

believe that evidence warrants close review particularly where interventions involve potentially irreversible effects on a vulnerable population of minors and adolescents.

Commenters stated that the absence of a Congressional restriction on FFP for sex-rejecting procedures implies we lack authority to impose one by regulation. We do not agree. Our authority here derives from sections 1902(a)(19), 1902(a)(30)(A), and 2101(a) of the Act. These provisions include substantive standards that we are authorized to implement through regulations, including through conditions on FFP.

Comment: Commenters raised broader concerns that a broad reading of these provisions would confer essentially unbounded agency discretion to terminate coverage for politically disfavored services, that States cannot realistically absorb such a large funding shift despite CMS' idea that State-only funding remains available, and that defining an FFP exclusion by clinician intent rather than service type is an approach unsupported by the statute's text.

Response: We do not agree. Section 1102 of the Act provides the Secretary authority to make and publish "such rules and regulations, not inconsistent with th[e] Act, as may be necessary for the efficient administration of the functions with which the Secretary is charged under th[e] Act." Based on the potential risk of harm to children, this rule requires the discontinuation of Federal Medicaid and CHIP funding for sex-rejecting procedures. Sections 1902(a)(19) and 1902(a)(30)(A) of the Act require that Medicaid payments be consistent with quality of care and Medicaid-covered care and services be provided in a manner consistent with the best interests of beneficiaries. In addition, section 2101(a) of the Act calls for the provision of CHIP in a manner that is effective and efficient and coordinated with other sources of health benefits coverage for children.

Sections 1902(a)(19), 1902(a)(30), and 2101(a) of the Act are provisions that the Secretary is responsible for administering. CMS has been delegated the authority to ensure that Medicaid and CHIP State plans are consistent with these statutory requirements, and thus, this rule is a proper exercise of the Secretary's authority under section 1102 to carry out those functions.

Comment: Many commenters indicated that the proposed rule did not satisfy the requirements under section 1902(a)(19) that care be provided in a manner consistent with simplicity of administration and the best interests of the recipients, or under section

1902(a)(30)(A) to provide methods to assure that payments are consistent with quality of care. These commenters suggested that banning coverage for sex-rejecting procedures was not consistent with the best interests of recipients or with ensuring quality of care, and thus violated these provisions. Several commenters specifically stated that categorically denying coverage for sex-rejecting procedures without taking into account individualized clinical assessments, treating provider input, or medical necessity did not serve the patient's best interests or assure quality of care. A few commenters that stated the proposed rule undermined "quality of care" stated that the proposed rule took an entirely one-sided approach to sex-rejecting procedures, acknowledging and overstating the potential risks without considering their benefits. A commenter stated that the relevant medical studies and clinical practice guidelines demonstrated that sex-rejecting procedures were far more likely to help rather than harm gender-dysphoric adolescents." A few commenters stated that these services were in fact consistent with quality of care and denying care would jeopardize recipients' best interests, compromise quality of care, and place gender-dysphoric children at significant risk of harm. A commenter stated that while CMS claimed the proposed rule protected "best interests" and ensured "quality of care," it provided no evidence that denying established care served these requirements. A commenter who stated that categorically excluding coverage for sex-rejecting procedures was inconsistent with the statutory requirements at section 1902(a)(19) believed that the proposed rule was a politically motivated agency determination that contradicts medical expertise.

A commenter stated that courts have interpreted section 1902(a)(19) as requiring HHS to ensure that States covered medically necessary care in their State Medicaid programs, and that these courts have made clear that a policy that eliminated coverage of an entire category of services was not in the best interests of beneficiaries. This commenter claimed that this provision did not permit HHS to withhold payments for sex-rejecting procedures to youth; on the contrary, the commenter stated it compelled HHS to ensure Medicaid coverage of these services when they were necessary.

A few commenters stated that the proposed rule did not meet the requirements of section 1902(a)(19) of the Act that care and services shall be provided "in a manner consistent with

simplicity of administration." The commenters stated that the limitations and exceptions set forth in the proposed rule and the different age standards for Medicaid and CHIP added significant complexity to the administration of the programs. A few commenters cited the CMS Innovation Center, Key Concepts: "Quality of Care", stating that HHS had interpreted "quality of care" to mean, "[t]he degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge. High quality care means that providers follow current best medical evidence and prioritize decisions that are consistent with peoples' values, needs, and preferences for a positive patient experience."¹⁵⁰

