LDL ['bad'] cholesterol," "cardiovascular disease," "hypertriglyceridemia" (high levels of triglycerides (fats) in the blood, leading to plaque buildup in arteries (atherosclerosis) which can result in heart attacks, strokes, blood clots, and similar complications), and possibly of "type 2 diabetes," among other health risks. WPATH 8, *supra*, at S254, App'x C, Tbl. 2 (cleaned up); *see also* WPATH 7, *supra*, at 40 (similar).

94. Giving adolescent boys high doses of estrogen induces hyperestrogenemia. According to WPATH 8, this causes "breast growth" "decrease

in muscle mass and strength," "softening of skin/decreased oiliness," and various forms of sexual dysfunction.

95. According to WPATH 8, induced hyperandrogenism in adolescent boys also, at a minimum, increases the risk of "venous thromboembolism" (life-threatening blood clots), "infertility," "cholelithiasis" (gallstones), "hyperkalemia" (high potassium levels that cause life-threatening heartbeat abnormalities, muscle weakness, or paralysis), "meningioma" (a primary central nervous system tumor), "polyuria/dehydration" (increased urine production), "weight gain," "hypertriglyceridemia" (high levels of triglycerides (fats) in the blood, leading to plaque buildup in arteries (atherosclerosis) which can result in heart attacks, strokes, blood clots, and similar complications), "cardiovascular disease," "cerebrovascular disease" (affecting the blood flow and blood vessels in the brain), and possibly "hypertension" (high blood pressure), "erectile dysfunction," "type 2 diabetes," "low bone mass/osteoporosis" (leading to weak and brittle bones), and "hyperprolactinemia" (high levels of the hormone prolactin, causing infertility and other issues). WPATH 8, *supra*, at S254, App'x C, Tbl. 2 (cleaned up); *see also* WPATH 7, *supra*, at 38, 40 (similar).

96. By suppressing sexual development during puberty, a cross-sex hormone regimen for minors will likely cause lifelong sterility. Levine, *supra*, at 67; WPATH 8, *supra*, at S254, App'x C, Tbl. 2 (warning of a "clinically significant" risk of infertility). That is why WPATH and the Endocrine Society recommend warning "adolescents" seeking gender-change interventions about the "potential loss of fertility and available

options to preserve fertility." WPATH 8, *supra*, at S57, S156–57 (discussing the risk of infertility from hormone interventions); Endocrine Society Guideline, *supra*, at 3871 (similar).

97. Bottom-surgery (the removal of healthy reproductive organs) also causes irreversible sterility. As WPATH acknowledges, the surgeries also lead to an increased risk of infection and other serious and potentially lifelong medical complications. WPATH 7, *supra*, at 62–64.

98. WPATH, the Endocrine Society, and other interest groups nevertheless claim the side effects and downsides of gender-change interventions, including infertility, are often outweighed by the purported benefits of reduced psychological distress resulting from gender dysphoria, improved mental well-being, and allegedly reduced suicide risk.

99. But the evidence available to date is not robust enough to conclude these hormones and surgeries increase long-term mental health outcomes, and persons with gender dysphoria continue to commit suicide at vastly disproportionate rates even after all these interventions. *See* Levine, *supra*, at 49–61.

100. Some experts believe this protocol may actually decrease mental wellbeing and increase suicide by, among other things, preventing desistance. Some believe it to be an unethical experiment on humans, particularly on minors. There is no universal consensus on these clinical or ethical questions, but one thing is clear: the evidence of benefit is weak at best, and the evidence of harm is clear. *See* Levine, *supra*, at 22–30; The Cass Review, *Independent Review of Gender Identity Services for Children and*

You People: Interim Report 47 (Feb. 2022), HHS-OS-2022-0012-4075 (finding no consensus); Comment of the Society for Evidence Based Gender Medicine (Oct. 3, 2022), HHS-OS-2022-0012-73218 (arguing that the empirical evidence of a benefit is weak and is outweighed by clear evidence of harm); Comment of Florida AHCA (Oct. 28, 2022), HHS-OS-2022-0012-69566 (same).

101. In other words, as the Fifth Circuit has observed, "the WPATH Standards of Care reflect not consensus, but merely one side in a sharply contested medical debate." *Gibson v. Collier*, 920 F.3d 212, 221 (5th Cir. 2019).

102. National public health authorities have taken a variety of views on the safety and efficacy of this protocol.

103. Start with HHS. In 2016, during the Obama Administration, HHS refused to require national coverage of gender-reassignment surgeries under Medicare, concluding in a thorough review that "[b]ased on an extensive assessment of the clinical evidence …, there is not enough high quality evidence to determine whether gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria and whether patients most likely to benefit from these types of surgical intervention can be identified prospectively." Tamara S. Jensen et al., Decision Memo, CAG #00446N (Aug. 30, 2016), https://perma.cc/R2ME-YQRA. "Overall, the quality and strength of evidence were low due to mostly observational study designs with no comparison groups, subjective endpoints, potential confounding (a situation where the association between the intervention and outcome is influenced

by another factor such as a co-intervention), small sample sizes, lack of validated assessment tools, and considerable lost to follow-up." *Id.*

104. In 2020, HHS again concluded that there is "a lack of scientific and medical consensus to support" this gender-change regimen. 85 Fed. Reg. at 37,187. HHS expressly noted the "lack of high-quality scientific evidence supporting such treatments." *Id.*

105. But during the Biden Administration, HHS changed its tune. In 2022, the Office of Population Affairs released a two-pager entitled "Gender-Affirming Care and Young People." https://perma.cc/H3CS-94KX. In this two-pager, the Office of Population Affairs asserted that "[r]esearch demonstrates that" so-called "gender-affirming care improves the mental health and overall well-being of gender diverse children and adolescents." *Id.* HHS further asserted that "[f]or transgender and nonbinary children and adolescents, early gender-affirming care is crucial to overall health and well-being." *Id.* The two-pager prominently highlighted the treatment guidelines from the Endocrine Society and WPATH. *Id.* At the same time, in the 2022 Notice, HHS threatened to sue anyone who disagreed with this purported "standard of care."

106. HHS's change in position is more striking because the international trend is in the opposite direction. The "public healthcare entities of Sweden, Finland, France, Australia, New Zealand, and the United Kingdom have raised concerns about the risks associated with puberty blockers and cross-sex hormone treatment and

supported greater caution and/or more restrictive criteria in connection with such interventions." *Eknes-Tucker*, 80 F.4th at 1218; Levine, *supra*, at 31.

107. For example, the Swedish National Board of Health has stated that "the risks of hormonal interventions for gender dysphoric youth outweigh potential benefits." *Summary of Key Recommendations from the Swedish National Board of Health and Welfare (Socialstyrelsen/NBHW)*, SEGM.org (Feb. 27, 2022), HHS-OS-2022-0012-10295, https://perma.cc/NWB6-3XEU. Finland's Council for Health Choices has concluded that gender-change interventions in minors are "an experimental practice" and that "no irreversible treatment should be initiated" before adulthood. *Medical Treatment Methods for Dysphoria Related to Gender Variance in Minors* (2020), https://perma.cc/PX74-4LBK. The United Kingdom has similarly restricted puberty blockers after finding the evidence inadequate to conclude they are safe and effective to treat gender dysphoria. *B.P.J. by Jackson v. W. Va. State Bd. of Educ.*, No. 23-1078, 2024 WL 1627008, at *18 n.7 (4th Cir. Apr. 16, 2024) (Agee, J., concurring in part and dissenting in part).

108. Plenty of governments are skeptical on this side of the Atlantic too. At least 21 states in the United States prohibit hormone treatment and surgery for minors suffering from gender dysphoria. *L.W.*, 83 F.4th at 471 (citing statutes).

II. Florida's Actions to Protect the Public from Experimental Treatments for Gender Dysphoria

109. Florida, for its part, has concluded that the alleged psychological benefits of gender-change interventions are far too speculative to justify the risks, particularly

in minors. Florida has accordingly acted to protect the health and safety of its citizens, protect the fertility and health of its youth, and promote the ethical practice of medicine.

A. Florida Guidance

110. "The purpose" of the Florida Department of Health ("DOH") "is to promote the health of all residents and visitors," by, among other things, "[r]egulat[ing] health practitioners for the preservation of the health, safety, and welfare of the public." Fla. Stat. § 20.43(1)(g).

111. On April 20, 2022, in response to the misleading two-pager published by the HHS Office of Population Affairs, DOH provided its own public guidance on the treatment of gender dysphoria in children. *Treatment of Gender Dysphoria for Children and Adolescents* (Apr. 20, 2022), https://perma.cc/BB4N-2QH4.

112. DOH noted that "[s]ystematic reviews on hormonal treatment for young people show a trend of low-quality evidence, small sample sizes, and medium to high risk of bias." *Id.* Citing a "lack of conclusive evidence, and the potential for long-term, irreversible effects," the DOH concluded that "social gender transition" should not be recommended to youth, "puberty blockers or hormone therapy" should not be prescribed to children under 18, and that "gender reassignment surgery should not be a treatment option for children or adolescents." *Id.*

B. Florida Medicaid

113. Medicaid is a public assistance program that provides medical services for low-income individuals. 42 U.S.C. §§ 1396-1, 1396a. It is "the primary federal

program for providing medical care to indigents at public expense." *Mem'l Hosp. v. Maricopa Cnty.*, 415 U.S. 250, 262 n.19 (1974). The program is administered jointly by the States and the federal government through a "contract[ual]" relationship. *NFIB v. Sebelius*, 567 U.S. 519, 577 (2012).

114. Florida Medicaid reimburses the "services and procedures" of a medical doctor when "medically necessary for the treatment of an injury, illness, or disease." Fla. Stat. § 409.905(9). But "clinically unproven" or "experimental treatments" are not reimbursed. *Id.* To qualify as medically necessary, AHCA rules require that the treatment be "consistent with generally accepted professional medical standards as determined by the Medicaid program, and not experimental or investigational." Fla. Admin. Code r. 59G-1.010(2.83).

115. Pursuant to its obligations, AHCA separately investigated the safety and efficacy of gender transition interventions to treat psychological distress. To make this determination, AHCA followed its regulatory process. *Id.* r. 59G-1.035.

116. As required by that process, on June 2, 2022, AHCA published a report, titled "Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria." https://perma.cc/7RZM-L3SN ("GAPMS Report").

117. The GAPMS Report included a lengthy review of the available evidence and literature, and the actions taken by public health authorities, and concluded that so-called "gender-affirming care" interventions are "experimental and investigational":

> Following a review of available literature, clinical guidelines, and coverage by other insurers and nations, Florida Medicaid has determined that the research supporting sex reassignment treatment is insufficient to demonstrate efficacy and safety. In addition, numerous studies, including the reports provided by the clinical and technical experts listed above, identify poor methods and the certainty of irreversible physical changes. Considering the weak evidence supporting the use of puberty suppression, cross-sex hormones, and surgical procedures when compared to the stronger research demonstrating the permanent effects they cause, these treatments do not conform to GAPMS and are experimental and investigational. *Id.* at 3.

118. The GAPMS Report concluded that the "treatments pose irreversible consequences, exacerbate or fail to alleviate existing mental health conditions, and cause infertility and sterility." *Id.* at 38. Consequently, the GAPMS Report "does not recommend sex reassignment treatment as a health service that is consistent with generally accepted professional medical standards." *Id.*

119. The GAPMS Report also attached five assessments by subject-matter experts in the field. *Id.* at 2. One of those five assessments "examined the quality of 61 articles published between 2020 and 2022" purporting to support treatment for gender dysphoria. *Id.* at 27. The expert review concluded these articles were of "low quality" and do not permit an inference that hormonal or surgical treatments reduce distress or suicide rates. *Id.*

120. Following the recommendations of the GAPMS Report, AHCA went through a public notice-and-comment rulemaking process and held a public hearing on the topic.

121. Thereafter, on August 21, 2022, AHCA promulgated Rule 59G-1.050(7). Under Rule 59G-1.050(7), Florida Medicaid will not cover services related to gender

transition including puberty blockers, hormone and hormone antagonists, sex-reassignment surgeries, and "any other procedures that alter primary or secondary sex characteristics." Fla. Admin. Code r. 59G-1.050(7).

C. Florida Medical Ethics

122. Under Florida law, DOH has a duty to regulate "health practitioners for the preservation of the health, safety, and welfare of the public." Fla. Stat. § 20.43(g).

123. The Florida Board of Medicine ("Board") is the state agency responsible for the regulation of licensed physicians. The Board has authority to establish "standards of practice and standards of care" for licensed physicians. Fla. Stat. § 458.331(1)(v).

124. On July 28, 2022, DOH petitioned the Board to initiate rulemaking on treatment of gender dysphoria in children and adults. DOH Petition, https://perma.cc/97HK-Y4XS.

125. The Petition observed that the "lack of quality evidence in support of gender transition treatments" had caused "confusion" in the medical community and posed a danger to public health. *Id.* at 5. It further observed that "the use of such treatments for gender dysphoria should be considered experimental and should require fully informed consent of the risks and limitations." *Id.* at 5–6. In particular, the Petition observed that "[c]hildren do not possess the cognitive or emotional maturity to comprehend the consequences of these invasive and irreversible procedures." *Id.* at 6. The Petition asked the Board to adopt a standard of care prohibiting surgery, puberty blockers, and hormones to treat gender dysphoria for patients under 18 years of age

and requiring the use of pre-approved informed consent forms for adults receiving these treatments. *Id.* at 6–7.

126. Effective March 16, 2023, the Florida Board of Medicine published Rule 64B8-9.019 which prohibits "(a) [s]ex reassignment surgeries, or any other surgical procedures, that alter primary or secondary sexual characteristics; [and] (b) [p]uberty blocking, hormone, and hormone antagonist therapies" for treatment of gender dysphoria in minors, except for minors already being treated with these drugs. Fla. Admin. Code r. 64B8-9.019.

127. Effective March 28, 2023, the Board of Osteopathic Medicine published Rule 64B15-14.014, which is identical to Rule 64B8-9.019. Fla. Admin. Code r. 64B15-14.014.

D. Florida Health and Safety Laws

128. On May 17, 2023, Florida Governor Ron DeSantis signed into law SB 254. SB 254 prohibits "sex-reassignment prescriptions or procedures" for minors, requires informed consent in adults, and requires that sex-reassignment services for adults be performed by a licensed physician. *See* Fla. Stat. §§ 456.001 (definitions), 456.52 (restrictions). SB 254 also prohibits the use of state funds for sex-reassignment interventions. *Id.* § 286.311.

129. On May 17, 2023, Governor DeSantis also signed into law HB 1521. HB 1521 requires educational institutions, detention facilities, correctional institutions, juvenile correctional facilities, and public buildings with a restroom or changing

facility to designate separate facilities based on sex or to provide one-person unisex facilities. *See* Fla. Stat. § 553.865(5), (12).

III. The 2024 Rules

130. The 2024 Rules are comprised of two different sets of rules. HHS is promulgating one set of rules purporting to implement Section 1557, to be codified in Part 92 of Title 45 of the Code of Federal Regulations and enforced by OCR (the "OCR Rules"). CMS is also promulgating separate non-discrimination rules for specific aid programs, relying on both Section 1557 and provisions of the Social Security Act and the Public Health Service Act.

131. With some exceptions, the 2024 Rules will be effective on Friday, July 5, 2024. 89 Fed. Reg. at 37,522.

A. The OCR Rules

132. The OCR Rules generally provide: "Discrimination on the basis of sex includes, but is not limited to, discrimination on the basis of: (i) Sex characteristics, including intersex traits; (ii) Pregnancy or related conditions; (iii) Sexual orientation; (iv) Gender identity; and (v) Sex stereotypes." 89 Fed. Reg. at 37,699, *to be codified at* 45 C.F.R. § 92.101(a)(2).

133. Section 206 would require covered entities such as hospitals, clinics, and pharmacies receiving federal funds to ensure "equal access" without discriminating based on sex. 89 Fed. Reg. at 37,700, *to be codified at* 45 C.F.R. § 92.206(a).

134. According to Section 206, equal access means health care providers may not "[d]eny or limit health services, including those that have been typically or exclusively provided to, or associated with, individuals of one sex, to an individual based upon the individual's sex assigned at birth, gender identity, or gender otherwise recorded." *Id.*, *to be codified at* 45 C.F.R. § 92.206(b)(1).

135. Section 206 further prohibits any policy or practice that separates or treats persons based on sex, including any policy or practice that prevents an individual from being treated "consistent with the individual's gender identity," if this causes the person harm—including emotional or dignitary harm—that is more than *de minimis*. *Id.* at 37,701, *to be codified at* 45 C.F.R. § 92.206(b)(3). For example, HHS explains, a hospital that assigns patients to dual-occupancy rooms based on sex would be *required* to allow a man who identifies as a woman to share a room with a woman. *Id.* at 37,593 ("A covered entity will be in violation of this rule if they refuse to admit a transgender person for care or refuse to place them in facilities consistent with their gender identity, because doing so would result in more than *de minimis* harm."); NPRM, 87 Fed. Reg. at 47,866–67.

136. Section 206 also specifically prohibits denying or limiting "health services sought for purpose of gender transition or other" so-called "gender-affirming care that the covered entity would provide to an individual *for other purposes* if the denial or limitation is based on an individual's sex assigned at birth, gender identity, or gender otherwise recorded." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.206(b)(4) (emphasis added). That includes, according to HHS, "counseling, hormone therapy,

surgery, and other services designed to treat gender dysphoria or support gender affirmation or transition." NPRM, 87 Fed. Reg. at 47,834 n.139; *see* 89 Fed. Reg. at 37,596 ("gender-affirming care" includes "hormone therapy, surgery, and other related services").

137. For example, under Section 206, it would be presumptively discriminatory for a clinic to prescribe and administer puberty blockers to treat precocious puberty—an FDA-approved use—but not a "gender transition"—a non-FDA-approved use. It would similarly be presumptively discriminatory for a hospital to provide an orchidectomy to treat testicular cancer, but refuse to remove healthy testicles for a "gender transition."