Response: We do not agree with commenters who contend that prohibiting FFP for sex-rejecting procedures is inconsistent with the best interests of Medicaid recipients or with quality of care as required by sections 1902(a)(19) and 1902(a)(30)(A) of the Act. Our determination reflects a thorough and careful review of the evidentiary record. The HHS Review conducted an umbrella review of systematic reviews addressing the benefits and harms of hormonal and surgical interventions for children and adolescents diagnosed with gender dysphoria and found that the overall quality of evidence concerning the effects of these interventions on psychological outcomes, quality of life, regret, and long-term health is very low. It further identified plausible risks of significant harms, including infertility, sexual dysfunction, impaired bone density, adverse cognitive impacts, cardiovascular and metabolic disorders, psychiatric disorders, and surgical complications. These findings—combined with the independent assessments of health authorities in the United Kingdom, Sweden, and Finland, each of which concluded that the risks of these interventions may outweigh the benefits for children at the population level—support our conclusion that FFP for sex-rejecting procedures used for the purposes described in this rule is not consistent with quality of care or the best interests of recipients.

We have carefully reviewed the peer-reviewed studies and clinical guidelines submitted by commenters in opposition to this rule. We acknowledge that some studies report positive mental health outcomes associated with sex-rejecting

¹⁵⁰ "Quality of Care," CMS, accessed June 1, 2026, <https://www.cms.gov/priorities/innovation/key-concepts/quality-care>.

medical interventions. However, as the HHS Review and independent systematic reviews explain, these studies are largely characterized by methodological limitations, short follow-up periods, small sample sizes, high dropout rates, and insufficient attention to confounding factors. The clinical guidelines that rely on those studies, including those issued by WPATH, have been found by independent assessors to fall short of accepted standards for evidence-based guideline development, including for management of conflicts of interest, transparency of evidence review, and separation of advocacy from scientific assessment.¹⁵¹

The existence of clinical guidelines endorsing a practice, and of studies reporting some beneficial outcomes, does not require us to finance that practice with Federal Medicaid and CHIP funds when the overall evidence base is characterized by very low certainty and the potential for irreversible harm. Evaluating quality of care involves a substantive assessment of the evidence, and based on that assessment, we have determined that the services covered by this rule do not meet the quality of care standard for FFP.

We also note that the cited CMS Innovation Center definition of “quality of care,” “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge” is, if anything, supportive of our position. The current state of professional knowledge, as reflected in the HHS Review and in the reassessments of multiple European health authorities, does not establish that sex-rejecting procedures reliably increase the likelihood of desired health outcomes for children diagnosed with gender dysphoria.

Regarding complexity of administration, we acknowledge that purpose-based restrictions introduce operational considerations that require attention. As discussed elsewhere in this final rule, CMS has considered these implementation issues, including the administrative steps required of States and the alignment of the CHIP requirements with the Medicaid framework. We also recognize that States may need to undertake administrative actions such as updating

State Plan Amendments, coordinating with managed care plans and providers, and engaging legal counsel and senior leadership during implementation.

Comment: Many commenters believed the proposed rule infringed on States’ rights to control the practice of medicine. Many commenters stated that the proposed rule violated section 1801 of the Social Security Act, which prohibits the Federal government from exercising control over the practice of medicine. Several commenters suggested that the proposed rule and the “Hospital Condition of Participation: Prohibiting Sex-Rejecting Procedures for Children” (Hospital COP) proposed rule exhibited conflicting stances on sex-rejecting procedures because in the proposed Hospital COP rule, CMS indicated it has authority to establish the condition of participation, despite 42 U.S.C. 1395’s prohibition on Federal control over the practice of medicine, because sex-rejecting procedures are “not health care.” In contrast, these commenters indicated they believe this rule designates sex-rejecting procedures as health care and relies upon that designation for establishing Medicaid/CHIP restrictions on sex-rejecting procedures. Several commenters did not agree with CMS’ statement in the proposed Hospital COP rule that sex-rejecting procedures were not health care, stating that this framing is circular and contrary to the positions of established medical organizations. Several commenters believed that Congress intended for the control over the practice of medicine to lie with the States and thus the proposed rule was a violation of States’ rights, as CMS lacked explicit Congressional authorization or statutory authority for this rule. A few commenters stated that courts and CMS have often recognized that States have the primary authority to regulate or control the practice of medicine, pointing to a variety of legal, statutory, and regulatory precedent including *Linder v. United States*, 268 U.S. 5, 18 (1925); *Judge Rotenberg Educational Center, Inc. v. U.S. Food & Drug Admin.*, 3 F.4th 390, 399–400 (D.C. Cir. 2021); *in Re: Subpoena No. 25–1431–014*, 2025 WL 3252648 *2–3 (E.D. Penn. 2025); *Oregon v. Ashcroft*, 368 F.3d 1118 (9th Cir. 2004); *Gonzales v. Oregon*, 546 U.S. 243 (2006); 90 FR at 59,447–59,448; *United States v. Skrmetti*, 605 U.S. 495, 522–523 (2025); *New York v. United States*, 505 U.S. 144, 162, 167 (1992); and *Nat’l Fed’n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 554 (2012). A commenter suggested that the proposed rule removed States’ ability to adjust Medicaid coverage and