138. Section 206(c) purports to provide a safe harbor. A covered entity need not provide such services when the covered entity typically declines to provide such services to any individual for any diagnosis or when they are "not clinically appropriate for a particular individual." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.206(c). Accordingly, HHS at least acknowledges that a doctor can refuse to perform a prostate exam on a person "who does not anatomically have a prostate." *Id.* at 37,607. And OCR would review whether the services are "clinically appropriate" for a particular individual in the first instance. When it comes to gender-change interventions, OCR indicates it would review "medical necessity standards or guidelines" and "the clinical, evidence-based criteria or guidelines relied upon to make the medical necessity determination; and the medical substantiation for the medical necessity determination." *Id.* at 37,613. Decisions based on evidence or ethical and

moral reasoning that OCR deems insufficient "may be considered evidence of pretext for discrimination." *Id.*

139. Although OCR disclaims an attempt to mandate standards of care for gender-transition services in the final rule, the proposed rule mentioned the clinical "guidelines" it expects covered entities will follow: the guidelines of the WPATH and Endocrine Society, the entities discussed above at length. NPRM, 87 Fed. Reg. at 47,868 (asserting that covered entities "should follow clinical practice guidelines and professional standards of care," and citing WPATH 7 & Endocrine Society Guideline). OCR doesn't disavow that endorsement in the final rule or provide any examples of competing guidelines that would not require covered entities to support a "gender-transition."

140. The decision to refuse gender-change interventions "must not be based on unlawful animus or bias, or constitute a pretext for discrimination." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.206(c). This circular reasoning grants HHS wide discretion to decide who has "discriminated." HHS has made clear that it views a general or categorical refusal to provide gender-change interventions as "unlawful animus," even if required by state law. HHS repeatedly emphasizes that it might be permissible to refuse a gender-change intervention "*for a particular individual*," *id.*, *to be codified at* 45 C.F.R. § 92.206(c) (emphasis added), after exercising "*individualized* clinical judgment," *Id.* at 37,575, 37,595–97 (emphasis added). The negative implication is obvious: Any doctor who reviews the evidence above and decides that

a specific gender-change intervention is categorically too risky or unethical is a "discriminator."

141. OCR further announces that it will target any provider who does not hew to HHS's changed (and quite suspect) view of the evidence. OCR states its enforcement decisions will be informed by "consideration of … whether that covered entity demonstrated a willingness to refer or provide accurate information about gender-affirming care." 89 Fed. Reg. at 37,598. But a doctor who reviews the evidence and concludes, like 21 states and several Western European countries, that a gender-change protocol for minors or adults is dangerous and experimental medicine is not showing sufficient "willingness to … provide" HHS-approved "accurate information." *See* NPRM, 87 Fed. Reg. at 47,874.

142. Even providers that don't categorically rule out gender-change interventions can face enforcement at the whim of OCR under a malleable standard. If OCR concludes that a provider "reflect[ed] unlawful animus or bias" by "assert[ing]" a "judgment" that gender-change interventions are unwarranted in a particular case, *id.* at 37,598, then OCR can initiate enforcement proceedings, leading to a Star Chamber hearing in which HHS acts as prosecutor, judge, and jury. 45 C.F.R. §§ 80.8(c), 80.10; *see generally* HHS, *Guidelines—Civil Rights Reviewing Authority Review of Civil Rights Enforcement Decisions for HHS Programs*, https://perma.cc/D8RB-C654.

143. As the proposal made clear, in the view of HHS, claiming that gender-change interventions are "experimental or cosmetic would be considered evidence of pretext because this characterization is not based on current standards of medical

care," that is, the WPATH standards and the Endocrine Society Guideline discussed above. NPRM, 87 Fed. Reg. at 47,874. In other words, according to HHS, simply agreeing with the Florida Board of Medicine Standards of Medical Care, Finland's Council for Health Choices, or the Sixth Circuit, is evidence of animus. OCR seeks not just to coerce every covered entity to provide gender-transition interventions; it wants to chill any speech by covered entities that would discourage such interventions.

144. In response to First Amendment concerns about "what would be required of providers in terms of expressing support of transgender people who wish to access gender-affirming care, using the name and pronouns requested by patients, and speaking about gender-affirming care," OCR simply noted that whether "discrimination is unlawful or considered harassment is necessarily fact-specific" and that "conduct, including verbal harassment, that is so severe or pervasive that it creates a hostile environment on the basis of sex is a form of sex discrimination." 89 Fed. Reg. at 37,596.

145. As a result, under the OCR Rules, covered entities arguably cannot tell their patients that in their best medical opinions, gender-transition efforts or procedures are categorically experimental and dangerous. The OCR Rules arguably force covered entities to give patients the impression that "gender-transition" efforts can in some cases be clinically indicated or beneficial. They suggest that OCR may determine that a healthcare entity creates a hostile environment when it speaks in ways that categorically deny the medical legitimacy of gender transitions.

146. The OCR Rules likewise may consider it discrimination for a covered entity to categorically speak or write using a patient's pronouns that align with his or her sex according to the patient's biology if the patient prefers different pronouns that correspond to his or her gender identity. Under the OCR Rules, covered entities might need to refer to those persons using pronouns that are inconsistent with their sex.

147. Under the OCR Rules, covered entities may need to tell patients that males can get pregnant, give birth, and breastfeed. As HHS explains in the proposal, doctors are responsible for "'discrimination, stigma, and erasure'" if they speak or act in way that treats "pregnancy and childbirth … as something exclusively experienced by … women." NPRM, 87 Fed. Reg. at 47,865.

148. Section 207 applies to entities involved in federally funded health insurance and health-related coverage administered by HHS, such as Medicaid or CHIP. Section 207 generally prohibits discrimination in a variety of healthcare coverage and claim practices, in insurance benefit design, and in marketing practices. 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.207(a), (b)(1), (b)(2).

149. In addition, separate provisions within Section 207 specifically make it presumptively discriminatory for a covered entity to impose limits or restrictions on coverage or claims, including cost sharing, "based upon the individual's sex assigned at birth, gender identity, or gender otherwise recorded." *Id.*, *to be codified at* 45 C.F.R. § 92.207(b)(3). In the proposal, HHS suggested that denying "hormone therapy coverage" to a transgender person of color for a gender transition is, alone, evidence of "pervasive" "transphobia and racism." NPRM, 87 Fed. Reg. at 47,870.

150. Section 207 also makes it per se discriminatory to have a "categorical coverage exclusion or limitation for all health services related to gender transition or other gender-affirming care." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.207(b)(4).

151. Section 207 further makes it presumptively discriminatory to "deny or limit coverage, deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage, for specific health services related to gender transition or other gender-affirming care if such denial, limitation, or restriction *results in* discrimination on the basis of sex." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.207(b)(5) (emphasis added). This results-oriented text doesn't appear to require a discriminatory motive, but would reach facially neutral insurance policies that tend to screen out services used by transgender individuals, even if those policies are not motivated by sex or gender identity. *See Brnovich v. Democratic Nat'l Comm.*, 141 S. Ct. 2321, 2332 (2021) (citing 52 U.S.C. § 10301(a)).

152. That is, apparently, the point: according to HHS, excluding coverage for gender-transition services is unlawful disparate treatment because "transgender individuals are the only individuals who seek transition-related care." NPRM, 87 Fed. Reg. at 47,871. But by that logic, an issuer's refusal to cover vasectomies is discriminatory because only a male can get a vasectomy. *But see Eknes-Tucker*, 80 F.4th at 1229–30 ("[T]he regulation of a course of treatment that, by the nature of things, only transgender individuals would want to undergo" is not discrimination "on the

basis of sex" unless it were "mere pretext designed to effect an invidious discrimination" (cleaned up)).

153. Section 207(c) also purports to provide a safe harbor. It says it is not discriminatory to deny coverage "where the covered entity has a legitimate, nondiscriminatory reason for denying or limiting coverage of the health service or determining that such health service fails to meet applicable coverage requirements, including reasonable medical management techniques such as medical necessity requirements." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.207(c). "Such coverage denial or limitation must not be based on unlawful animus or bias, or constitute a pretext for discrimination," *id.*, *to be codified at* 45 C.F.R. § 92.207(c), which OCR will assess based on the "guidelines" discussed above. But there is no safe harbor for categorical judgments of medical necessity.

154. Failure to comply with the prohibitions of Section 1557 may cause Florida to lose all federal funding, including Medicaid funding. 45 C.F.R. §§ 80.8, 92.303.

B. The CMS Rules

155. The 2024 Rules also amend regulations relating to Medicaid, CHIP, and the Program of All-Inclusive Care for the Elderly ("PACE") (collectively, "CMS Rules").

156. The CMS Rules amend three pre-existing Medicaid and CHIP rules to include HHS's new, expansive interpretation of sex discrimination. The first relates to contracts with entities that deliver services. Those contracts must now include a

promise that the entities "will not discriminate against individuals eligible to enroll on the basis of … sex which includes sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes; and will not use any policy or practice that has the effect of discriminating on the basis of …sex which includes discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes." 89 Fed. Reg. at 37,691, *to be codified at* 42 C.F.R. § 438.3(d)(4). Under this rule, it would seem, any facially neutral policy or practice that has a discriminatory *effect* on transgender individuals, not just a discriminatory purpose, may violate the relevant contract.

157. In addition, those same entities must "promote the delivery of services in a culturally competent manner to all enrollees, … and regardless of sex which includes … gender identity." *Id.*, *to be codified at* 42 C.F.R. § 438.206(c)(2).

158. The other two rules require that States "have methods to promote access and delivery of services in a culturally competent manner to all beneficiaries, … and regardless of *sex* which includes sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes." *Id.* at 37,692, *to be codified at* 42 C.F.R. §§ 440.262 (Medicaid), 457.495(e) (CHIP).

159. For these amendments, CMS relies not only upon its authority under Section 1557, but also upon Section 1902(a)(4) of the Social Security Act ("SSA") for Medicaid, 42 U.S.C. § 1396a(a)(4), and Section 2101(a) of the SSA for CHIP, *id.* § 1397aa(a).

160. "CMS interprets sections 1902(a)(4) and 2101(a) of the SSA as authorizing CMS to adopt regulations prohibiting discrimination on the basis of gender identity or sexual orientation because such prohibitions on discrimination are necessary for the proper and efficient operation of a state plan, are in the best interest of beneficiaries, and enable states to provide child health assistance in an effective and efficient manner." NPRM, 87 Fed. Reg. at 47,892.

161. Under this regime, HHS also serves as lawmaker, prosecutor, and jury. HHS can withhold payments from States for noncompliance with state-plan requirements after notice and a hearing. 42 U.S.C. § 1396c; 42 C.F.R. § 430.35. When a State challenges that decision in court, "[t]he findings of fact by the Secretary, if supported by substantial evidence, shall be conclusive." 42 U.S.C. § 1316(a)(4); 42 C.F.R. § 430.38(c)(1).

162. PACE is a Medicare and Medicaid program that helps people meet their health care needs in the community instead of going to a nursing home or other care facility.

163. In Florida, PACE is administered by AHCA in consultation with the Department for Elder Affairs.

164. The 2024 Rules amend two PACE regulations: 42 C.F.R. §§ 460.98(b)(3) and § 460.112(a). Section 460.98 regulates services provided by State PACE programs, while § 460.112 establishes the rights of PACE participants. The 2024 Rules change the word "sex" to "sex (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex

stereotypes)" in the PACE regulations. *See* 89 Fed. Reg. at 37,692, *to be codified at* 42 C.F.R. §§ 460.98(b)(3), 460.112(a).

165. In addition to Section 1557, CMS relies upon the Public Health Service Act ("PSA") to promulgate the PACE-related statutory provisions, specifically Sections 1894(f)(A) and 1934(f)(A) of the SSA. 42 U.S.C. § 1395eee(f); *id.* § 1396u-4(f).

IV. Injury to Florida

166. AHCA and DMS administer health-related programs or activities that receive federal financial assistance or programs or activities administered by HHS as defined in the 2024 Rules, so they are subject to the 2024 Rules. They must comply with the rules or risk losing federal funds and being subject to private lawsuits for discrimination.

167. AHCA administers the state Medicaid, CHIP, and PACE programs, which are regulated by the 2024 Rules. Ex. 1 ¶ 2. Under state law, Florida Medicaid and CHIP currently do not cover or reimburse gender-transition hormonal or surgical interventions. *See* Ex. 1 ¶ 10–11.

168. In total, Florida Medicaid, CHIP, and PACE received $24,671,603,227 in federal funds from HHS in Fiscal Year 2022-2023. Ex. 1 ¶ 9.

169. DMS purchases and administers healthcare coverage plans for Florida's 310,750 active and retired state employees and their families. Specifically, the Division of State Group Insurance within DMS purchases and administers state employee and

retiree health insurance under the Florida State Group Health Insurance Program. DMS receives federal financial assistance from CMS through, for example, the Retiree Drug Subsidy. Ex. 2 ¶ 6. DMS is therefore a covered entity for this purpose under the OCR Rules.

170. For approximately 40 years, insurance coverage procured for the State Group Health Insurance Program has excluded gender-change interventions. Ex. 2 ¶ 7.

171. Florida law also requires generally excluding coverage for "sex-reassignment prescriptions or procedures" in "the state group health insurance program." Fla. Stat. § 286.311.

172. The 2024 Rules would purport to make that exclusion of coverage discriminatory. 45 C.F.R. § 92.207(b)(4). This would injure DMS and require the plan to incur additional claim costs. Ex. 2 ¶ 10.

173. Florida's Agency for Persons with Disabilities receives HHS funding and has a policy and practice of separating multiple-occupancy rooms in state hospitals on the basis of sex, regardless of gender identity.

174. Florida has also promulgated laws, rules, and standards of care restricting gender-change interventions and separating facilities based on sex to protect the health, safety, and fertility of Florida residents, particularly minors. *See supra* Part II. Florida has a sovereign interest in protecting these laws from conflicting federal agency rules that do not comply with federal law. *Florida v. Nelson*, 576 F. Supp. 3d 1017, 1032 (M.D. Fla. 2021) ("the state suffers sovereign injury when unlawful agency action

preempts state law"); *see also Texas v. United States*, 787 F.3d 733, 749 (5th Cir. 2015) ("States have a sovereign interest in the power to create and enforce a legal code" (cleaned up)).

A. Florida's Medicaid and CHIP Program

175. Under the 2024 Rules, Florida may not refuse reimbursement or coverage for gender-change interventions on the ground that they are "experimental" and not medically necessary healthcare treatments. The 2024 Rules would therefore require covering puberty blockers, cross-sex hormones, surgeries, and related services to treat gender dysphoria under Florida Medicaid, CHIP, and other state programs subject to the 2024 Rules, contrary to Florida law. Fla. Admin. Code r. 59-1.050(7); Fla. Stat. § 286.311.

176. According to WPATH 8, the purportedly medically necessary drug interventions for a gender transition include:

a. Prescribing and administering puberty blockers off-label, and;

b. Prescribing supraphysiological levels of cross-sex hormones off-label and related visits and tests.

177. According to WPATH 8, the purportedly "medically necessary" so-called "gender-affirming surgical procedures," WPATH 8, *supra*, at S18, S128, include the following:

a. "Hysterectomy" (removal of healthy uterus);

b. "Mastectomy" (removal of healthy breasts);

c. "Salpingo-oophorectomy" (removal of healthy ovaries and fallopian tubes);

d. "Orchiectomy" (removal of healthy testicles);

e. "Phalloplasty" (constructing penis-like structure using tissue from skin), including "urethral lengthening," "prosthesis," "colpectomy" (closure of healthy vagina), "colpoclesis" (shortening of healthy vagina), and "scrotoplasty" (creating new scrotums);

f. "Metoidioplasty" (constructing penis-like structure using tissue from a hormone-enlarged clitoris), including "urethral lengthening," "prosthesis," "colpectomy" (closure of healthy vagina), "colpoclesis" (shortening of healthy vagina), and "scrotoplasty" (creating new scrotums);

g. "Vaginoplasty" (constructing vagina-like structure), including methods of "[penile] inversion" (using combination of skin surrounding penis and scrotal skin), "peritoneal [flaps pull-through]" (pulling down peritoneum (inner lining of abdominal wall) into space between rectum and urethra/prostate), and "intestinal" technique (using section of terminal large intestine);

h. "Vulvoplasty" (constructing vulva-like structures)

i. "Hair line advancement and/or hair transplant;"

j. "Facelift/mid-face lift (following alteration of the underlying skeletal structures);"

k. "Platysmaplasty" (neck lift);

l. "Blepharoplasty" (eye and lid modification);

m. "Rhinoplasty" (nose reshaping);

n. "Cheek" surgery, including "implant[s]" and "lipofilling;"

o. "Lip" surgery, including "augmentation" and "upper lip shortening;"

p. "Lower jaw" surgery, including "augmentation" and "reduction of the mandibular angle" (cutting or shaving the corner of the lower jaw);

q. "Chin reshaping" surgery;

r. "Chondrolaryngoplasty" (shaving down Adam's apple);

s. "Vocal cord surgery;"

t. "Breast reconstruction" and "augmentation" (mammoplasty);

u. "Body contouring" surgeries, including "liposuction," "lipofilling," and "implants" (such as "pectoral, hip, gluteal, [and] calf");

v. "Monsplasty" (reduction of mons pubis tissue around the public bone, which is more pronounced in biological females);

w. "Nipple-areola tattoo;"

x. "Uterine transplantation" (uterus from donor);

y. "Penile transplantation" (penis from donor);

z. "Hair removal," including "laser epilation" (laser removal) or "electrolysis" (permanent removal by destroying hair follicles).

WPATH 8, *supra*, at S258, App'x E (cleaned up).

178. WPATH claims that "it is imperative to understand this list is not intended to be exclusive." WPATH 8, *supra*, at S258, App'x E.

179. The 2024 Rules will have a "substantial" fiscal effect on Florida. NPRM, 87 Fed. Reg. at 47,903. Although the total potential fiscal exposure is difficult to measure, covering gender-transition treatments under Florida Medicaid and CHIP could cost some $200,000,000 a year. Ex. 1 ¶ 21.

180. This cost, to be sure, pales in comparison with the human cost of aiding and abetting experimental interventions that could render thousands of Floridian minors infertile for life.

B. Florida's Standard of Care

181. "[T]he State has a significant role to play in regulating the medical profession," *Gonzales v. Carhart*, 550 U.S. 124, 157 (2007), as well as "an interest in protecting the integrity and ethics of the medical profession," *Washington v. Glucksberg*, 521 U.S. 702, 731 (1997). This includes "maintaining high standards of professional conduct" in the practice of medicine. *Barsky v. Bd. of Regents of Univ. of N.Y.*, 347 U.S. 442, 451 (1954).

182. The State also "has an interest in protecting vulnerable groups … from mistakes," *Glucksberg*, 521 U.S. at 731, and in "the elimination of particularly gruesome or barbaric medical procedures," *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 301 (2022). Furthermore, "[i]t is evident beyond the need for elaboration that a State's interest in 'safeguarding the physical and psychological well-being of a

minor' is 'compelling.'" *New York v. Ferber*, 458 U.S. 747, 756 (1982) (quoting *Globe Newspaper Co. v. Superior Court*, 457 U.S. 596, 607 (1982)).

183. As described in Part II, Florida has enacted laws and promulgated rules delineating the proper standard of medical care as it relates to children suffering from gender dysphoria. Florida's Board of Medicine and Board of Osteopathic Medicine developed their standard of care after careful review of the available literature and studies. The Florida legislature and Surgeon General have also reached similar conclusions about health and safety and restricted cross-sex hormones and surgeries for minors more broadly.

184. Most medical providers in Florida, however, accept federal funds and are "covered entit[ies]" under the 2024 Rules. The 2024 Rules will therefore force healthcare providers in Florida to choose between accepting federal funds and complying with Florida law regarding treatments for persons suffering from gender dysphoria. Indeed, under the 2024 Rules, compliance with Florida's ethical requirements, laws, and regulations may be deemed a pretextual reason for discriminating, triggering an Office of Civil Rights investigation, and potentially, an enforcement proceeding.

V. Injury to Catholic Medical Association Members

A. The OCR Rules' New Policy and Training Requirements

185. The OCR Rules prohibit covered entities from having or applying policies not "consistent with" the OCR Rules' definition of sex discrimination or the

Rules' prohibitions. The OCR Rules require covered entities to adopt and publish policies that comply with the OCR Rules. 89 Fed. Reg. at 37,696–99, *to be codified at* 45 C.F.R. §§ 92.8(a), (b), & (h), 92.101.

186. The OCR Rules require covered entities to provide an updated notice of nondiscrimination to patients stating that they will not discriminate on the basis of gender identity. 89 Fed. Reg. at 37,697, *to be codified at* 45 C.F.R. § 92.10(a)(1)(i). The notice to patients must be provided annually and on request. *Id.* at 37,698, *to be codified at* 45 C.F.R. § 92.10(a)(2)(i)–(ii).

187. The notice must be posted "at a conspicuous location on the covered entity's health program or activity website" and "[i]n clear and prominent physical locations … where it is reasonable to expect individuals seeking service from the health program or activity to be able to read or hear the notice." *Id.*, *to be codified at* 45 C.F.R. § 92.10(a)(2)(iii)–(iv).

188. The OCR Rules require covered entities to train each relevant employee on the OCR Rules' required policies and procedures and document that training. *Id.* at 37,697, *to be codified at* 45 C.F.R. § 92.9(a)–(c).

189. Under the OCR Rules, covered entities must submit an assurance of compliance to HHS that they have adopted the OCR Rules' new policies as a contractual condition of receipt of federal funding, or else they will be unable to apply or maintain eligibility for federal funding. *Id.* at 37,696, *to be codified at* 45 C.F.R. § 92.5.

190. Every time a covered entity requests a federal health funding payment from HHS, it impliedly certifies to HHS that it follows governing regulations, and the

OCR Rules import the prohibition on gender identity discrimination into those implied certifications. Covered entities unwilling to agree to make such an assurance or certification of compliance cannot apply for or maintain eligibility for federal health funding from HHS unless an exception applies.

B. The OCR Rules' New Liability Risks

191. Failure to follow the OCR Rules and their interpretation of Section 1557, Title IX, and HHS regulations risks the burdens and costs of federal investigations and enforcement proceedings. It also risks disallowance, exclusion, suspension, and debarment from receipt of federal funding.

192. Failure to follow the OCR Rules and their interpretation of Section 1557, Title IX, and HHS regulations arguably risks liability under a cause of action in civil litigation, including in suits brought by the public.

193. CMA members care for all people without discrimination on the basis of sex or any other characteristic prohibited by law. They believe that a patient with medical needs should be given the best care possible, regardless of the patient's identity. But CMA members cannot harm or lie to patients.

194. Based on the Hippocratic Oath, on science, on medical ethics, on conscience, and on religious faith, CMA members like Dr. Parker and Dr. Van Meter hold the categorical position that providing, facilitating, referring for, or endorsing gender-transition efforts violates their core religious beliefs and their medical oath to "do no harm." CMA members hold the categorical view that gender-transition procedures harm patients—particularly children—and can result in infertility, heart

attacks, strokes, and other chronic illnesses, and that medical science does not support the provision of such procedures. CMA members hold the categorical view that sex is a biological, immutable characteristic—a scientific reality, not a social construct. CMA members hold the categorical view that to eliminate sex-specific private spaces violates fundamental rights to privacy, dignity, safety, and security.

195. CMA members' categorical exclusion of providing, facilitating, or affirming gender transitions, and their commitment to state law, precludes CMA members from:

a. Prescribing puberty blockers, cross-sex hormone therapies, or other similar ongoing interventions to treat gender dysphoria or for transition efforts;

b. Performing surgeries to treat gender dysphoria or for transition efforts, including removing healthy organs from people who purport to identify as the opposite sex, nonbinary, or otherwise not as their sex;

c. Referring patients for any and all such interventions, procedures, services, or drugs, or affirming the same;

d. Saying in their professional opinions or through staff that these gender-transition efforts are the standard of care, are safe, are beneficial, are not experimental, are not cosmetic, or should otherwise be recommended;

e. Refraining from expressing views, options, policies, and opinions critical of transition efforts;

f. Treating and referring to patients according to gender identity and not sex, such as using patients' self-selected pronouns according to gender identity in communications or in writing (rather than using no pronouns or using pronouns based on sex);

g. Saying that males can be pregnant or give birth;

h. Allowing patients to access single-sex programs and facilities, such as restrooms, by gender identity rather than sex;

i. Repealing or modifying policies, procedures, and practices against the above procedures, drugs, and interventions for transition efforts; and

j. Providing assurances of compliance, express or implied certifications of compliance, and notices of compliant policies as to the OCR Rules' gender-identity requirements.

196. CMA members like Dr. Parker and Dr. Van Meter are actively practicing medicine and seeing patients. They provide services to patients reimbursed by federal financial assistance.

197. The OCR Rules impact CMA members in their practice of medicine as individual physicians who are regulated by the OCR Rules. And the OCR Rules impact some of these members as corporate principals and owners of medical practices that are regulated by the OCR Rules—for example in their duty to create, implement, and train staff on policies and to ensure compliance with the OCR Rules in their businesses' medical practices.

198. The OCR Rules impose the following no-win choice on CMA members: (1) abandon or violate their convictions on gender and incur the costs of compliance with the OCR Rules; (2) maintain their positions and practices but arguably falsify their policies, notices, and assurances of compliance to HHS and then risk continuing liability and investigative demands from OCR with no promise they will be deemed categorically exempt from the loss of eligibility for participation in Medicaid, Medicare, and CHIP, and other federal financial assistance programs; or (3) exit the medical field and abandon their patients.

199. If CMA members were to comply with the OCR Rules, they would lose their integrity and reputation of practicing with sound judgment and good medical ethics, making patients less likely to trust them, and driving patients and employees away from their practices.

200. If CMA members do not comply with the OCR Rules, CMA members will have to defend themselves from investigations and enforcement actions, losing time, money, and resources that they could use for medical care.

201. If CMA members do not comply with the OCR Rules, CMA members will find it difficult to be employed in the field of medicine, as almost all medical practices receive federal financial assistance from HHS.

202. It is no answer to say that entities may seek a religious or conscience exemption. Seeking such an assurance of exemption from HHS will cost time and money—$987.70 per entity according to HHS estimates—for uncertain results: there

is no guarantee that HHS will issue an assurance of exemption or will do so in time to avoid irreparable harm. 89 Fed. Reg. at 37,684.

203. Many CMA members like Dr. Parker and Dr. Van Meter live in states that restrict gender-transition procedures. Without an exemption, the OCR Rules force these doctors to choose between (a) following state law and their consciences and violating the OCR Rules, or (b) following the OCR Rules and violating state law and their consciences. They will not violate state law.

204. Dr. Parker is a board-certified OB/GYN hospitalist serving female Medicare and Medicaid patients in labor & delivery and emergency room ("ER") settings at OhioHealth Mansfield Hospital in Mansfield, Ohio. He works as an OB Hospitalist employed by Pediatrix Medical Group of Ohio, part of Pediatrix Medical Group.

205. In his past OB/GYN practice for females, he regularly provided medically indicated hysterectomies and provided medically indicated estrogen and testosterone hormones. He is board-certified to provide these services again in future clinical settings, but he cannot provide these services for gender-transition purposes.

206. Dr. Parker routinely records all OB/GYN patients as female. He uses the correct biological and binary pronouns: she/her. He does not facilitate male access to hospital restrooms designated for females, or vice versa, based on gender identity.

207. Dr. Parker at times treats patients who identify as transgender, non-binary, or otherwise contrary to their sex. He has cared for such a patient who was in labor having a baby. He does not—and will not—call a woman giving birth "a man."

In the past, hospital colleagues have said men could get pregnant and said that a certain patient was a man who was pregnant. Dr. Parker corrected them: the patient was a woman who was pregnant. Every time he encounters this issue, he wants to be free to explain that only females can get pregnant and give birth.

208. Dr. Parker does not wish to attend required training from his hospital or his physician group to follow a "nondiscrimination" policy on gender identity. He will attend such training as required but he will not agree to follow such a policy. He would rather be fired than harm his patients.

209. Dr. Van Meter is a pediatric endocrinologist seeing Medicaid and CHIP pediatric patients at his independent practice, Van Meter Pediatric Endocrinology, P.C., in Atlanta, Georgia. About seven percent of his patients are Medicaid patients, and if his patients need hospitalization, he provides care at two local hospitals that receive Medicaid and CHIP funding.

210. Dr. Van Meter regularly provides puberty blockers and sex hormones for medical reasons. He regularly cares for patients who identify as transgender, non-binary, or otherwise contrary to their sex, as well as patients who struggle with gender incongruence. He regularly receives patient requests to provide puberty blockers and cross-sex hormones for gender-transition purposes, but as a matter of sound medical judgment and good conscience, Dr. Van Meter does not and will not provide puberty blockers or hormones for gender-transition purposes.

211. Dr. Van Meter regularly provides his medical opinion against starting gender-transition procedures. He regularly uses pronouns for patients that accord with

biological and binary sex in conversation and in writing. He cannot use pronouns contrary to biology, even though he is regularly asked to do so.

212. Dr. Van Meter provides access to male and female restrooms for patients and their visitors based on biological and binary sex. Because of safety, dignity, privacy, and conscience concerns, he does not and will not ensure access to these facilities by gender identity.

213. Dr. Van Meter has adopted an official policy statement on his website encompassing these policies, and he does not wish to change this policy statement to be consistent with the OCR Rules, although he will do so in compliance with the OCR Rules if not protected by judicial relief. He does not wish to adopt or share a contrary policy or notice with patients. He will not reeducate his staff to comply with the OCR Rules, nor will he attend such training if required by his hospital.

214. Dr. Parker and Dr. Van Meter have already spent time and resources to avoid non-compliance with the OCR Rules, and if the OCR Rules go into effect, they will have to spend even more time and resources. Neither wants to stop seeing patients receiving federal financial assistance or to stop being affiliated with hospitals, but each would rather stop seeing patients receiving federal financial assistance and lose local hospital affiliations than adopt a policy under which they would harm a patient. Were they to lose their eligibility to serve in practices that serve patients receiving federal financial assistance, it would threaten their livelihoods and harm their patients, who would lose their established providers.

215. The OCR Rules threaten to drive similarly situated healthcare providers out of the medical profession, and it will dissuade students from choosing to practice medicine, reducing care for underserved, low-income, and rural patients.

COUNT I
(OCR Rules)

Violation of the Administrative Procedure Act
Agency Action Not in Accordance with Law, In Excess of Statutory Authority

216. Plaintiffs incorporate by reference paragraphs 1–215.

217. Defendants HHS and CMS are "agenc[ies]" under the APA. 5 U.S.C. § 551(1).

218. The 2024 Rules are a "rule" under the APA. 5 U.S.C. § 551(4).

219. The 2024 Rules are a "final agency action" subject to judicial review. 5 U.S.C. § 704.

220. Under the APA, a court must "hold unlawful and set aside agency action" that is "not in accordance with law, in excess of statutory authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C).

221. The OCR Rules define discriminating "on the basis sex" in a manner that is contrary to Section 1557 and Title IX.

222. The Eleventh Circuit has held that "sex" in Title IX "unambiguously" means "biological sex," not "sexual orientation" or "gender identity," *Adams*, 57 F.4th at 812–15, so the same is true under Section 1557, *see Sex*, American Heritage Dictionary 1605 (5th ed. 2011) ("Either of two divisions, designated female and male,

by which most organisms are classified on the basis of their reproductive organs and functions.").

223. Relying on the reasoning in *Bostock*, which interprets a different statute, the 2024 Rules nevertheless define "on the basis of sex" to necessarily include discriminating based on "sexual orientation and gender identity."

224. But *Bostock* cannot apply here.

225. *First*, as *Adams* holds, because Title IX, and hence Section 1557, expressly permits specific kinds of sex group separation, such as separate living facilities for each sex, discriminating based on gender identity is not necessarily prohibited discrimination based on sex under Title IX.

226. *Second*, Section 1557 specifically excludes from its scope "transsexualism" and a "gender identity disorder" "not resulting from physical impairments." 42 U.S.C. § 18116(a) (prohibiting discrimination "on the ground prohibited under … section 794 of title 29"); 29 U.S.C. § 705(20)(F)(i) (providing "transsexualism" and "gender identity disorders not resulting from physical impairments" are not a "disability" under section 794). Those terms at the time were synonymous with having a transgender identity, so transgender persons that don't have a disorder of sex development—a physical impairment—don't have a "disability" and are excluded from "section 792 of title 29." The specific exclusion of transgender identity governs the general prohibitions of Section 1557, so the general term "based on sex" cannot be read to include discriminating based on transgender identity in Section 1557.

227. But even if *Bostock* applied here, its reasoning wouldn't authorize the OCR Rules. *Bostock*'s reasoning, if it applies at all, applies when an individual is requesting a health care treatment that is "to the [covered entity's mind], materially identical in all respects, except that one" service is sought by one sex, and not the other. *Bostock*, 590 U.S. at 660. That doesn't authorize the OCR Rules. Removing a testicle or uterus with cancer is not "materially identical" to removing a healthy testicle or uterus to address a psychological condition. In both cases, the surgery is requested by one sex: only males have testicles removed, only females have a uterus removed. The thing that changes is the therapeutic purpose. A covered entity's refusal to remove healthy reproductive organs discriminates instead based on clinical purpose, not a patient's sex. *Eknes-Tucker*, 80 F.4th at 1233–34 (Brasher, J., concurring); *L.W.*, 83 F.4th at 481–82. Thus, as the Eleventh Circuit has held, a State does not discriminate or stereotype "on the basis of sex" (the text used in Title IX) when it forbids a hormonal overdose or the removal of healthy organs for a gender transition. *Eknes-Tucker*, 80 F.4th at 1227–30 (Equal Protection Clause).

228. Similarly, prescribing testosterone to treat abnormally delayed puberty or low levels of testosterone (in men or women) is not medically the same thing as prescribing supraphysiological levels of testosterone to embark a minor or adult in a gender transition protocol. The treatment (hormone levels), clinical purpose, and risks of the treatment are materially different.

229. Because HHS's definition of discriminating "on the basis of sex" exceeds the prohibition of Title IX as defined by binding Eleventh Circuit precedent and the

scope of Section 1557, the OCR Rules are contrary to law and in excess of statutory authority.

230. Several other provisions of law and principles confirm that HHS has exceeded its statutory authority.

231. *First*, HHS's departure from text is confirmed by Section 1554 of the ACA, which prohibits any HHS rules that "violate the principles of informed consent and the ethical standards of health care professionals." 42 U.S.C. § 18114(5). In Florida, and many other places, principles of informed consent and ethical standards forbid precisely the kind of medical interventions HHS seeks to compel. Under our federal system of government, state legislatures and medical boards, not HHS, decide the principles of informed consent and the ethical standards of health care professionals. Section 1554 confirms that Section 1557 doesn't alter the federal structure with regard to state laws requiring informed consent or setting ethical standards of care.