benefits based on local population health needs and threatened the long-term stability of primary care and mental health providers, and thus they opposed CMS’ infringement on the practice of medicine. A commenter indicated that the proposed rule may place Federally Qualified Health Centers and Certified Community Behavioral Health Centers in conflict with State scope of practice laws.

Response: We do not agree with commenters who stated that this rule violates section 1801 of the Social Security Act, 42 U.S.C. 1395, by impermissibly interfering with the practice of medicine or with States’ traditional authority to regulate medical practice. We address this issue and the other concerns raised by comments individually below.

Section 1801 of the Act. Section 1801 provides that nothing in title XVIII of the Act (governing Medicare) “shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided.” This provision is part of the Medicare title of the Act and does not apply to Medicaid or CHIP. This rule is consistent with prior Medicaid rules that impose conditions on Federal Medicaid payment for services. Regardless, this rule does not direct physicians regarding what services they may recommend or provide; it does not dictate the manner in which any medical services are provided; it does not impose sanctions on providers for furnishing sex-rejecting procedures; it does not exclude providers from federal health care programs for furnishing sex-rejecting procedures; it does not alter the scope of professional practice under applicable State law; it does not govern the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; and it does not control the administration or operation of any medical institution, agency, or person.

Consistency with the Hospital COP proposed rule. We acknowledge that commenters have identified potential differences between the characterization of sex-rejecting procedures in the Hospital COP proposed rule and their characterization in this rule. While the NPRM for this rule and the Hospital COP rule were released on the same date, this rule is being finalized pursuant to sections 1902(a)(19), 1902(a)(30)(A), and 2101(a) of the Act. This rule and the proposed Hospital COP rule operate independently of one another. We continue to separately review comments received on the

¹⁵¹ Jo Taylor et al., “Clinical guidelines for children and adolescents experiencing gender dysphoria or incongruence: a systematic review of guideline quality (part 1),” *Archives of Disease in Childhood* 109, Supp. 2 (2024): s65–s72, doi:10.1136/archdischild-2023-326499.

Hospital COP proposed rule. This rule's validity rests independently on sections 1902(a)(19), 1902(a)(30)(A), and 2101(a) of the Act.

State's Traditional Authority to regulate medical practice. We agree with commenters that the States have traditionally used their police powers to regulate the practice of medicine. And, the Supreme Court has noted that it has traditionally "never assumed lightly that Congress has derogated State regulation" in the health care context. *N.Y. Conference of Blue Cross & Blue Shield Plans v. Traveler's Ins. Co.*, 514 U.S. 645 (1995). But as this quotation suggests, the presumption is not absolute, especially where there is a compelling Federal interest because Federal funding is involved or where there is a clear national interest in uniformity across State lines. For example, the Medicare program pre-empts all state laws "with respect to" the Medicare Advantage and Part D programs, under sections 1856(b)(3) and 1860D–12(g) of the Act. Therefore, we do not agree that CMS is impermissibly interfering with States' traditional police powers to regulate the practice of medicine.

Comment: Several commenters stated that neither section 1902(a)(19) nor section 1902(a)(30)(A) of the Act allowed CMS to base funding decisions on the HHS Secretary's interpretation of accepted standards of medical practice. A few commenters stated the rule was inconsistent with CMS' historical deference to States and medical providers on matters of medical necessity and appropriate clinical care under the Medicaid and CHIP programs. These commenters believed that CMS had not provided sufficient justification or evidence to override the judgment of medical providers and substitute its own clinical policy regarding the treatment of gender dysphoria. A commenter suggested that claiming this rule was necessary under sections 1902(a)(19) and 1902(a)(30)(A) of the Act was pretextual. The commenter believed that this sudden reversal in policy was based on political pressure. A commenter stated concern that CMS was substituting its judgment for the consensus of the entire American medical establishment and suggested that this contradicted the fundamental purpose of section 1902(a)(19) of the Social Security Act, which required care to be provided in ways that benefit recipients according to recognized medical standards, not according to politically motivated agency determinations that contradict medical expertise. Similarly, another commenter stated the proposed rule would