232. *Second*, Congress must "enact exceedingly clear language if it wishes to significantly alter the balance between federal and state power." *U.S. Forest Serv. v. Cowpasture River Preservation Ass'n*, 590 U.S. 604, 622 (2020). States enjoy the "general power" of governing. *NFIB v. Sebelius*, 567 U.S. at 536. Moreover, "[t]here is no question that state and local authorities possess considerable power to regulate public health," and regulate the ethics and standards of medical professionals. *NFIB v. OHSA*, 595 U.S. 109, 121 (2022) (Alito, J., concurring). Vesting OCR with vast power to second-guess the judgments of state medical boards and determine what is "clinically

appropriate" seriously alters the balance of power between state and federal governments and intrudes upon the medical profession—an area traditionally regulated by the States.

233. *Third*, and relatedly, in areas traditionally regulated by the states, such as the medical profession, courts begin with the assumption "that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Wyeth v. Levine*, 555 U.S. 555, 565 (2009). The 2024 Rules openly seek to preempt state laws or regulations reflecting the judgment that gender-transition interventions such as hormones and surgeries are not clinically appropriate to treat psychological distress arising from gender dysphoria. 89 Fed. Reg. at 37,535, 37,598. Section 1557 is an ordinary discrimination law; it does not clearly and manifestly preempt laws regulating the standard of medical care. Indeed, the ACA contains an express savings clause, confirming no broad "obstacle" preemption applies. *See* 42 U.S.C. § 18041 ("Nothing in this title shall be construed to preempt any State law that does not prevent the application of the provisions of this title.").

234. *Fourth*, Congress must "speak clearly when authorizing an agency to exercise powers of 'vast economic and political significance.'" *Ala. Ass'n of Realtors v. HHS*, 594 U.S. 758, 764 (2022) (cleaned up). Section 1557 doesn't clearly authorize the OCR Rules.

235. *Fifth*, because Section 1557 is a Spending Clause statute, Congress had to prohibit gender identity discrimination and prohibit disparate impacts

"unambiguously." *Adams*, 57 F.4th at 815. No clear statement appears on the face of the statute.

236. *Sixth*, the 2024 Rules violate Title IX's religious exemption. 20 U.S.C. § 1681(a)(3). The 2024 Rules exceed HHS's authority as cabined by Title IX and incorporated into Section 1557 because Section 1557 does not apply when it would violate the religious tenets of a covered entity.

237. *Seventh*, the 2024 Rules violate the Church Amendments, 42 U.S.C. § 300a-7, which protect the right of healthcare entities that receive federal funding to refuse to participate, perform, or assist with gender-transition procedures, including when it would be contrary to his religious beliefs or moral convictions.

COUNT II
(OCR Rules)

Violation of the Administrative Procedure Act
Arbitrary and Capricious

238. Plaintiffs incorporate by reference paragraphs 1–215.

239. Defendants HHS and CMS are "agenc[ies]" under the Administrative Procedure Act ("APA"). 5 U.S.C. § 551(1).

240. The OCR Rules are a "rule" under the APA. 5 U.S.C. § 551(4).

241. The OCR Rules are a "final agency action" subject to judicial review. 5 U.S.C. § 704.

242. Under the APA, a court must "hold unlawful and set aside agency action" that is "arbitrary [or] capricious." 5 U.S.C. § 706(2)(A).

243. An agency rule is arbitrary or capricious if it fails to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S. Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 44 (1983). An agency rule is also arbitrary and capricious "if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id.*

244. The OCR Rules are arbitrary and capricious for several reasons.

245. *First*, the OCR Rules never define "sex." But without defining sex, HHS cannot reasonably explain what it means to discriminate "based on" sex. HHS failed to adequately consider and find that, in medical practice as in education, sex is a biological reality.

246. *Second*, the OCR Rules' decision to embrace the WPATH and Endocrine Society Guideline runs counter to the evidence before the agency. Florida and other commenters put forth numerous studies and scholarly reviews showing these groups rely on weak evidence and that there is no consensus on gender-transition interventions.

247. *Third*, HHS failed to consider a significant aspect of the problem: the numerous negative side effects associated with "gender care." HHS never acknowledged, for example, that its preferred "standard of care" may render an untold

number of minors and adults infertile for life. HHS needs to consider that disadvantage.

248. *Fourth*, HHS arbitrarily departs from prior policy positions without adequate explanation. In the 2020 Rules, HHS said there was no medical or professional consensus that the benefits of gender-transition interventions outweighed the costs, as the evidence of a benefit was weak. HHS doesn't explain why the evidence is no longer weak.

249. *Fifth*, HHS improperly ignored the reliance interests of patients who want to keep receiving care from healthcare providers who object to gender transitions. HHS failed to adequately consider alternative policies.

250. Accordingly, the 2024 Rules' attempt to coerce covered entities into following a new federal standard of care for gender dysphoria is arbitrary and capricious and in violation of the APA.

COUNT III
(OCR Rules)

Violation of the Spending Clause

251. Plaintiffs incorporate by reference paragraphs 1–215.

252. Section 1557 is a Spending Clause statute. "[I]f Congress intends to impose a condition on the grant of federal moneys, it must do so unambiguously," so "States [can] exercise their choice knowingly." *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981). "A safeguard of our federalist system is the demand

that Congress provide the States with a clear statement when imposing a condition on federal funding." *Adams*, 57 F.4th at 815.

253. "States cannot knowingly accept conditions of which they are 'unaware' or of which they are 'unable to ascertain.'" *Arlington Cent. Sch. Dist. Bd. of Educ. v. Murphy*, 548 U.S. 291, 296 (2006).

254. At the time that the ACA was passed in 2010, no federal courts or agencies interpreted "based on sex" in Title IX to include discrimination based on gender identity. *See Adams*, 57 F.4th at 815–17 (interpretation of Title IX that prohibits discrimination on the basis of gender identity cannot survive the Spending Clause's clear statement rule).

255. Nor does 1557 by its terms unambiguously prohibit refusals to provide medical interventions with a *different* clinical purpose.

256. Under the OCR Rules, Florida now faces the untenable choice of surrendering its power to protect the health and safety of Floridians or losing billions of dollars in federal funding without adequate notice that this would be part of the bargain.

257. Accordingly, the OCR Rules violate the Spending Clause.

COUNT IV
(CMS Rules)

Violation of the Administrative Procedure Act
Agency Action Not in Accordance with Law, In Excess of Statutory Authority

258. Plaintiffs incorporate by reference paragraphs 1–215.

259. Defendants HHS and CMS are "agenc[ies]" under the APA. 5 U.S.C. § 551(1).

260. The 2024 Rules are a "rule" under the APA. 5 U.S.C. § 551(4).

261. The 2024 Rules are a "final agency action" subject to judicial review. 5 U.S.C. § 704.

262. Under the APA, a court must "hold unlawful and set aside agency action" that is "not in accordance with law, in excess of statutory authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C).

263. The CMS rules prohibit Medicaid and CHIP managed care organizations from having policies or practices that result in discrimination based on gender identity. 89 Fed. Reg. at 37,691, *to be codified at* 42 C.F.R. § 438.3(d)(4).

264. These rules are not authorized by Section 1557. For the reasons given above (Count I), Section 1557 doesn't protect against "gender identity" discrimination.

265. Section 1557 also requires intentional discrimination on the basis of sex: It prohibits different treatment based on animus, not facially neutral policies or practices that have "*the effect* of discriminating" on the basis of sex or gender identity. The law, like Title IX, prohibits discriminatory intentions, not just discriminatory consequences or outcomes.

266. Section 1902(a)(4) of the SSA, 42 U.S.C. § 1396a(a)(4), also does not give HHS authority to impose gender-identity non-discrimination rules on the states and its managed-care organizations. Non-discrimination rules are not "methods of

administration"; they are civil rights regulations. CMS's limitless reading of "methods of administration" is inconsistent with both text and statutory context, as well as the "clear notice" requirements for spending legislation and the major questions doctrine.

267. Section 2101(a) of the SSA, *id.* § 1397aa(a), also doesn't authorize this rule for CHIP. This vague statement of purpose doesn't grant any rulemaking authority or authorize CMS to legislate gender-identity non-discrimination rules. CMS's limitless reading of this statement of purpose is inconsistent with text and statutory context, as well as the "clear notice" requirements for spending legislation and the major questions doctrine.

268. The CMS rules also prohibit PACE organizations from discriminating against any participant based on gender identity. 89 Fed. Reg. at 37,692, *to be codified at* 42 C.F.R. §§ 460.98, 460.112.

269. Sections 1894(f)(A) and 1934(f)(A) of the SSA, 42 U.S.C. § 1395eee(f); *id.* § 1396u-4(f), similarly do not give CMS authority to legislate gender-identity non-discrimination rules for PACE. CMS's limitless reading of these rulemaking grants is inconsistent with the statutory context, as well as the "clear notice" requirements for spending legislation and the major questions doctrine.

270. The CMS rules also require that Medicaid and CHIP managed care organizations "promote the delivery of services in a culturally competent manner to all enrollees … regardless of sex which includes … gender identity." 89 Fed. Reg. at 37,691, *to be codified at* 42 C.F.R. § 438.206(c)(2).

271. Similarly, the CMS rules require that States' fee-for-service Medicaid programs "have methods to promote access and delivery of services in a culturally competent manner to all beneficiaries … regardless of sex which includes … gender identity." *Id.* at 37,692, *to be codified at* 42 C.F.R. § 440.262.

272. Further, the CMS rules require that State CHIP plans include methods for assuring that "access to and delivery of services in a culturally competent manner to all beneficiaries, as described in [42 C.F.R. § 440.262]." *Id.*, *to be codified at* 42 C.F.R. § 457.495(e).

273. All the "cultural competence" provisions appear to be intended to require that states require that transgender persons be referred to by pronouns that do not align with their sex.

274. The Social Security Act does not authorize CMS to impose speech codes or require adherence to a specific view of how to address transgendered individuals. Instead, the statute authorizes Medicaid rules specifying "methods of administration" that the Secretary concludes are "necessary for the proper and efficient operation of the plan." 42 U.S.C. § 1396a(a)(4). Requiring the use of pronouns that differ from the individual's sex does not advance the goal of "efficient" "administration" of the Medicaid program—it's about prescribing what should be orthodox in public discourse. That's beyond the reach of CMS's authority to publish rules that increase efficiency. Moreover, CMS's limitless reading of the term "methods of administration" is inconsistent with both text and statutory context, as well as the "clear notice" requirements for spending legislation and the major questions doctrine.

275. For similar reasons, Section 2101(a) of the SSA, *id.* § 1397aa(a), also doesn't authorize the CHIP version of this rule. This vague statement of purpose doesn't grant any rulemaking authority or authorize CMS to legislate pronoun rules. CMS's limitless reading of this statement of purpose is inconsistent with text and statutory context, as well as the "clear notice" requirements for spending legislation and the major questions doctrine.

276. Nor does Section 1902(a)(19) of the SSA, *id.* § 1396a(a)(19), authorize CMS to mandate the use of pronouns that differ from sex. That provision requires that State Medicaid plans contain safeguards that are "necessary to assure that" care and services are provided "in a manner consistent with simplicity of administration and the best interests of the recipients." *Id.* This general language doesn't grant any rulemaking authority or authorize CMS to legislate pronoun rules. CMS's limitless reading of this requirement of State Medicaid plans is inconsistent with text and statutory context, as well as the "clear notice" requirements for spending legislation and the major questions doctrine.

COUNT V
(CMS Rules)

Violation of the Administrative Procedure Act
Arbitrary and Capricious

277. Plaintiffs incorporate by reference paragraphs 1–215.

278. Defendants HHS and CMS are "agenc[ies]" under the APA. 5 U.S.C. § 551(1).

279. The CMS Rules are a "rule" under the APA. 5 U.S.C. § 551(4).

280. The CMS Rules are a "final agency action" subject to judicial review. 5 U.S.C. § 704.

281. Under the APA, a court must "hold unlawful and set aside agency action" that is "arbitrary [or] capricious." 5 U.S.C. § 706(2)(A).

282. An agency rule is arbitrary or capricious if it fails to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *State Farm*, 463 U.S. at 44. An agency rule is also arbitrary and capricious "if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id.*

283. The CMS Rules are arbitrary and capricious for several reasons.

284. *First,* they never define "sex." But without defining sex, CMS cannot reasonably explain what it means to discriminate based on sex or to provide "culturally competent" care regardless of sex.

285. *Second*, CMS relied on factors that Congress never intended it to consider. Congress authorized regulations to improve the efficiency of Medicaid and CHIP administration. Congress did not intend CMS to require "pursuing health equity"—*i.e.*, gender ideology. 89 Fed. Reg. at 37,668.

286. *Third*, CMS failed to consider a significant aspect of the problem when promulgating its "culturally competent" care requirements: the risk that providers will

leave the Medicaid and CHIP programs if required to use pronouns that differ from sex, creating a shortage of providers that harms Medicaid and CHIP recipients.

COUNT VI
(CMS Rules)

Violation of the Spending Clause

287. Plaintiffs incorporate by reference paragraphs 1–215.

288. The SSA is a Spending Clause statute. "[I]f Congress intends to impose a condition on the grant of federal moneys, it must do so unambiguously," so "States [can] exercise their choice knowingly." *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981). "A safeguard of our federalist system is the demand that Congress provide the States with a clear statement when imposing a condition on federal funding." *Adams*, 57 F.4th at 815.

289. "States cannot knowingly accept conditions of which they are 'unaware' or of which they are 'unable to ascertain.'" *Arlington Cent. Sch. Dist. Bd. of Educ.*, 548 U.S. at 296.

290. Neither the SSA nor the Public Health Service Act clearly authorize CMS to impose rules against discriminating on the basis of gender identity.

291. The SSA also does not clearly authorize CMS to impose rules requiring "culturally competent" care, especially when that appears to require the use of ungrammatical pronouns that differ from sex.

292. Accordingly, the CMS Rules violate the Spending Clause.

COUNT VII
(OCR Rules)

Violation of the First Amendment Guarantees of Free Speech and Association

293. Plaintiffs incorporate by reference paragraphs 1–215.

294. Under the First Amendment to the U.S. Constitution, "Congress shall make no law … abridging the freedom of speech … or the right of the people peaceably to assemble …." U.S. Const. amend. I.

295. CMA members' speech, association, and practice in healthcare are burdened in violation of the First Amendment.

296. The OCR Rules seek to restrict and compel speech and to regulate speech based on content and viewpoint. The OCR Rules require policies, opinions, referrals, and pronouns affirming gender-transition efforts, and they restrict speech taking a contrary view.

297. The OCR Rules violate CMA members' right of expressive association (or freedom of assembly) by coercing them to participate in facilities, programs, groups, and other healthcare-related endeavors that are contrary to their convictions and that express messages with which CMA members disagree.

298. The OCR Rules impose an unconstitutional condition on CMA members' receipt of federal funding.

299. The government lacks any compelling interest, and its mandates are not narrowly tailored to achieve any such interests.

300. If Section 1557 or Title IX is found to prohibit discrimination on the basis of gender identity, these statutes violate the First Amendment of the U.S. Constitution as applied to CMA members and all similarly situated healthcare professionals.

COUNT VIII
(OCR Rules)

Violation of the Religious Freedom (First Amendment and Religious Freedom Restoration Act)

301. Plaintiffs incorporate by reference paragraphs 1–215.

302. RFRA prohibits the federal government from substantially burdening a person's exercise of religion unless the government demonstrates that the burden is the least restrictive means of furthering a compelling government interest. 42 U.S.C. § 2000bb-1(a).

303. Under the First Amendment to the U.S. Constitution, "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof …." U.S. Const. amend. I.

304. RFRA and the Free Exercise Clause apply to the OCR Rules, the statutes underlying them, and HHS's enforcement of them.

305. CMA members exercise their religious beliefs through providing healthcare and through expressing messages in their healthcare practices, including to low-income and underserved populations in Medicaid, Medicare, and CHIP.

306. CMA members' provision of healthcare in accord with their religious beliefs does not prevent anyone from obtaining services from other providers.

307. The OCR Rules substantially burden their exercise of religion.

308. The OCR Rules are not neutral or generally applicable.

309. The OCR Rules observe other statutory and informal exemptions.

310. The OCR Rules contemplate the possibility of exemptions for some religious providers but not others. The OCR Rules thus may favor some religious beliefs over others.

311. The OCR Rules further no compelling or legitimate governmental interest and are not the least restrictive means of furthering any interests.

312. Defendants' actions promulgating and enforcing the OCR Rules violate CMA members' religious-exercise rights and hybrid free-speech and religious-exercise rights under RFRA and the First Amendment. In the alternative, if Section 1557 or Title IX is found to prohibit discrimination on the basis of gender identity, these statutes violate RFRA and the First Amendment for the same reasons.

PRAYER FOR RELIEF

For these reasons, Plaintiffs ask the Court to:

a) Hold unlawful, set aside, and vacate the 2024 Rules;

b) Issue preliminary injunctive relief enjoining Defendants from enforcing the 2024 Rules during the pendency of this case, or, in the alternative, postpone the effective date of the 2024 Rules during the pendency of this case pursuant to 5 U.S.C. § 705;

c) Issue permanent injunctive relief enjoining Defendants from enforcing the 2024 Rules;

d) Declare that the 2024 Rules are contrary to law and arbitrary and capricious;

e) Declare that under any theory of Section 1557 and Title IX, Defendants may not require covered entities to:

i. Perform, provide, refer for, facilitate, affirm, or refrain from criticizing or from categorically rejecting "gender transition" interventions;

ii. Speak in ways that the entities contend inaccurately refers to a patient's sex, such as in pronoun usage, writing, or conversation, or be forced to say that men can get pregnant and give birth;

iii. Allow members of one sex into the healthcare programs or private spaces of the other sex in their facilities, such as by allowing males into female restrooms; or

iv. Make statements in their policies, notices, or website statements, or train staff, or speak to patients or visitors, or submit assurances or certifications of compliance, to the effect that the entity will not discriminate on the basis of gender identity.

f) Award Plaintiffs costs and reasonable attorneys' fees.

g) Award such other relief as the Court deems equitable and just.

May 6, 2024

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UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

STATE OF FLORIDA, et al.,

Plaintiffs,

v. Case No. 8:24-cv-1080-WFJ-TGW

DEPARTMENT OF HEALTH
AND HUMAN SERVICES, et al.,

Defendants.
_____/

ORDER

Before the Court is Plaintiffs State of Florida, Florida Agency for Health Care Administration ("AHCA"), Florida Department of Management Services ("MS") (collectively, "Florida"), and Catholic Medical Association's ("CMA") Motion for Stay or Preliminary Injunction (Dkt. 12) of Final Rule. Defendants Department of Health and Human Services, Secretary of the Department of Health and Human Services (collectively "HHS"), Centers for Medicare and Medicaid Services, Administrator of the Centers for Medicare and Medicaid Services (collectively, "CMS"), and Director of the Office for Civil Rights have responded (Dkt. 33). Plaintiffs have replied (Dkt. 35). On June 21, 2024, the Court held a hearing on this matter. Upon careful consideration, and with the benefit of able argument by both sides, the Court grants Plaintiffs' Motion within the State of Florida. The subject

rules are stayed in Florida. Defendants are preliminarily enjoined within the State of Florida as follows.

BACKGROUND

The instant case is about Defendants' changed interpretation of the Affordable Care Act's ("ACA") prohibition on sex discrimination, and Defendants' attempt to enforce their new rules through the Final Rulemaking to be codified at 45 C.F.R. §§ 92.101, 92.206, 92.207 and 42 C.F.R. § 438.3(d)(4). *See* 89 Fed. Reg. 37,522 (May 6, 2024). Specifically, Defendants interpret the ACA's proscription against discrimination *on the basis of sex* to include discrimination *on the basis of gender identity*. *Id.* at 37,699 (emphasis added). They now maintain, among other things, that ACA covered providers may not "[d]eny or limit health services sought for purpose of gender transition or other gender-affirming care that the covered entity would provide to an individual for other purposes if the denial or limitation is based on an individual's sex assigned at birth, gender identity, or gender otherwise recorded." *Id.* at 37701. Plaintiffs disagree with Defendants' interpretation of the ACA. They ask the Court to enjoin Defendants from enforcing it against them.

The Final Rules considered here are broad and significant in application. As HHS has noted, "almost all practicing physicians in the United States are reached by Section 1557 [the provision at issue] because they accept some form of Federal

remuneration apart from Medicare Part B." *Nondiscrimination in Health Programs and Activities,* 81 Fed. Reg. 31,375, 31,446 (May 18, 2016).

I. The ACA and Title IX

In 2010, Congress passed the ACA seeking to improve healthcare coverage for Americans. Pub. L. No. 111-148, 124 Stat. 119. Section 1557 of the ACA furthers this goal by mandating that no individual shall, "on the ground prohibited under . . . Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.) . . . be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any health program or activity, any part of which is receiving Federal financial assistance[.]" 42 U.S.C. § 18116(a). Title IX then itself provides that "[n]o person in the United States shall, *on the basis of sex*, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance[.]" 20 U.S.C. § 1681(a) (emphasis added).[1]

[1] Title IX contains a number of sex-specific exceptions to this general language. 20 U.S.C. § 1686, for instance, provides that nothing contained within Title IX "shall be construed to prohibit any educational institution receiving funds under this Act, from maintaining separate living facilities for the different sexes." Further, § 1681(a) "shall not apply to an educational institution which is controlled by a religious organization if the application of this subsection would not be consistent with the religious tenets of such organization." *Id.* at § 1681(a)(3). The ACA itself also states that, "[n]otwithstanding any other provision of [the ACA,] HHS "shall not promulgate any regulation that . . . violates the principles of informed consent and the ethical standards of health care professionals[.]" 42 U.S.C. § 18114(5).

In addition to borrowing Title IX's "on the basis of sex" language, section 1557 also incorporates Title IX and Title VI's "enforcement mechanisms[.]" 42 U.S.C. § 18116(a). This essentially means that HHS's Office for Civil Rights ("OCR") may initiate investigations to determine whether "covered entities" have failed to comply with section 1557's anti-discrimination provision. *See* 20 U.S.C. § 1682; 45 C.F.R. §§ 80.7, 92.303(a). Where compliance cannot be secured voluntarily after an adverse finding, HHS must follow an administrative process before withholding federal funding. 20 U.S.C. § 1682. "[A]ny person aggrieved" by such action may also obtain judicial review. *Id.* at § 1683.

II. HHS's Implementation of Section 1557

On May 6, 2024, HHS issued a "final rule and interpretation" regarding section 1557 (the "Rule," "Rules," or "Final Rules"). *See generally* 89 Fed. Reg. 37,522. As relevant here, the Rules provide that discrimination "on the basis of sex includes, but is not limited to, discrimination on the basis of . . . [g]ender identity[.]" 45 C.F.R. § 92.101(a)(2)(iv) (effective July 5, 2024). The Rules expand on this interpretation through 45 C.F.R. §§ 92.206, 92.207 and 42 C.F.R. § 438.3(d)(4).

At section 92.206 the Rule addresses covered entities' obligation to provide "equal access to its health programs and activities without discriminating on the basis of sex." 45 C.F.R. § 92.206(a) (effective July 5, 2024). According to HHS, this obligation specifically prohibits four things:

> (1) denying or limiting "health services, including those that have been typically or exclusively provided to, or associated with, individuals of one sex, to an individual based upon the individual's sex assigned at birth, gender identity, or gender otherwise recorded;"
>
> (2) denying or limiting, "on the basis of an individual's sex assigned at birth, gender identity, or gender otherwise recorded, a health care professional's ability to provide health services if such denial or limitation has the effect of excluding individuals from participation in, denying them the benefits of, or otherwise subjecting them to discrimination on the basis of sex under a covered health program or activity;"
>
> (3) adopting or applying "any policy or practice of treating individuals differently or separating them on the basis of sex in a manner that subjects any individual to more than de minimis harm, including by adopting a policy or engaging in a practice that prevents an individual from participating in a health program or activity consistent with the individual's gender identity;" and
>
> (4) denying or limiting "health services sought for purpose of gender transition or other gender-affirming care that the covered entity would provide to an individual for other purposes if the denial or limitation is based on an individual's sex assigned at birth, gender identity, or gender otherwise recorded."

Id. at § 92.206(b)(1)–(4). The Rule adds, "[n]othing in this section requires the provision of any health service where the covered entity has a legitimate, nondiscriminatory reason for denying or limiting that service, including where . . . the covered entity reasonably determines that such health service is not clinically appropriate for a particular individual." *Id.* at § 92.206(c). What ostensibly matters is that a "covered entity's determination must not be based on unlawful animus or bias, or constitute a pretext for discrimination." *Id.*

At section 92.207 the Rule focuses on "health insurance coverage and other health-related coverage." 45 C.F.R. § 92.207(a) (effective July 5, 2024). It provides that covered insurers must not "[h]ave or implement a categorical coverage exclusion or limitation for all health services related to gender transition or other gender-affirming care" or "[o]therwise deny or limit coverage, deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage, for specific health services related to gender transition or other gender affirming care[.]" *Id.* at § 92.207(b)(4)–(5). Section 92.207(c) states that "reasonable medical management techniques such as medical necessity requirements" may provide a "legitimate, nondiscriminatory reason for denying or limiting coverage of" certain health services. *Id.* at § 92.207(c).

The final change concerns 42 C.F.R. § 438.3(d)(4).[2] Unlike the previously mentioned revisions, this one addresses "standard contract requirements" for entities that deliver services under Medicaid and CHIP.[3] 42 C.F.R. § 438.3(d)(4) (effective July 9, 2024). These contracts must now affirmatively state that the contracting

[2] Although Plaintiffs' complaint addresses a number of "CMS Rules," Dkt. 1 at 46–49, Plaintiffs' Motion for Stay or Preliminary Injunction only focuses on 42 C.F.R. § 438.3(d)(4). The Court will therefore largely limit its contracts analysis to 42 C.F.R. § 438.3(d)(4).

[3] Medicaid and CHIP are joint federal-state programs that enable states to extend medical coverage to low-income individuals under Title XIX (Medicaid) and Title XXI (CHIP) of the Social Security Act. 42 U.S.C § 1396, *et. seq.*; *id.* § 1397aa, *et. seq.* To participate in either, each state must create a specific plan that fulfills the conditions specified in 42 U.S.C. § 1396a(a) or 42 U.S.C. §§ 1397aa–1397bb and submit the plan for approval. *Id.* § 1396a(b); *id.* §1397ff(a)–(c); 42 C.F.R. § 457.150(a)–(c). Upon approval, states administer and fund their plans, and the federal government provides funding to help defray costs.

entity will "not discriminate against individuals eligible to enroll on the basis of race; color; national origin; disability; or sex which includes sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes; and will not use any policy or practice that has the effect of discriminating" on the same grounds. *Id.* In addition, participating states must ensure that these same entities "promote the delivery of services in a culturally competent manner to all enrollees . . . regardless of sex which includes sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity and sex stereotypes[.]" 42 C.F.R. § 438.206(c)(2) (effective July 9, 2024).

III. Florida

Florida believes that gender-change interventions are "experimental" and risk irreversible damage. Dkt. 1 at 33. It has therefore "concluded that the alleged psychological benefits of gender-change interventions are far too speculative to justify the risks, particularly in minors." *Id.*[4]

[4] In 2022, the Florida Department of Health ("DOH") released guidance to this effect. *See Treatment of Gender Dysphoria for Children and Adolescents* (Apr. 20, 2022), https://perma.cc/BB4N-2QH4. The DOH explained that "[s]ystematic reviews on hormonal treatment for young people show a trend of low-quality evidence, small sample sizes, and medium to high risk of bias. A paper published in the International Review of Psychiatry states that 80% of those seeking clinical care will lose their desire to identify with the non-birth sex." *Id.* The DOH also noted its belief that "encouraging mastectomy, ovariectomy, uterine extirpation, penile disablement, tracheal shave, the prescription of hormones which are out of line with the genetic make-up of the child, or puberty blockers, are all clinical practices which run an unacceptably high risk of doing harm." *Id.*

In line with this view, Florida has issued "standards of practice and standards of care" for licensed physicians. Fla. Admin. Code r. 64B8-9.019. The Florida Board of Medicine prohibits "[s]ex reassignment surgeries, or any other surgical procedures that alter primary or secondary sexual characteristics" as well as "[p]uberty blocking, hormone, and hormone antagonist therapies" in the treatment of minors with gender dysphoria. *Id.* The Florida Board of Osteopathic Medicine similarly prohibits such treatments. Fla. Admin. Code r. 64B15-14.014.

Florida has also passed a number of other laws and regulations that are relevant here. Rule 59G-1.050(7) provides that Florida Medicaid does not cover "puberty blockers, hormones and hormone antagonists, sex reassignment surgeries, or any other procedures that alter primary or secondary sexual characteristics" for the treatment of gender dysphoria. Fla. Admin. Code r. 59G-1.050(7). SB 254 prohibits "[s]ex-reassignment prescriptions or procedures" for "patients younger than 18 years of age," and the expenditure of state funds for the same. Fla. Stat. §§ 286.311, 456.001, 456.52. And HB 1521 mandates that covered entities must generally provide both females and males "restrooms and changing facilities for their exclusive use, respective to their sex[.]" Fla. Stat. § 553.865(2), (5), (12).

Given the foregoing, Florida asserts that compliance with the Rules will require it to violate its own laws and regulations. Florida further asserts that non-compliance will result in a significant loss of funds as well as private lawsuits.

IV. Catholic Medical Association

Like Florida, "CMA and its members hold the position that gender-transition procedures are unethical and dangerous." Dkt. 1 at 9.[5] CMA's members also have "overlapping religious objections." *Id.* They believe that the Rules interfere with their right "to the conscientious and faithful practice of medicine." *Id.*

CMA focuses on aspects of the Rules that have not been previously mentioned but which ultimately depend on Defendants' interpretation of discrimination "on the basis of sex." Among other things, the Rules will require CMA members who qualify as "covered entities" to: (1) "submit an assurance . . . that the entity's health programs and activities will be operated in compliance with section 1557" as amplified by the Final Rules; (2) "implement a written policy" that "states the covered entity does not discriminate on the basis of" healthcare for gender-identity; (3) "train relevant employees of its health programs and activities on the civil rights policies" embodied in the Rules; and (4) "provide a notice of nondiscrimination" on the basis of gender-identity "to participants, beneficiaries, enrollees, and applicants of its health programs and activities, and members of the public." 89 Fed. Reg. 37,696–98. Non-compliance may result in remedial action. *Id.*

[5] According to the Complaint, CMA is the largest association of Catholic individuals in healthcare with "2,500 members nationwide in all fields of practice." Dkt. 1 at 8. Additionally, "[m]ost CMA members provide medical care in health programs and activities that receive federal financial assistance and are subject to Section 1557." *Id.* at 9.

CMA claims that these specific requirements, and the Rules as a whole, impose a "no-win" scenario for its members to: (1) "abandon or violate their convictions on gender and incur the costs of compliance"; or (2) "maintain their positions and practices but arguably falsify their policies, notices, and assurances of compliance to HHS and then risk continuing liability"; or (3) "exit the medical field and abandon their patients." Dkt. 1 at 60. Ultimately, CMA maintains that its members' "categorical exclusion of providing, facilitating, or affirming gender transitions, and their commitment to state law, precludes CMA members from" complying with the Rules. *Id.* at 58.

CMA's approximately 2,500 members are nationwide. For reasons stated below, the undersigned believes a nationwide injunction issuing here is improvident. Thus, CMA's motion for a preliminary injunction will be denied, although its Florida members will be under this Court's order. CMA's other requested remedies must await a decision on the merits.

V. Procedural History

On May 6, 2024, Plaintiffs filed the instant lawsuit against Defendants. Plaintiffs generally assert that the Rules violate the Administrative Procedure Act ("APA"), the Spending Clause, the First Amendment's guarantee of free speech and association, and the First Amendment and Religious Freedom Restoration Act's ("RFRA") guarantees of religious freedom. *Id.* at 64–81.

Plaintiffs now move for a stay or preliminary injunction concerning 45 C.F.R. §§ 92.101, 92.206, 92.207 and 42 C.F.R. § 438.3(d)(4). *See generally* Dkt. 12. Defendants oppose such relief on the merits. *See generally* Dkt. 33. They also suggest that Plaintiffs lack standing and that Plaintiffs' claims are not ripe for review. *Id.* at 26–33.

LEGAL STANDARDS

To obtain a preliminary injunction concerning the Rules, Plaintiffs must show that: (1) they have "a substantial likelihood of success on the merits; (2) irreparable injury will be suffered unless the injunction issues; (3) the threatened injury to the movant outweighs whatever damage the proposed injunction may cause the opposing party; and (4) if issued, the injunction would not be adverse to the public interest." *Siegel v. LePore*, 234 F.3d 1163, 1176 (11th Cir. 2000) (en banc). "The first two factors are 'the most critical.'" *Swain v. Junior*, 958 F.3d 1081, 1088 (11th Cir. 2020) (quoting *Nken v. Holder*, 556 U.S. 418, 434 (2009)). Further, "the third and fourth factors [tend to] merge when, as here, the government is the opposing party." *Gonzalez v. Governor of Georgia*, 978 F.3d 1266, 1271 (11th Cir. 2020) (cleaned up) (citations omitted).

5 U.S.C. § 705 provides that, "[o]n conditions as may be required and to the extent necessary to prevent irreparable injury," a court may "issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve

status or rights pending conclusion of" a review. The showing required for stay under section 705 of the APA is not materially different than that required for a preliminary injunction. *Cook Cnty., Illinois v. Wolf*, 962 F.3d 208, 221 (7th Cir. 2020); *see also Purpose Built Fams. Found., Inc. v. United States*, No. 22-60938-CIV, 2022 WL 6226946, at *2–4 (S.D. Fla. July 29, 2022).

DISCUSSION

I. Justiciability

Defendants suggest that Plaintiffs lack standing, that Plaintiffs' claims are not ripe, and that implied preclusion issues exist. The Court will address each of these contentions before turning to consider the merits.

a. Standing

"Courts have jurisdiction to hear a case only when the plaintiff has standing to sue." *Baughcum v. Jackson*, 92 F.4th 1024 (11th Cir. 2024). Standing has three requirements: (1) "the plaintiff must have suffered an injury in fact—an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical"; (2) "there must be a causal connection between the injury and the conduct complained of—the injury has to be fairly traceable to the challenged action of the defendant and not the result of the independent action of some third party not before the court"; and (3) "it must be likely, as opposed to merely speculative, that the injury will be redressed by a

favorable decision." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992) (cleaned up) (internal quotations and citations omitted). "The party invoking federal jurisdiction bears the burden of establishing these elements." *Id.* at 561. CMA's standing is not relevant here.

Florida has shown that it faces an imminent injury in fact. "Government regulations that require or forbid some action by the plaintiff almost invariably satisfy both the injury in fact and causation requirements." *Food & Drug Admin. v. All. for Hippocratic Med.*, No. 23-235, 2024 WL 2964140, at *7 (U.S. June 13, 2024). Here, among other things, the Rules force Florida to begin expending state funds on gender-transition healthcare in contravention of its own laws. *Compare* 45 C.F.R. § 92.207(a) (barring "categorical coverage exclusion or limitation for all health services related to gender transition or other gender-affirming care") *with* Fla. Stat. §§ 286.311, 456.001, 456.52 (prohibiting "[s]ex-reassignment prescriptions or procedures" for "patients younger than 18 years of age," and the expenditure of state funds for the same). This alone represents an imminent injury to Florida's sovereign "interest in enforcing [its] duly enacted laws without contradiction from the federal government." *State of Tennessee v. Dep't of Educ.*, No. 22-5807, 2024 WL 2984295, at *10 (6th Cir. June 14, 2024). And Florida "need not expose [itself] to liability to have standing to challenge the enforcement of [the Rules]." *W. Virginia by &*

through Morrisey v. U.S. Dep't of the Treasury, 59 F.4th 1124, 1137 (11th Cir. 2023) (internal quotations and citation omitted).