transform the Federal-State partnership into a vehicle for Federally-imposed clinical judgements, overriding State determinations about State-specific standards for Medicaid and forcing States to choose between serving residents' health needs and receiving Federal Medicaid funds where the State chooses to support covering sex-rejecting procedures for its residents. A commenter stated that Congress left decisions about appropriate medical services and procedures to the States and their providers and has explicitly prohibited CMS from supplanting State authority in this area.

Response: We do not agree with commenters who characterize this rule as an impermissible intrusion into physicians' scope of practice or into States' authority to regulate the practice of medicine. The rule does not regulate what physicians may recommend, what procedures providers may furnish on a voluntary basis, or what services States may authorize under their own authority. It establishes the conditions under which FFP is available under the Medicaid and CHIP programs. That is a distinct legal question governed by the Medicaid and CHIP statutes, not by principles of medical licensure or State regulation of clinical practice.

Comment: A few commenters stated that the proposed rule served the best interests of Medicaid recipients consistent with section 1902(a)(19) of the Act and ensured that payment methodologies were consistent with quality of care consistent with section 1902(a)(30)(A) of the Act. These commenters noted concern that interventions that caused significant harm to children, including permanent sterility, irreversible physical changes, and lifelong medicalization, absent evidence of benefit, could not meet the best interests and quality of care standards under these statutory provisions. A few commenters also stated that where statutory quality or best interest standards were implicated, CMS had not only the authority but the obligation to act, and that in the proposed rule, CMS was acting within its delegated oversight authority to align FFP with statutory quality-of-care and best interest mandates. These commenters stated that the Medicaid program was not required to subsidize every medical procedure and, in this case, the current evidentiary landscape did not demonstrate sufficiently robust, long-term health benefits to mandate Federal payment participation for sex-rejecting procedures. In addition, a commenter noted that HHS holds broad authority under section 1902(a)(19) of the Act (and other cited statutes) to

regulate Federal health programs, including payment criteria, exclusions for substandard care, and waste prevention. A commenter noted that quality of care was defined by the balance between demonstrated therapeutic benefit and foreseeable risk. This commenter further stated that where interventions carried significant and potentially permanent physiological effects, the evidentiary threshold supporting Federal funding must be correspondingly rigorous, and that the Federal government had long recognized heightened protective obligations in contexts involving children, particularly when irreversible outcomes were implicated. This commenter also suggested that the provisions of section 1902(a)(19) and (a)(30)(A) of the Act were not merely procedural; instead, they established substantive guardrails for FFP and that the Federal government retained authority to define the scope of FFP consistent with statutory directives governing quality and efficiency. This commenter noted that States retained authority to fund services using State-only dollars, preserving the federalism balance. Finally, a commenter addressed the principle of medical necessity, stating that medical necessity required more than a clinician's subjective judgment; it required a reasonable evidentiary basis that the intervention was likely to improve health outcomes and that its benefits outweighed its risks. The commenter noted that States and CMS shared a duty to ensure that Medicaid funds were not used for interventions that were experimental, unsafe, or contrary to the welfare of children and that sex-rejecting procedures for children did not meet the threshold of medical necessity and should not be subsidized with Federal dollars.

Response: We appreciate the comments from those who recognized that this rule is consistent with sections 1902(a)(19) and 1902(a)(30)(A) of the Act. The current evidentiary record regarding sex-rejecting procedures for children—characterized by very low certainty of benefit and plausible evidence of risks of significant, potentially irreversible harms—does not support FFP for these procedures for the purposes described in this rule. Our determination to that effect is a reasoned implementation of section 1902(a)(19) and 1902(a)(30)(A) of the Act, consistent with our responsibility to ensure that States comply with those sections of the Act.

Comment: A commenter believed that the proposals in the rule were consistent with CMS' delegated authority and

agreed with CMS' interpretation of the authority to regulate services offered by the CHIP programs under the imperative to align with quality and patient protection obligations, particularly where pediatric populations were concerned. The commenter also highlighted that the proposed rule preserved the principles of federalism, which allowed States to fund sex-rejecting procedures using State-only funding. A commenter noted that CMS had the statutory authority to define the scope of FFP based on quality concerns, and the CHIP program existed within that authority.

Response: We appreciate the support expressed by commenters for our exercise of delegated authority and the authority to regulate services offered by CHIP. We also appreciate their recognition that this rule preserves federalism by permitting States to fund sex-rejecting procedures using State-only resources.

Comment: Many commenters believed that the proposed rule should not apply to "children under 19" because at age 18, a person is considered a legal adult who can make their own decisions, and thus the rule impacted adult medical care. A few commenters stated that this would create a burden for providers, who must then verify whether an 18-year-old patient is enrolled in Medicaid or CHIP benefits before deciding on treatment planning.

Response: We acknowledge commenters' concerns about the application of the CHIP prohibition to 18-year-old enrollees, who would be legal adults under the law of most States. As explained in the proposed rule and this final rule, the age threshold of "under 19" for CHIP reflects Congress's statutory definition of "targeted low-income child" at section 2110(c)(1) of the Act, which defines that term to mean "an individual under 19 years of age." Our use of this threshold directly tracks with Congress's statutory definition that governs CHIP eligibility and aligns the rule's scope with the program's statutory structure.

We recognize that this creates an operational distinction between 18-year-old Medicaid enrollees, for whom FFP is not prohibited under the Medicaid component of this rule, and 18-year-old CHIP enrollees, for whom the prohibition applies. This distinction reflects the different statutory definitions applicable to Medicaid and CHIP and is explained in the preamble of this rule. We also reiterate that States are not prohibited from covering sex-rejecting procedures for 18-year-old CHIP enrollees using State-only funds.

Comment: A commenter in support of the rule thanked CMS for recognizing that the age of a "child" in CHIP includes those who are up to age 19.

Response: We appreciate the comment recognizing that the different age thresholds applied in this rule to Medicaid and CHIP reflect deliberate choices, which are consistent with Congress's distinct statutory structures of those programs. As explained in the proposed rule, the "under 18" threshold for Medicaid corresponds to the age of majority recognized in nearly all States and Territories, while the "under 19" threshold for CHIP reflects the statutory definition of "targeted low-income child" at section 2110(c)(1) of the Act.

Comment: Many commenters stated concern that the proposed rule was arbitrary and capricious and/or violated the Administrative Procedure Act (APA). Many commenters indicated that they believed the proposed rule ignored established medical consensus and evidence around the safety, efficacy, and benefits of sex-rejecting procedures, and thus the proposed rule was arbitrary and capricious. Many commenters suggested that CMS failed to consider the reliance interests of patients, their families, providers and State Medicaid agencies on Medicaid and CHIP coverage of sex-rejecting procedures and in doing so violated the APA. Several commenters stated that CMS exceeded its authority in promulgating the proposed rule, raising concerns under the APA. Several commenters indicated they believed CMS failed to consider reasonable alternatives to the proposed rule, thereby violating the APA. Several commenters stated that by prohibiting FFP to States for certain pharmaceutical or surgical interventions for individuals with gender dysphoria but allowing FFP for those same pharmaceutical or surgical interventions for individuals with other diagnoses or for individuals with disorders of sexual development, the proposed rule was arbitrary. A few commenters indicated that they believed by departing from the prior policy of allowing States to determine medical necessity for Federal benefits without a reasoned explanation for the change, the proposed rule was arbitrary. A few commenters indicated that they believed CMS failed to provide "fair notice" of the proposed rule. A few commenters stated the proposed rule was arbitrary and capricious because CMS failed to consider significant costs associated with the proposed rule. A commenter suggested that any rule CMS finalized on this topic must be a logical outgrowth of the proposed rule and if CMS "introduces new definitions, expands the scope of prohibited

treatments, alters the scientific rationale, or changes enforcement mechanisms in ways that interested parties could not reasonably have anticipated from the proposal," they believed additional notice and comment periods would be necessary.

Response: We do not agree with commenters who contend that this rule is arbitrary and capricious or otherwise violates the APA. Generally, under the APA, agency action is not arbitrary and capricious if the agency has considered relevant factors, examined the relevant data, and articulated a satisfactory explanation for its action.¹⁵² This rule meets those standards.