Having addressed injury in fact, the other questions of standing are causation and redressability. Defendants do not address these factors. *See generally* Dkt. 33. Still, it is worth noting that they are satisfied. Plaintiffs' alleged injuries are directly caused by Defendants' promulgation of the Rules and imminent (July 5, 2024) enforcement of the same. A preliminary injunction will delay this enforcement. The Florida Plaintiffs have standing.

b. Ripeness

The ripeness doctrine asks "whether there is sufficient injury to meet Article III's requirement of a case or controversy and, if so, whether the claim is sufficiently mature and the issues sufficiently defined and concrete, to permit effective decision-making by the court." *Elend v. Basham*, 471 F.3d 1199, 1211 (11th Cir. 2006) (internal quotations and citations omitted). "In cases involving pre-enforcement review, like this one, the standing and ripeness analysis tend to converge." *Baughcum*, 92 F.4th at 1036.

Florida has alleged sufficient injury to satisfy the constitutional component of ripeness for the same reason that it satisfied the injury in fact component of standing. "If, in a suit challenging the legality of government action, the plaintiff is himself an object of the action . . . there is ordinarily little question that the action or inaction

has caused him injury." *Texas v. EEOC*, 933 F.3d 433, 46 (5th Cir. 2019) (internal quotations and citations omitted). The "common-sense inquiry" called for to determine whether Florida and CMA are objects of the Rules "is easy here." *Id.* The Rules explicitly apply to "covered entities," such as the Florida Plaintiffs, and mandate assurances, notices, training, and healthcare work that they do not currently provide. *See* 89 Fed. Reg. 37,522–24, 37,696–98. Florida, moreover, is "trapped in a bind" between the Rules and Florida law, which categorically precludes gender transition procedures for minors with gender dysphoria. *Florida v. Nelson*, 576 F. Supp. 3d 1017, 1030 (M.D. Fla. 2021); *see also Texas v. United States*, 787 F.3d 733, 749 (5th Cir. 2015) (explaining that "being pressured to change state law constitutes an injury"). There is simply no question that Plaintiffs face imminent injury where Defendants have expressed no intention to forego enforcement of the Rules.

This brings the Court to the prudential component of ripeness, which focuses on "both the *fitness* of the issues for judicial decision and the *hardship* to the parties of withholding judicial review." *Harrell v. The Fla. Bar*, 608 F.3d 1241, 1258 (11th Cir. 2010) (emphasis in original). In analyzing the fitness prong, courts are generally "concerned with questions of 'finality, definiteness, and the extent to which resolution of the challenge depends upon facts that may not yet be sufficiently developed.'" *Id.* (quoting *Ernst & Young v. Depositors Econ. Prot. Corp.,* 45 F.3d

530, 535 (1st Cir.1995)). "If a claim is fit for judicial decision, that is the end of the inquiry, and the matter is ripe, given that the absence of a hardship cannot tip the balance against judicial review under those circumstances." *Club Madonna, Inc. v. City of Miami Beach*, 924 F.3d 1370, 1380 (11th Cir. 2019) (cleaned up) (internal quotations and citation omitted).

Florida's claims are fit for judicial decision. "A facial challenge presenting a purely legal argument … 'is presumptively ripe for judicial review' because that type of argument does not rely on a developed factual record." *Id.* (quoting *Harris v. Mexican Specialty Foods, Inc.*, 564 F.3d 1301, 1308 (11th Cir. 2009)); *see Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 167 (2014). Here, Plaintiffs' central challenge is purely legal in nature. They argue that the Rules are facially invalid because Defendants have erroneously interpreted the Title IX and ACA proscription against discrimination on the basis of sex to include discrimination on the basis of gender identity. There is no need for trial-like factual development at this stage. "The lines are drawn, the positions taken, and the matter is ripe for judicial review." *Florida v. Weinberger*, 492 F.2d 488, 493 (5th Cir. 1974).

The Court also notes that Plaintiffs would suffer hardship without judicial review. *See Club Madonna*, 924 F.3d at 1380. "Potential litigants suffer substantial hardship if they are forced to choose between foregoing lawful activity and risking substantial legal sanctions." *Cheffer v. Reno*, 55 F.3d 1517, 1524 (11th Cir. 1995).

In the instant case, the Rules force Plaintiffs to choose between foregoing ostensibly legal healthcare policies and practices or risking private lawsuits and the withholding of federal funds that are likely unrecoverable. This is sufficient hardship. *See Texas v. Brooks-LaSure*, 680 F. Supp. 3d 791, 804 (E.D. Tex. 2023) (finding that Texas faced sufficient hardship where it had to "comply" with a CMS bulletin or "face fund disallowance"); *U.S. Army Corps of Engineers v. Hawkes Co.*, 578 U.S. 590, 600 (2016) (Plaintiffs "need not assume such risks while waiting for [Defendants] to 'drop the hammer' in order to have their day in court"). Plaintiffs' claims are ripe.

c. Implied Preclusion

The final justiciability issue to consider is implied preclusion. District courts generally "have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States." 28 U.S.C. § 1331. Here the Administrative Procedure Act, 5 U.S.C. 706, assigns all legal interpretations to the courts. The prime issue here is whether the Final Rules are legally compliant with and covered by Title IX in the Eleventh Circuit. The APA mandates this task is not impliedly precluded.

In some circumstances "[a] special statutory review scheme . . . may preclude district courts from exercising jurisdiction over challenges to federal agency action." *Axon Enter., Inc. v. FTC*, 598 U.S. 175, 185 (2023). Defendants suggest that section 1557 and 42 U.S.C. § 1316 represent such schemes.

Defendants are mistaken with respect to section 1557. The threshold implied preclusion issue is whether Congress has created a "comprehensive review process . . . that oust[s] district court jurisdiction[.]" *Axon Enter.*, 598 U.S. at 186 (citing *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 208 (1994). Congress did no such thing through section 1557. As previously mentioned, section 1557 incorporates Title IX and Title VI's "enforcement mechanisms[.]" 42 U.S.C. § 18116(a). Neither contain a special statutory review scheme that vests review in the courts of appeal or provides a comprehensive review process. They instead provide that "[a]ny department or agency action . . . shall be subject to such judicial review as may otherwise be provided by law for similar action taken by such department or agency on other grounds." 20 U.S.C. § 1683; 42 U.S.C. § 2000d-2. There is consequently no implied preclusion of Plaintiffs claims concerning 45 C.F.R. §§ 92.101, 92.206, and 92.207. *See Louisiana v. U.S. Env't Prot. Agency*, No. 2:23-CV-00692, 2024 WL 250798, at *19 (W.D. La. Jan. 23, 2024) (finding that "42 U.S.C. § 2000d-2 is not a special statutory scheme"); *Tennessee*, 2024 WL 2984295, at *18 (6th Cir. June 14, 2024) (finding that Title IX does not "implicitly preclude[] the States from brining an APA pre-enforcement challenge").

Title 42 U.S.C. § 1316's interaction with the contracts provision of 42 C.F.R. § 438.3(d)(4) creates a closer question, but not by much. Unlike section 1557, section 1316 creates a valid and comprehensive review process. *See* 42 U.S.C. §

1316(a)–(e). But here, Plaintiffs' claims are not "of the type Congress intended to be reviewed within this statutory structure." *Thunder Basin Coal Co.*, 510 U.S. at 212. Section 1316 addresses determinations concerning whether state plans "submitted to the Secretary by a State for approval under subchapter I, X, XIV, XVI, or XIX . . . conform[] to the requirements for approval under such subchapter" and general item disallowance. 42 U.S.C. § 1316(a)–(e). These matters are wholly collateral to the review of managed-care-plan contracts which are reviewed under 42 C.F.R. § 438.3(a). Additionally, Plaintiffs' claims concerning 42 C.F.R. § 438.3(d)(4) ultimately present legal APA and constitutional issues that are outside of HHS and CMS's expertise. It is unclear how Plaintiffs could seek such administrative review without "betting the farm" through immediate and wholesale defiance of the Final Rule—something courts "normally do not require plaintiffs" to do and something courts "do not consider" to be "a meaningful avenue of relief." *Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 490–91 (2010).

In sum, Congress' intent to allocate initial review of Plaintiffs' claims to HHS or CMS is not "fairly discernable in [42 U.S.C. § 1316 or 42 U.S.C. § 18116(a)]." *Thunder Basin*, 510 U.S. at 207. The Court has subject matter jurisdiction over Plaintiffs' claims.

II. Injunctive Factors

a. Likelihood of Success on the Merits

HHS and the Final Rule interpret Title IX, and hence section 1557, to prohibit discrimination based on "gender identity." 89 Fed. Reg. at 37,699 (45 C.F.R. § 92.101(a)(2)). The Final Rule is stillborn and a nullity if Title IX does not prohibit discrimination on the basis of "gender identity." The Eleventh Circuit has spoken on this point, clearly: Title IX does not address discrimination on the basis of gender identity. *Adams v. Sch. Bd. of St. John's Cnty.*, 57 F. 4th 791, 812–15 (11th Cir. 2022) (*en banc*). Frankly, this ends the issue—the new Rule appears to be a dead letter in the Eleventh Circuit.

The plaintiff in *Adams*, like HHS here, contended that the Title VII employment case of *Bostock v. Clayton County*, 590 U.S. 644, 659–60 (2020), means that Title IX barred discrimination on gender identity grounds.[6] The Eleventh Circuit held otherwise. In Title IX, and hence in section 1557, "because of sex" unambiguously means "biological sex" (male and female), and not "gender identity." *Adams*, 57 F.4th at 812–13. And although *Bostock*, too, proceeded on the assumption that "sex" means biological sex, *Adams* said that "the statutory context of Title IX" requires a different result. *Id.* at 813. As the *Adams* Court noted, Title IX includes many sex-specific exceptions and instructs that the prohibition must be

[6] *Bostock* held that an employer discriminates "because of sex" under Title VII of the Civil Rights Act of 1964 when he fires a male for no reason other than identifying as a woman, but "retains an otherwise identical employee" who is a female, because in that case, the individual's sex is a but-for-cause of the disparate treatment. 590 U.S. at 659.

read to permit separating living facilities based on sex, which is inconsistent with protecting "gender identity." *Id.* at 814–15 & n.7; *see* 20 U.S.C. § 1686. If Title IX were read to protect "gender identity," the Court reasoned, Title IX's carve-outs "would be rendered meaningless" whenever they came "into conflict with a transgender person's gender identity." *Adams*, 57 F.4th at 813–14. This "would provide more protection against discrimination on the basis of transgender status under the statute . . . than it would against discrimination on the basis of sex." *Id.* at 814. "That conclusion cannot comport" with the text and context of Title IX. *Id.*

A further reasoning of the Eleventh Circuit was that Title IX, unlike Title VII, was enacted under the "Spending Clause." *Adams*, 57 F.4th at 815. "A safeguard of our federalist system is the demand that Congress provide the States with a clear statement when imposing a condition on federal funding." *Id.* That "clear-statement" rule required rejecting the plaintiff's argument, because Title IX does not clearly protect gender identity. The text of Title IX says nothing about gender identity.

Notably, the federal Government's argument here about Title IX, including its argument about the spending clause, is precisely the argument it made, and flatly lost, in *Adams*. Amicus Brief of United States, Dkt. 254, No. 18-1359, *Adams*, ecf.call.uscourts.gov/n/bean/serulet/TansportRoam, last consulted June 30, 2024. Repeating the same failed argument from *Adams* will likely render the same result.

In discussing its definition of "sex" under Title IX to include gender identity,

HHS cites the reversed District Court opinion in *Adams*. *Id*. at 37573 n.110. And when incorporating *Bostock* into Title IX, HHS cites the controlling *en banc Adams* decision but notes it is contrary, using the signal "But cf." *Id*. at 37574 n.116.

In the Final Rule, HHS recognizes that "Section 1557 is best read to incorporate existing interpretations of what constitutes sex discrimination under Title IX, including regulatory interpretations *and case law*." 89 Fed. Reg. at 37,638 (emphasis added). In the Eleventh Circuit, that case law includes *Adams*.

HHS argues the Court should limit *Adams* to its facts ("transgender restroom issues") and apply *Bostock*'s reasoning to uphold the Final Rule. But *Adams* rejected applying *Bostock*.

Respect for Executive Branch interpretation of a statute was previously "especially warranted when an Executive Branch interpretation was issued roughly contemporaneously with enactment of the statute and remained consistent over time." *Loper Bright Enters. v. Raimondo*, 603 U.S. — , No. 22-1219, 2024 WL 3208360, at *9 (June 28, 2024). In contrast the Executive Branch interpretation of Title IX now conjured comes decades after the enactment of Title IX and, as seen below, the interpretation has changed repeatedly over time.

As *Loper* states, the whole point of having a written statute is "every statute's meaning is fixed at the time of enactment." *Id*. at *16. *Adams* recognizes this. Title IX, decades old, did not change meaning in 2024. HHS's attempt to alter

prospectively the meaning of Title IX shows the wisdom of *Loper's* statement that "agencies have no special competence in resolving statutory ambiguities. Courts do." *Id*. at *16. The Administrative Procedures Act, § 706, which is the present guidepost, "demand[s] that courts exercise independent judgment in construing statutes administered by agencies." *Id*. at *19; 5 U.S.C. § 706.

Eknes-Tucker v. Governor of Ala., 80 F.4th 1205 (11th Cir. 2023), also suggests that Plaintiffs will likely prevail on the merits. *Eknes-Tucker* involved a challenge to an Alabama law prohibiting gender-transition interventions in minors, particularly puberty blockers and cross-sex hormones. *Id.* at 1210, 1227. Interpreting the Equal Protection Clause, the Eleventh Circuit held that "the statute does not discriminate based on sex." *Id.*

The Alabama law prohibited drugs used for a specific medical purpose of treating gender dysphoria. *Id*. The purpose of the treatment was to end the gender dysphoria by facilitating likely gender transition or at least enabling it. Any reference to sex or difference in treatment was due to the medical purpose of the drugs coupled with biological facts about the sexes, not stereotypes. *Id.* at 1229. Only females may take supraphysiologic levels of testosterone for a gender transition, and only males can take supraphysiologic levels of estrogen for a gender transition. *Id.* at 1213, 1228. The Court said prohibiting these treatments is not discriminating on the basis of sex under Equal Protection scrutiny. "[T]he regulation of a course of treatment

that only gender nonconforming individuals can undergo" was not stereotyping "based on sex" "unless the regulation [is] a pretext for invidious discrimination against such individuals." *Id.* at 1228–30.

Like *Adams*, the *Eknes-Tucker* Court distinguished *Bostock*.[7] The Court emphasized the "different factual context" involved in *Eknes-Tucker* and *Bostock*—*Eknes-Tucker* involved a law regulating medical treatments, not a rule penalizing a transgender individual in employment for no reason other than being transgender. *Id.* at 1229. So too, here.

Eknes-Tucker held that a ban on gender-transition interventions does not intentionally discriminate "on the basis of sex." The same phrase is used in Title IX and imported into section 1557, increasing the likelihood that Plaintiff will prevail on the merits.

Section 206(b)(4) of the Rule makes it presumptively discriminatory for covered entities to "[d]eny or limit" puberty blockers, cross-sex hormones, or surgeries "sought for purpose of gender transition," so long as those entities provide the services for "other purposes." 89 Fed. Reg. at 37,701 (45 C.F.R. § 92.206(b)(4)).

[7] The Eleventh Circuit's recent decision in *Lange v. Houston County* does not govern here. 101 F.4th 793 (11th Cir. 2024). In that case, the Eleventh Circuit held that an employer violates Title VII when it denies health-insurance coverage for all gender transitions. But *Lange* (like *Bostock*) interprets Title VII, which is not a Spending Clause statute like section 1557. *Fitzpatrick v. Bitzer*, 427 U.S. 445, 458 (1976) (Brennan, J., concurring). So unlike section 1557, Title VII need not satisfy the requirement of clear and unambiguous notice. *Adams*, 57 F.4th at 815. *Adams* and *Eknes-Tucker* distinguished Title VII.

But this is insufficient to establish a prima face discrimination claim, as a patient seeking "gender transition" is not similarly situated to a patient seeking a drug or procedure to treat a different medical condition or diagnosis. *See Eknes-Tucker*, 80 F.4th at 1228; *id.* at 1233 (Brasher, J., concurring) (same); *L.W. v. Skrmetti*, 83 F.4th 460, 481–82 (6th Cir. 2023) (same in equal protection case).

To use *Bostock*'s language, HHS provides no reason to presume that a woman seeking a hysterectomy to treat cancer is "to [the doctor's mind], materially identical in all respects" to a woman seeking a hysterectomy for a gender transition. *Bostock*, 590 U.S. at 660. The diagnosis relevant to gender transition treatment—gender dysphoria—has a very different etiology and balance of risks. *See Eknes-Tucker*, 80 F.4th at 1233 (Brasher, J., concurring). Because the medical purpose is different, not similar, let alone "materially identical," intentional sex discrimination cannot be presumed. *Eknes-Tucker*, 80 F.4th at 1228; *Bostock*, 590 U.S. at 660.

One can envision many other factual scenarios showing that the Rule likely reaches well beyond "discrimination." For example, it is not actionable discrimination for a local hospital to provide an orchiectomy to a teenage boy with testicular cancer, yet refuse to even consider castrating a teenage gender dysphoric with healthy testicles. The diagnoses and medical purposes are not similarly situated.