Evidence base. We conducted a thorough review of the available evidence, including the HHS Review, which conducted an umbrella review of systematic reviews assessing the benefits and harms of hormonal and surgical interventions for children and adolescents with gender dysphoria, as well as the Cass Review commissioned by the National Health Service in England, and the independent systematic reviews that informed policy changes by health authorities in Sweden and Finland. We have examined this evidence, acknowledged its limitations, and reached a reasoned conclusion that the very low certainty of benefit and plausible evidence of risks of significant, irreversible harms does not support FFP for these procedures for the purposes described in this rule. The existence of peer-reviewed studies and clinical guidelines supporting a different view does not render our determination arbitrary; it reflects a substantive difference in interpretation of a genuinely contested evidentiary record, which is the kind of judgment that lies within our expertise and discretion.

Reliance interests. In this rule, as well as in the proposed rule, we acknowledge the interests of States, providers, and beneficiaries who have relied on FFP for sex-rejecting procedures and have carefully considered those reliance interests in this rule. The approach we are finalizing addresses these issues because we carefully considered those reliance interests but concluded they are outweighed by the potential for significant and irreversible harm to children in circumstances where the evidentiary basis for benefit is very uncertain. That is a reasoned weighing of competing considerations, not a failure to consider an important aspect of the problem. Moreover, the reliance

¹⁵² See *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42–43 (1983).

interests at stake are mitigated by States' ability to continue covering these services with State-only funds, and by the prospective application of this rule following a full notice-and-comment rulemaking process. Additionally, we are finalizing the provision of FFP for a limited tapering period for a discrete category of affected beneficiaries. Specifically, for current Medicaid and CHIP beneficiaries who are receiving cross-sex hormone therapy as part of sex-rejecting procedures as of the effective date of this final rule, State Medicaid and CHIP Agencies may continue to claim FFP for those cross-sex hormone therapy medications for a tapering period of up to 6 months from the effective date of this final rule. This tapering period is intended to provide beneficiaries and their treating providers a reasonable opportunity to phase off these medications in a manner that allows for clinical discretion if desired. As noted earlier, we concluded that a 6-month period strikes the appropriate balance between providing a reasonable period for individuals to consider discontinuing cross-sex hormones and avoiding unnecessarily prolonging the availability of Federal funding for procedures that raise the child safety concerns animating this rule. The 6-month tapering period is not intended to serve as a clinical guideline. Treating providers may find a different timeline for tapering off cross-sex hormones to be appropriate.

Statutory authority. As discussed at length elsewhere in this rule, sections 1902(a)(19), 1902(a)(30)(A), and 2101(a) of the Act authorize CMS to establish conditions on FFP. This rule is an exercise of that authority.

Alternatives. The proposed rule identified taking no action as the primary alternative considered and provided a detailed explanation of why we determined Federal regulatory action was warranted. We also note that the rule itself represents a more carefully calibrated approach than a blanket prohibition: the pharmaceutical or surgical interventions included within the definition of sex-rejecting procedures remain Federally matched when treating an individual with a medically verifiable disorder of sexual development; for purposes other than attempting to align an individual's physical appearance or body with an asserted identity that differs from the individual's sex; or to treat complications, including any infection, injury, disease, or disorder that has been caused by or exacerbated by the performance of sex-rejecting procedure(s). This targeted, purpose-based approach represents our effort to

narrow the restriction to the specific evidentiary concerns at issue while preserving FFP for other uses.

Arbitrary distinction argument. Several commenters stated that this rule was arbitrary because it permits FFP for sex-rejecting procedures when provided for other diagnoses while prohibiting it when provided to treat gender dysphoria. We do not agree. Our conclusion that the evidence base is insufficient to support FFP for this particular use of these procedures, while remaining sufficient for other uses, reflects a substantive, evidence-grounded distinction, not an arbitrary one.

Fair notice. The proposed rule published on December 19, 2025 set forth our legal and factual rationale in detail and provided a full public comment period. The notice and comment process satisfied the APA's procedural requirements. Commenters had a meaningful opportunity to engage with our reasoning and submit evidence and arguments, as the large volume of substantive comments received demonstrates.

Comment: Several commenters requested that their comments, including any articles, studies, or other supporting materials and documentation provided with their comments, be considered part of the formal administrative record.

Response: We have considered all comments received during the public comment period, including the studies, reports, clinical guidelines, and other materials submitted by commenters as attachments or referenced through hyperlinks. All comments received through the close of the comment period are part of our review in developing this final rule, and all materials submitted directly through the rulemaking docket will be maintained as part of the administrative record in accordance with applicable records management requirements.

Comment: Many commenters believed the proposed rule violated section 1927 of the Act, which established the Medicaid Drug Rebate Program. Several commenters believed section 1927 of the Act generally required State Medicaid programs to cover all medically accepted indications of all FDA-approved outpatient drugs, with limited exceptions, and the statute did not permit CMS or States to selectively exclude some medically accepted indications of covered drugs. A few commenters stated that under section 1927(d)(2) of the Act, Congress established a very limited list of excludable indications under the Medicaid program, and drugs used to

treat gender dysphoria were not a part of this list of exclusions. A few commenters expressed concern that the proposed rule, if finalized, would be operationally unworkable as it related to section 1927 of the Act because there is no claims field or modifier that can reliably encode whether a drug, device, or procedure was furnished "to align a child's appearance or body with an asserted identity," and therefore prescriber intent cannot be captured. A commenter stated that court decisions in multiple lawsuits against States that have chosen to restrict covered outpatient drugs, like direct-acting antivirals for Hepatitis C Virus, in the Medicaid Drug Rebate Program, demonstrate that States must cover all covered outpatient drugs for medically indicated purposes.

Response: We do not believe this rule conflicts with or violates section 1927 of the Act because the rule does not categorically exclude from Medicaid coverage any covered outpatient drug for which a manufacturer participating in the Medicaid Drug Rebate Program has paid a rebate. Rather, the rule limits FFP only for a specific use of certain otherwise covered outpatient drugs in a defined population, while States would remain required to cover those drugs for all other medically accepted indications, including uses approved by FDA or supported by applicable compendia. We believe this limitation is authorized under sections 1902(a)(19) and 1902(a)(30)(A) of the Act.

We acknowledge that this FFP restriction creates operational complexity because pharmacy claims typically do not capture the indication for which a drug is being prescribed. States will need to develop prior-authorization processes, utilization management protocols, and other administrative tools to implement this restriction in a manner consistent with both this rule and their obligations under section 1927 of the Act. However, these processes already occur in other circumstances. For example, States are permitted to exclude from coverage drugs when prescribed for weight loss under section 1927(d)(2)(A) of the Act. As noted above, however, although GLP-1 agonists are often prescribed for weight loss, they are also prescribed for other purposes, such as hemoglobin A1C control for patients with diabetes or pre-diabetes. States that have elected to not cover GLP-1 agonists for weight loss nevertheless must have processes in place to cover those same agents when prescribed to patients for A1C control. Similarly, states are permitted to exclude drugs when prescribed for sexual dysfunction under section

1927(d)(2)(K) of the Act, but the statute there contains an exception for other purposes “for which the agents have been approved by” the FDA. There again, States must have already developed processes to assure coverage for approved uses of the drugs while denying coverage for statutorily excluded purposes. We believe that States are in a position to develop coding edits that would deny coverage for outpatient drugs when prescribed for sex-rejecting procedures subject to the payment prohibition in the same manner that they have implemented coding edits to deny coverage for outpatient drugs when prescribed for a purpose for which States may choose not to cover those drugs, such as drugs when prescribed for weight loss or sexual dysfunction.

We believe sections 1902(a)(19) and 1902(a)(30)(A) of the Act provide independent authority to limit FFP for uses of covered outpatient drugs that we determine are inconsistent with quality of care and beneficiary protection standards, notwithstanding section 1927’s general drug coverage framework. In our view, section 1927 does not eliminate the agency’s broader responsibility to ensure that Medicaid funds are expended in a manner consistent with quality of care and the best interests of beneficiaries, particularly where we have determined, based on a substantive evidentiary assessment, that a specific use of a drug presents significant concerns regarding safety, effectiveness, or long-term harm for a defined population.

Comment: Several commenters believed the proposed rule violated various statutes and laws that protect individuals with disabilities or that the proposed rule discriminated against individuals with disabilities. Several commenters stated that the proposed rule violated section 504 of the Rehabilitation Act by providing unequal access to healthcare. Several commenters believed the proposed rule violated the Americans with Disabilities Act (ADA) by discriminating against individuals with disabilities in public services and accommodations, including hospitals. A commenter believed the proposed rule violated section 508 of the Rehabilitation Act, which prohibits discrimination on several bases, including disability. A commenter stated that in 2022, the Fourth Circuit ruled in *Williams v. Kincaid*, 45 F. 4th 759 (4th Cir. 2022) that gender dysphoria could be considered a disability under the ADA. A commenter believed HHS was aware that the proposed rule violated the Rehabilitation Act as evidenced by a

separate HHS Office of Civil Rights (OCR) proposed rule, which extended the statutory exclusion for “gender identity disorders not resulting from physical impairments” to include “gender dysphoria not resulting from physical impairments.” This commenter stated that the HHS OCR proposed rule was “incompatible with the purpose and historical meaning of that statute” and this Medicaid and CHIP proposed rule still violated the Rehabilitation Act because the rule failed to make adequate exceptions for gender dysphoria that does result from a physical impairment.