Sections 207(b)(4) and (b)(5) prohibit a reimbursement policy or practice limiting gender-transition reimbursements if the policy or practice is "categorical"

or "results in sex discrimination." 89 Fed. Reg. at 37,701 (45 C.F.R. §§ 92.207(b)(4), (5)). HHS justifies this based on an argument that limiting coverage for a gender transition is a proxy for discriminating on the basis of gender nonconformity "because transgender individuals are the only individuals who seek transition-related care." Notice of Proposed Rule Making, 87 Fed. Reg. at 47,871. But *Eknes-Tucker* rejected that same argument: "the regulation of a course of treatment that only gender nonconforming individuals can undergo" is not discriminating "based on sex" (the same words used in Title IX) "unless the regulation [is] a pretext for invidious discrimination against such individuals." *Eknes-Tucker*, 80 F.4th at 1228–30. So *Eknes-Tucker* conflicts with these rules.

The Eleventh Circuit has concluded that limiting gender-transition treatments for minors such as pharmaceuticals or hormones is "rational." *Eknes-Tucker*, 80 F.4th at 1225. Surgery, which HHS addresses but *Eknes-Tucker* did not, would be all the more medically intrusive and "rational" to restrict.

Both *Eknes-Tucker* and the Final Rule forbid "pretext," but the Final Rule prohibits far more than "pretext," and its framework is the opposite of *Eknes-Tucker*'s. *Eknes-Tucker* requires a plaintiff to show "pretext" to establish that a state discriminated on the basis of sex. By contrast, under the Final Rule, a covered entity that bars coverage for gender-transition treatments would be presumed to discriminate based on sex, without any showing of pretext. Under the Final Rule, a

hospital's categorical denial of care ("no castration, hysterectomies, or mastectomies for gender transition") would be in violation of the Rule if the hospital provided those services for other reasons, like cancer.

The CMS contracts Rule would amend the standard contract requirements under Medicaid and CHIP to require prohibiting any policy or practice that has the "*effect of* discriminating" based on an individual's "gender identity." 89 Fed. Reg. at 37,691 (42 C.F.R. §§ 438.3(d)(4) (emphasis added), 457.1201(d)). But as explained above, section 1557 likely does not prohibit discriminating based on gender identity, and likely does not forbid the discriminatory effects that HHS defines. For additional statutory authority, HHS invokes the Social Security Act, which was also enacted under the Spending Clause and therefore likewise requires a "clear" statement of Congress. *See* 89 Fed. Reg. at 37,668.[8] But there is no clear statement. The Spending Clause failure was one of the salient points of the *Adams* opinion. 57 F.4th at 815.

In this regard, HHS defends the CMS contracts Rule by invoking its authority to adopt "methods of administration" for Medicaid that are "necessary for the proper

[8] HHS raises an affirmative defense. It argues that the claim is untimely under the Little Tucker Act's statute of limitations. 28 U.S.C. § 2401(a). This is meritless. The six-year statute of limitations "begins to run when the agency issues the final action that gives rise to the claim." *Alabama v. PCI Gaming Auth.*, 801 F.3d 1278, 1292 (11th Cir. 2015). To the extent earlier rules are implicated, HHS reopened them by vastly expanding them to gender identity medical services and contracting. *See Kennecott Utah Copper Corp. v. U.S. Dep't of Interior*, 88 F.3d 1191, 1227 (D.C. Cir. 1996). These claims accrued upon issuance of the Final Rule. *See Corner Post, Inc. v. Bd. of Governors of the Fed. Rsrv. Sys.*, 2024 WL 3237691, at *7 (July 1, 2024).

and efficient operation of the [state Medicaid] plan." 42 U.S.C. § 1396a(a)(4). But imposing these vast duties and canceling Florida law is far afield from "methods of administration."

Congress offered examples of "methods of administration," giving "more precise content" to the term. *United States v. Williams*, 553 U.S. 285, 294 (2008). It includes setting "personnel standards," providing for "medical personnel in the administration … of the plan," and transporting "beneficiaries … to and from providers." 42 U.S.C. § 1396a(a)(4). That list of routine administrative tasks looks nothing like the power to declare new civil rights guarantees for groups of people. When the SSA was enacted, States had no "clear notice" from the face of the statute that HHS could force them to adopt very costly contracts expanding treatments due to alleged disparate impacts on transgender individuals. *Adams*, 57 F.4th at 815. The contract requirement "is markedly different from" other contract requirements HHS has imposed. *Ala. Ass'n of Realtors*, 594 U.S. 758, 764 (2021); *see generally* 42 C.F.R. § 438.3. The CMS contracts Rule, like the Title IX Rule, simply rewrites the statute. That is Congress' job alone. For the foregoing reasons, Plaintiffs have established a likelihood of success on the merits.

b. Florida Faces Irreparable Harm

For many of the same reasons they establish standing and hardship, Plaintiffs also show they will suffer "irreparable harm" absent a stay. *West Virginia*, 59 F.4th

at 1149.

If the Rule is implemented, on July 5, 2024, Florida will face irreparable harm. Florida's covered entities will have to file an assurance of compliance to avoid termination of funds. They must amend their policies and begin trainings on the new rules. 45 C.F.R. §§ 92.5, 99.8, 99.9.

The Plaintiff agencies and the healthcare providers they regulate must either clearly violate Florida law, or clearly violate the new Rule. To comply with the Rule, DMS would have to alter its policy against reimbursing managed care plan members for sex-change treatments. This is not possible because DMS cannot amend its self-funded insurance plan without permission from the Florida legislature, which is not is session and which has previously barred payment of tax dollars for gender transition treatment. DMS will clearly suffer irreparable harm if the Rule is not stayed.

Other Plaintiffs would be in a similar bind. Under current law AHCA cannot use state funds for these gender change services in state Medicaid. Fla. Admin. Code r. 59G-1.050(7). HHS lawyers have previously said this present Florida AHCA law violates the Rule.[9] Even if AHCA could violate state law by expanding coverage for

[9] Brief for the United States as Amicus Curiae at 26 n.10, *Dekker v. Fla. Agency for Health Care Admin.*, No. 23-12155 (11th Cir. Dec. 4, 2023), https://perma.cc/9UYG-SVPL.

these services it cannot print money. And the Rule provides nothing for the vast added, unallotted expense.

The federal government generally enjoys immunity from suit. *West Virginia*, 59 F.4th at 1149. So these costs can never be recovered. *See*, *e.g.*, *Odebrecht Const., Inc. v. Sec., Fla. Dep't of Transp.*, 715 F.3d 1268, 1289 (11th Cir. 2013). Unrecovered monetary loss is irreparable harm. *Georgia v. President of the United States*, 46 F.4th 1283, 1302 (11th Cir. 2022).

Florida's Agency for Persons with Disabilities ("APD") also faces irreparable harm. Dkt. 12-2. APD has a policy of assigning dual-occupancy rooms in its residential living facilities on the basis of biological sex, regardless of an individual's gender identity. Presently, natal women have natal women roommates and natal males room with natal males. This makes sense given the residents APD serves. *See id*. But this would change.

The Rule would prohibit APD's room sharing policy if a biological male patient identified as a female, and refusing to lodge the natal male on the women's wing or with a female roommate would cause the natal male "more than de minimis harm." *See* § 206(b)(3) of Part 92; Dkt. 12, Ex. B; *see also* 89 Fed. Reg. at 37,593 ("A covered entity *will be* in violation of this rule if they refuse to admit a transgender person for care or refuse to place them in facilities consistent with their gender identity, because doing so would result in more than de minimis harm."

(emphasis added)). HHS earlier explained its view that "a hospital that assigns patients to dual-occupancy rooms based on sex would be prohibited from requiring a transgender woman [meaning a natal male expressing the female gender] to share a room with a cisgender man [meaning a natal male who expresses a male gender], regardless of how her sex is recorded in her insurance or medical records." NPRM, 87 Fed. Reg. at 47,866–67. HHS reiterated in its brief that "refusing to place a transgender person 'in facilities consistent with their gender identity' would result in more than de minimis harm." Dkt. 33 at 17 n.9. Absent a stay, APD may likely violate Florida law. *See* Fla. Stat. § 553.865(5), (12). APD plausibly states it would have to redesign facilities and/or hire additional staff for safety, to accommodate the preferences of gender-divergent residents. *Id*. at 9.

Florida also plausibly asserts injury in its sovereign capacity. The Final Rule injures Florida's "interest in enforcing [its] duly enacted laws without contradiction from the federal government." *Tennessee*, 2024 WL 2984295, at *10. Florida "will continue to face pressure to change their laws to avoid legal consequences." *Id.* at *25; *see also Florida v. Nelson*, 576 F. Supp. 3d 1017, 1039 (M.D. Fla. 2021); *Texas v. Becerra*, 577 F. Supp. 3d 527, 557 (N.D. Tex. 2021) ("irreparable harm exists when a federal regulation prevents a state from enforcing its duly enacted laws"). Case law has recognized this type of injury as supporting a stay. *West Virginia*, 59 F.4th at 1149.

HHS argues that a pending class action before a different court negates the need for equitable relief. *See Neese v. Becerra*, 640 F. Supp. 3d 668 (N.D. Tex. 2022). This case does not involve the Final Rule.

First, Florida, AHCA, DMS, and APD are not class members in *Neese*. Moreover, *Neese* did not provide equitable relief against Defendants. 640 F. Supp. 3d at 684–85. The judgment in *Neese*, now on appeal, does not stop HHS from enforcing the Final Rule against Plaintiffs.

Finally, the Court would note *Labrador v. Poe*, 601 U.S. — , 144 S. Ct. 921 (2024). Although arising in the context of a stay, the Supreme Court found that Idaho likely showed irreparable harm when a district judge struck down the state laws precluding puberty blockers and gender transition medical treatment for minors. *Id.*, 144 S. Ct. at 923–24 (concurrence). Here, of course, the Final Rule would similarly require repeal of substantive Florida statutes. *Labrador* suggests Florida faces irreparable harm.

c. The Balance of Harms and Public Interests Favor a Stay

The balance of harms and public interest factors "merge when, as here, the government is the opposing party." *Gonzalez v. Governor of Georgia*, 978 F.3d 1266, 1271 (11th Cir. 2020) (cleaned up). As discussed above, Plaintiffs will suffer harm and face unrecoverable, large monetary loss, legal jeopardy, and sovereign injury absent a stay.

Public Interest Requires a Lawful Rule

HHS and the public have an interest in HHS rules being legal. As noted, the Rule here appears to be contrary to the Eleventh Circuit's clear Title IX teachings in *Adams*; and *Eknes-Tucker* also teaches against the Rule indirectly. In the Eleventh Circuit, the Rule appears unlawful. "[O]ur system does not permit agencies to act unlawfully even in pursuit of desirable ends." *Ala. Ass'n of Realtors v. HHS*, 594 U.S. 758, 766 (2021); *see BST Holdings, LLC v. OSHA*, 17 F.4th 604, 618 (5th Cir. 2021) ("Any interest [the government] may claim in enforcing an unlawful [rule] is illegitimate."). In other words, the Rule invokes and relies on a Title IX that the Eleventh Circuit states does not exist.

Likewise, the reliance on the Social Security Act to impose costly new insurance/managed care contracts appears to be ultra vires to the Act. Neither is the Spending Clause requirement met, nor the stark changes permitted without a rewriting of that statute. The new Rules must be legal; and no deference on matters of legality need be shown the agency. *See Loper*, 2024 WL 3208360, at *22.

HHS's Rules Have Been Unstable, Ever-changing

A second reason why the public interest is furthered by a stay and injunction is that the Rule is ever-changing and unstable, buffeted by the prevailing political winds. The new Rule is the fourth version in the last eight years, which each version the opposite of the other. The repeated reversing of field by HHS presents large

compliance issues and costs for health care facilities and the states that regulate them; not to mention the stop-and-start effect on this sensitive area of health policy. This instability suggests that the public interest favors a preliminary pause to fully address on the merits this new, fourth version. And the instability shows little harm to HHS in keeping a steady hand rather than lurching change.

The stop/start timeline is illustrated in the case law. *See Religious Sisters of Mercy v. Becerra*, 55 F.4th 583, 589-591 (8th Cir. 2022). The first change was in 2016. Prior to 2016 the HHS rules did not require treatment and consideration of gender identity as part of healthcare nondiscrimination rules. This changed with a 2016 rule, *id.,* that stated "discrimination on the basis of sex includes discrimination on the basis of gender identity and sex stereotyping." *Id.* at 31,388; 31,467. The new rule barred providers from denying "transition-related care" based on explicit or categorical exclusions of services for purpose of gender transition. *Id.* at 31,439; 31,471. *See Religious Sisters,* 55 F.4th at 590.

After this change, though, HHS did another "180" and changed back again. *Id.* at 594; 85 Fed. Reg. 37,160 (June 19, 2020). In June 2020, HHS flatly repealed the 2016 rule, noting that it "repeal[ed] the 2016 Rule's definition of 'on the basis of sex'…" Instead, the 2020 HHS rule reverted to and relied upon the plain meaning of the term in Title IX. *Id.* at 37,178; *Religious Sisters,* 55 F.4th at 594. This change was the third rule within four years.

Now we have under review the fourth rule, as HHS has done one more about-face. Shortly after the Supreme Court issued its opinion in *Bostock,* President Biden issued an Executive Order stating that *Bostock's* reasoning meant that laws that prohibit sex discrimination, including Title IX, "prohibit discrimination on the basis of gender identity or sexual orientation," unless the laws contain sufficient indications to the contrary. *Executive Order No.* 13988, 86 FR 7023, 2021 WL 229396 (Jan. 20, 2021). The President thus ordered the head of each agency to rescind agency actions that were inconsistent with this definition he offered. Further, agencies were to promulgate new agency actions consistent with other laws including the APA, "as necessary to fully implement statutes that prohibit sex discrimination" as he defined it in the Order. *Id.* This fourth rule is the result: another 180-degree turn.

One need not be a cynic to predict that, if perchance there is a change in presidential administrations, we will have another sudden about-face by HHS and a fifth rule. This instability and repeated divergence is costly in many areas. It is entirely based upon national politics, and might support an argument that this sensitive issue of health and safety ought be left steady, or deferred to state medical regulators to decide in their public welfare role. In any event, this unstable regulatory regime does suggest there is little harm to a delay, and the public interest is here

served by a full decision on the factual merits and a preliminary stay, not to mention full development of real, hard science that was heretofore sparse in the field.

The Rule Requires Significant Alteration of Healthcare in Florida

The public has an interest in stable, orderly change in important public matters such as health care. The Final Rule would require covered entities to allow biological males who are transgender into female private spaces, including bathrooms, changing rooms, living facilities, dual-occupancy bedrooms, etc., if the natal males would otherwise suffer harm "more than de minimis." Unlike other more cautiously-worded provisions of HHS comments, HHS starkly stated, "[A] provider generally may accommodate a patient's preferences about roommate assignments. A covered entity will be in violation of this rule [Sec. 92.206] if they refuse to admit a transgender person for care or refuse to place them in facilities consistent with their gender identity because doing so would result in more than de minimis harm." 89 Fed. Reg. at 37,593. The Final Rule, moreover, allows no exceptions to this rule based on public safety or any similar rationales. That is not in the public interest, despite some minor harm that may be occasioned to gender-divergent patients by this injunction.

The Rule's commentary expressly declines to fully define the terms of "gender affirming care" or "gender identity" (other than to say it includes "transgender status") although the Rules are greatly about those subjects. 89 Fed.

Reg. 37,392; 37,596. HHS does say "gender affirming care generally refer[s] to a care designed to treat gender dysphoria that may include, but is not necessarily limited to, counseling, hormone therapy, surgery, and other related sources." 89 Fed. Reg. 37,596.

Section 92.206 of the Rule clearly mandates availability of gender transition services if similar services (hormone therapy, mastectomies, hysterectomies, etc.) are available to patients for reasons other than gender transitions. This is because "[w]hen medically necessary treatments are categorically excluded when sought by transgender enrollees for purposes of gender-affirming care, but the same treatments are covered for cisgender enrollees, such exclusions may deny transgender individuals access to coverage based on their sex." *Id.* at 37,671.

The Rule also seeks to make providers speak correctly about the subject to HHS's satisfaction, in addition to verbal assurance of compliance. The HHS commentary notes that in assessing a provider's good faith to avoid compliance sanctions the HHS will consider "whether that covered entity demonstrated a willingness to refer or provide accurate information about gender-affirming care, or is otherwise engaging in good faith efforts to ensure patients are receiving medically necessary care." *Id.* at 37,598. HHS commented that the Rule clarifies "that while providers may exercise clinical judgment when determining if a particular service is appropriate for an individual patient, they may not refuse gender-affirming care

based on a belief that such care is never clinically appropriate." *Id.* at 37,597. This is contrary to the public interest, if public interest may be defined as the laws of Florida passed by the citizens' elected representatives.

Public Interest Supports Merits-Based Consideration of HHS's "Care" Regimen

HHS's brief, notably, does not argue that encouraging gender-transition treatments serves the public interest. This is a litigation strategy as both the Rule and HHS's clear public stance are entirely to the contrary. Given the uncertain benefit, the evidence of public health harms, and HHS's failure to defend the public health benefit of gender-transition treatments in its brief, the Court concludes that encouraging widespread access of "gender affirming care" is an issue that the public interest requires to be developed thoroughly on the merits. And such an examination brings no harm to HHS.

The Final Rule compels the State to make gender-transition services available in the Medicaid managed care plans, and compels all covered entities to not preclude gender-transition treatments when such services (like mastectomies for cancer, testosterone for hypogonadism, etc.) are provided for other medical reasons. Covered entities may not categorially refuse to perform gender transition. No hospital in Florida could have a categorical exclusion for gender-transition surgeries even for minors, if similar procedures were done for non-gender purposes.

If a hospital's outreach program sponsored a women-only support or counseling group, that group would have to admit a natal male who identified as female, if refusing to admit the natal male would cause that person more than de minimis harm. And no contractor such as the Florida Medicaid multi-billion-dollar managed care plans could omit a full panoply of gender transition coverage (surgery, hormone formulary, etc.) if those services were provided for non-transition maladies. This presents a *very* expensive regimen paid for by the taxpayers but unfunded by the Rule.

An honest appraisal of the Rule shows it imposes the availability of gender transition medicine upon all covered entities, wanted or unwanted. The public interest requires a merits-based analysis of this.

Although the task here is to undertake a "facial review" of the new Rules, some issues of "public interest and balanced harms" requires the further discussion. HHS's basis for a "gender affirming care" regimen appear to be long on ipse dixit[10] and short on real, hard science. *See generally* HHS Office of Population Affairs, G*ender-Affirming Care and Young People,* opa.hhs.gov/site/default/files/2022-03/gender-affirming-care-young-people-March-2022, last consulted June 29, 2024. In this March 2022 HHS "fact sheet" the HHS advocated the panoply of "gender

[10] **Ipse dixit**. L. He himself said it; a bare assertion resting on the authority of an individual. Black's Law Dictionary (5th ed. 1979).

affirming care" including counseling, pharmaceuticals, and stating that surgeries are "typically used in adult or case-by-case in adolescence." This "fact sheet" was immediately followed up by the Department of Justice Assistant Attorney General Kristin Clarke's letter of March 31, 2022, sent to State's Attorneys General, which fairly reads as a veiled threat to bring federal enforcement actions and litigation in pursuit of this trans-care agenda.[11]

At times the HHS position about "gender affirming care" seems to be political. It is no surprise to any observer that politics on both sides of this issue are prevalent. Concerning the parties here, HHS's Assistant Secretary Levine previously urged the medical/advocacy group World Professional Association for Transgender Health ("WPATH") to drop proposed age limits for minor transgender surgery. The age limits in the proposed WPATH guidelines were 15 for mastectomies, 16 for breast augmentation or facial surgeries, and 17 for hysterectomies. Levine's staff informed WPATH that Levine was "confident, based on the rhetoric she is hearing in D.C., and from what we have already seen, that these specific lists of ages, under 18, will result in devastating legislation for trans care. [Levine] wonder[s] if the specific ages can be taken out." Levine's staff went on to tell WPATH that Levine "was very concerned that having ages (mainly for surgery) will affect access to care for trans

[11] The letter may be found at ECF No. 193-3, *Dekker v. Weida*, No. 4:22-cv-325-RH-MAF (N.D. Fla. 2023).

youth and maybe adults, too…" Levine's staff asked WPATH to remove the age limitations in the guidance for gender transition.[12] The WPATH has removed age limitations for minors on its guidance for transition surgeries.

It is in the public interest to address these issues with the benefit of a full record, substantively on the merits. The record now is sparse due to this "facial review"; further, the undersigned has no training in science or medicine. Despite this, several points are worth making.

A notable point about the Rule is that while it imposes significant "gender affirming care" and "transition treatment" requirements upon Florida, the HHS discounts, and in the commentary declares as "not germane to the proposed regulatory text," any uncertainty and lack of clarity concerning the safety and efficacy of the gender treatments HHS imposes. 89 Fed. Reg. 37672. HHS's boldness here is noteworthy and one might say brash, given that "[t]here are no large-scale population studies of gender dysphoria." American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders* (5th ed. 2022 Text Revision)

[12]A. Ghorayshi, *Biden Officials Pushed to Remove Agent Limits for Trans Surgery, Documents Show* (N.Y. Times June 25, 2024), https://www.nytimes.com/2024/06/25/health/transgender-minors-surgeries.html. In response to this article the administration was reported to have stated that it opposed gender-affirming surgery for minors. Rabin, Rosenbluth, Weiland, *Biden Administration Opposes Surgery for Transgender Minors,* (N.Y. Times June 28, 20240, https://www.nytimes.com/2024/06/28/health/transgender-surgery-biden.html?pvid+kwDIVPqfjXyF_P9pkx7qMxSW&smid=url-share. This latter statement contrasts with the HHS "fact sheet" which states the "gender-affirming surgeries" are "typically used in adulthood or case-by-case- in adolescence. *Gender Affirming Care*, *supra* at 39-40, opa.hhs.gov.

("DSM-5") at 515. The Rule radically changes the law in Florida, as a matter of medicine and expense, concerning the treatment of gender dysphoria in minors. Yet the predominant psychiatric disorder "guidebook," DSM-5, tells us that "[n]o general population studies exist of adolescent or adult outcomes of childhood gender variance." *Id.* at 516.

After counseling, the starting point for physical intervention in the "gender affirming care" regimen for minors is puberty blockers, often followed by cross-sex hormones, meaning supra-physical doses of testosterone for transitioning natal females, and estrogen for transitioning natal males. The Food and Drug Administration has *never* approved any of these drugs as "safe and effective" for these treatments. The reason why is that studies about these pharmaceuticals in this application lack full, hard scientific rigor. The entire gender-transition drug regimen, is "off label." Off label drug use generally is not illegal and not infrequent, but before an entire formulary and medical practice in Florida is involuntarily devoted to off-label drugs, perhaps a pause to study these merits is in order.

When the FDA regulates a drug "on-label," that assurance means the FDA has conducted or supervised sufficient testing to determine that the drug is safe for its intended use. *See Food & Drug Admin. v. Brown & Williamson Tobacco Corp.* 529 U.S. 120, 142 (2000). This has not occurred with puberty blockers or cross-sex hormones used for gender dysphoria or transition. The FDA in 2022 required a

warning label on one GnRH agonist used as an off-label transition puberty blocker; this drug may cause or correlate to the brain disorder pseudotumor cerebri (idiopathic intercranial hypertension) in minor females. The Food and Drug Administration, *Risk of Pseudotumor Cerebri Added to Labeling for Gonadotropin-Releasing Hormone Agonists* (2022), https://publications.aap.org/aapnews/news/20636/Risk-of-pseudotumor-cerebri-added-to-labeling-for?autologincheck=redirected (last consulted Jul. 1, 2024).

Off-label use of drugs bypasses the consumer safety and efficacy purpose of the FDA approval process and is nearly impossible to track. New or novel off label use, such as would be imposed by the Rule, is unlikely to be supported by strong, hard scientific evidence, because such use has not undergone extensive clinical phase trials that would ordinarily be required for such use. *See generally* Gail A. Van Norman, *Off-Label Use vs Off-Label Marketing of Drugs: Part 1: Off-Label Use—Patient Harms and Prescriber Responsibilities,* 8 J. Am. Coll. Cardiol Basic Trans. Science 224–233 (Feb. 8, 2023), https://www.jacc.org/doi/full/10.1016/j.jacbts.2022.12.011 (last visited Jul. 1, 2024).

HHS's present view on "gender affirming care" is far from shared by other medical authorities. And the science seems to be trending the other way. *See also*

Labrador v. Poe, supra (reinstating most of the Idaho law barring transition medicine for minors).

If the British National Health Service ("NHS") were subject to the HHS Rule, the NHS would be in violation, as the NHS has stopped new, non-experimental prescriptions for puberty blockers for minor gender transition throughout the U.K., and indefinitely in England. Department of Health and Social Care, *New Restrictions on Puberty Blockers* (2024), https://www.gov.uk/government/news/new-restrictions-on-puberty-blockers?ref=world-weary.com (last consulted Jun. 29, 2024). This bar comes on the heels of a peer-reviewed survey entitled the "Cass Report," which reported on the scarce evidence showing puberty suppression was safe and effective for gender transition and further considering the scarce evidence and questionable safety and efficacy of cross-sex hormone treatment. Hilary Cass, *Independent Review of Gender Identity Services for Children and Young People* (2024), https://cass.independent-review.uk/home/publications/final-report/ (last consulted Jun. 29, 2024). Other authorities expressing doubts about the efficacy of

such treatments include Sweden,[13] Finland,[14] France,[15] and Australia/New Zealand.[16]

The reason for these concerns appears that, despite statements to the contrary, the science behind these programs is reasonably disputed, and does not appear to be yet proven to anywhere near a medical certainty. One example is a recent survey that the undersigned asked all counsel to comment upon: Jonas F. Ludvigsson *et al.*, *A Systematic Review of Hormone Treatment for Children with Gender Dysphoria and*

[13] Sweden's National Board of Health and Welfare determined that "the risks of puberty blockers and gender-affirming treatment are likely to outweigh the expected benefits of these treatments," and determined that "[t]reatment with GnRH analogues, gender-affirming hormones, and mastectomy can be administered" only "in exceptional cases." Exhibit DX8 at 3, *Dekker v. Weida*, No. 4:22-cv-325-RH-MAF (N.D. Fla. 2023) (ECF No. 193-8); National Board of Health and Welfare, *Care of Children and Adolescents with Gender Dysphoria, Summary of National Guidelines December 2022* (2022), https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2023-1-8330.pdf (last visited June 26, 2022).

[14] Finland's Council for Choices in Healthcare urged extreme caution when providing gender transitioning services to children. It says that "[t]he reliability of the existing studies with no control groups is highly uncertain, and because of this uncertainty, no decisions should be made that can permanently alter a still-maturing minor's mental and physical development." Exhibit DX9 at 7, *Dekker v. Weida*, No. 4:22-cv-325-RH-MAF (N.D. Fla. 2023) (ECF No. 193-9); Council for Choices in Healthcare in Finland, *Medical Treatment Methods for Dysphoria Related to Gender Variance in Minors* (2020), https://segm.org/sites/default/files/Finnish_Guidelines_2020_Minors_Unofficial%20Translation.pdf (last visited June 26, 2022).

[15] [The French National Academy of Medicine] concludes that "great medical caution" must be taken "given the vulnerability, particularly psychological, of this population [of younger people presenting with gender dysphoria] and the many undesirable effects, and even serious complications, that some of the available therapies can cause." Exhibit DX13 at 1, *Dekker v. Weida*, No. 4:22-cv-325-RH-MAF (N.D. Fla. 2023) (ECF No. 193-13); French National Academy of Medicine, *Medicine and Gender Transidentity in Children and Adolescents* (2022), https://www.academie-medecine.fr/la-medecine-face-a-la-transidentite-de-genre-chez-les-enfants-et-les-adolescents/?lang=en (last visited June 26, 2022).

[16] The Royal Australian and New Zealand College of Psychiatrists has said that there's a "paucity of evidence" on the outcomes of those presenting with gender dysphoria. Exhibit DX14 at 1, *Dekker v. Weida*, No. 4:22-cv-325-RH-MAF (N.D. Fla. 2023) (ECF No. 193-14).

Recommendations for Research, 112 Acta Paediatrica (Apr. 17, 2023), https://onlinelibrary.wiley.com/doi/10.1111/apa.16791 (last visited Jul. 1, 2024) ("Ludvigsson"). *See* Dkt. 38. Defendants dispute the value of the study, but its findings are worthy of a merits-based inquiry and full record.

Ludvigsson surveyed the major databases and identified nearly 10,000 potentially germane studies. After screening, 24 were found to be timely (within the last decade) and appropriate for further analysis. Dkt. 38 at 3. Eight address the use of puberty blockers, three addressed the use of cross-sex hormones, and the remainder addressed both. The results[17] appear to show how sparse the *actual hard*

[17] Ludvigsson concluded there was insufficient evidence to assess the therapeutic effects of hormone treatments on children with gender dysphoria. Ludvigsson at 2280. Studies that examined mental health outcomes suggested an improvement in global function and self-reported quality of life for children receiving puberty blockers, but no change in suicidal ideation, depression, or anxiety. *Id*. at 2286 & tbl. 2. Notably, the studies showed no change in children's experience of gender dysphoria following hormone treatment. *Id*. Other studies showed, albeit with low certainty, that puberty blockers slow bone densification in growing children, with mixed data on whether later CHST accelerates densification sufficiently to fully compensate. *Id*. at 2286–88 & tbl. 3. Ludvigsson emphasized that study weaknesses limit the conclusions that can reliably be drawn. None of the twenty-four studies were randomized controlled trials, the gold-standard in evidence-based clinical practice. *Id*. at 2287; *see*, *e.g.*, NIH, *Clinical Research: Benefits, Risks, and Safety*, https://www.nia.nih.gov/health/clinical-trials-and-studies/clinical-research-benefits-risks-and-safety ("The gold standard for testing interventions in people is called a randomized controlled trial"); E. Hariton & J.J. Locascio, *Randomized controlled trials—the gold standard for effectiveness research*, 125 BJOG 1635 (Dec. 2018), https://doi.org/10.1111/1471-0528.15199. Data related to mental health outcomes was such poor quality that the certainty of the evidence could not be assessed. *Id*. at 2282, 2286 tbl.2. The studies' short time frames (generally less than four years) and methodologies did not permit assessment of long-term outcomes or separation of psychological treatment effects. *Id*. at 2282, 2288. And analyses were performed at a group-level when assessing an individual over time would be more appropriate. *Id*. at 2288.

Ludvigsson's analysis is consistent with other independent, systematic reviews, which have similarly concluded that the evidence of benefit of medical gender transition in minors weak, while the evidence of harm is clear. *See id*. at 2290; Expert Report of Stephen B. Levine 51–52 (Feb. 23, 2022), HHS-OS-2022-0012-68192/attachment_12 at 165–66,

evidence is that lies behind the "gender affirming care" regimen that HHS embraces and for which the Final Rule compels availability in Florida.

One recent study (2024) of puberty suppression for gender dysphoria concluded:

> "In mammals, the neuropsychological impacts of puberty blockers are complex and often sex specific….There is no evidence that cognitive effects are fully reversible following discontinuation of treatment. No human studies have systematically explored the impact of these treatments on neuropsychological function with an adequate baseline and follow up. There is some evidence of a detrimental impact of pubertal suppression on IQ in children."[18]

The public interest favors a merits-based inquiry to address these matters.

III. The Court denies the Catholic Medical Association's Petition

The Catholic Medical Association is a group of some 2500 health professionals across the nation practicing the healing arts. CMA petitioned here for an injunction, which is denied. Without need to opine on CMA's representational standing, the Court simply believes that a nationwide injunction to cover all CMA members is improvident in this case for jurisprudential reasons. The CMA may

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https://www.regulations.gov/comment/HHS-OS-2022-0012-68192 at attachment 12 (last consulted Jul. 1, 2024). Even proponents acknowledge the health risks associated with gender transition in minors and the limited data addressing its safety and efficacy. These scientific assessments have led other countries to restrict, not expand, minors' access to medical gender transition.

[18]S. Baxendale, *The Impact of Suppressing Puberty on Neuropsychological function: A Review*, 113 Acta Paediatrica, (Feb. 9, 2024), https://onlinelibrary.wiley.com/doi/full/10.1111/apa.17150 (last visited Jul. 1, 2024).

remain in the case for the merits determination, and its Florida members will certainly be covered by this injunction.

First, the Court does not know who the CMA members are. Generally judges prefer to adjudicate disputes between the parties presenting before them. Although the Court has the power under Fed. R. Civ. P. 65 to enter such an injunction, how that rule intersects, if at all, with possible class action status under Rule 23 is now unclear. Also, a judge must not issue an injunction if he or she cannot enforce it. If, perchance, a CMA member in Oregon were told by her hospital administrator to follow the Final Rule in its entirety based upon Ninth Circuit precedent, enforcement of the undersigned's injunction could be problematic.

Much of this present injunction is based on the likely illegality of the Final Rule under the two specific Eleventh Circuit holdings discussed above. Those rulings do not bind outside of the Eleventh Circuit.

Several Supreme Court justices have recently criticized the modern spate of nationwide or universal injunctions from District Courts. *See, e.g., Labrador v. Poe*, 144 S. Ct. at 921, 925. The Eleventh Circuit has counseled similarly. *Georgia v. President*, 46 F.4th at 1304. Those admonitions seem condign: A nationwide injunction issuing from a District Court ought to be the rare exception, not routine.

CONCLUSION

Accordingly, it is hereby **ORDERED** and **ADJUDGED:**

(1) Plaintiffs' Motion for Stay and Preliminary Injunction (Dkt. 12) is **GRANTED** within Florida only.

(2) Pending trial on the merits, the Final Rule entitled "Nondiscrimination in Health Programs and Activities," Final Rule, 89 Fed. Reg. 37,522 (May 6, 2024) is stayed in part, in Florida. The effective date of 45 C.F.R. §§92101(a)(2)(iv), 92.206(b), 92.207(b)(3)-(5), 42 C.F.R. § 438.3(d)(4) is postponed pending the disposition of the complaint on the merits. 5 U.S.C. § 705. For the duration of this Order, an assurance of compliance with Part 92, *see* 45 C.F.R. § 92.5, shall not be construed to assure compliance with any provisions stayed by this Order.

(3) Defendants are preliminarily enjoined from instituting or pursuing any enforcement proceedings under Section 1557, 42 U.S.C. § 18116(a), based on the interpretation of discrimination "on the basis of sex" to be codified at 45 C.F.R. § 92.101(a)(2)(iv), 92.206(b), or 92.207(b)(3)-(5).

(4) This Order runs throughout the State of Florida, applying to all Plaintiffs, including the State of Florida, the Florida Agency for Health Care Administration, the Florida Department of Management Services, and their agents, agencies, contractors, and instrumentalities. Further, all

covered entities within Florida are covered by this stay and injunction.

(5) The Court waives any bond requirement found at Fed. R. Civ. P. 65(e). *City of Atlanta v. Metropolitan Atlanta Transp. Auth.*, 636 F.2d 1084, 1094 (5th Cir. Unit B 1981).

DONE AND ORDERED at Tampa, Florida, July 3, 2024.

/s/ William F. Jung
WILLIAM F. JUNG
UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA

STATE OF FLORIDA, et al. Plaintiffs, v. **DEPARTMENT OF HEALTH AND HUMAN SERVICES**, et al., Defendants.	Case No. 8:24-CV-1080-WFJ-TGW

NOTICE OF APPEAL

Please take notice that Defendants hereby appeal to the United States Court of Appeals for the Eleventh Circuit from this Court's Order dated July 3, 2024, ECF No. 41.

Dated: August 30, 2024

Respectfully submitted,

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