Response: We do not agree with commenters who contend that this rule violates the Americans with Disabilities Act or sections 504 or 508 of the Rehabilitation Act by discriminating against individuals with gender dysphoria on the basis of disability. This rule does not deny Medicaid coverage, in general, to individuals with gender dysphoria. The rule’s restriction on FFP is based on the *purpose* for which specific pharmaceutical and surgical interventions are furnished, namely, whether they are being used to align a child’s physical appearance or body with an asserted identity that differs from the child’s sex. The FFP restriction applies for sex-rejecting procedures; it applies equally to all children for whom these procedures would be used for that purpose, regardless of status. Children with gender dysphoria who are enrolled in Medicaid and CHIP continue to have access to the full range of Federally-reimbursable mental health services, including psychotherapy.

We do not agree with commenters who contend that this rule violates the ADA and section 504 by discriminating against individuals with gender dysphoria. We take the same position as the HHS Office for Civil Rights set out in its 2025 Section 504 proposed rule: gender dysphoria not resulting from physical impairments does not constitute a covered disability. See Nondiscrimination on the Basis of Disability in Programs or Activities Receiving Federal Financial Assistance, 90 FR 59478, 59480 (Dec. 19, 2025). For more background on HHS’s Section 504 proposed rule and its analysis under Section 504 and the ADA, we refer commenters to that proposed rule and the separate rulemaking process. 90 FR 59478, 59480 (Dec. 19, 2025).

Regardless, this rule does not deny coverage to individuals with gender dysphoria on the basis of their diagnosis or disability status. The rule’s restriction is based on the *purpose* for which specific pharmaceutical and surgical interventions are furnished, namely,

whether they are being used to align a child’s physical appearance or body with an asserted identity that differs from the child’s sex. The restriction does not depend upon the beneficiary’s diagnosis; it applies equally to all children for whom these procedures would be used for that purpose, regardless of any disability status. Children with gender dysphoria who are enrolled in Medicaid and CHIP continue to have access to the full range of Federally reimbursable mental health services, including psychotherapy.

Comment: Several commenters commented on CMS’ comparison in the proposed rule of prohibiting FFP for sex-rejecting procedures furnished to children to prohibiting FFP for permanent sterilizations furnished to individuals under age 21 (at § 441.253), indicating they found the comparison inappropriate. A few commenters stated that the prohibition on FFP for permanent sterilizations furnished to children can be traced directly back to the Congress’s statutory definition of covered “family planning services”, which required informed consent for those services. Thus, the prohibition on sterilization services relied on Congressional authority that does not apply in the context of sex-rejecting procedures. A few commenters suggested that the comparison to the prohibition on sterilization services was inappropriate because they believed sex-rejecting procedures are not irreversible, unlike sterilization services. A few commenters stated that the prohibition on FFP for sex-rejecting procedures was not comparable to the prohibition on FFP for sterilization services because there was no evidence to suggest that children and youth enrolled in Medicaid and CHIP have been forced or coerced into sex-rejecting procedures, unlike children and youth previously sterilized in Federal programs. A few commenters believed the comparison did not apply because sex-rejecting procedures, unlike sterilization services, are not family planning services. A commenter stated the comparison did not apply because “there are no equally effective, alternative services available to treat adolescents with gender dysphoria.”

Response: We acknowledge commenters’ observations regarding the factual and legal distinctions between this rule and the regulations at § 441.253 restricting FFP for sterilizations furnished to individuals under age 21. Commenters are correct that the sterilization regulations were prompted by documented instances of coercion in Federal programs and were anchored in specific statutory language regarding

family planning services, a statutory context that differs from the one applicable here.

We referenced the sterilization regulations in the proposed rule not as a direct legal predicate but as a precedent illustrating that we have previously recognized, in a different context, that age-based limits on FFP for procedures with potentially irreversible consequences are an appropriate exercise of our rulemaking authority where concerns about the capacity of the affected population to meaningfully consent to or appreciate those consequences are well-founded.

Comment: Several commenters discussed the connection between the proposed rule and other ongoing Federal actions related to sex-rejecting procedures. Several commenters stated they believed the proposed rule, viewed alongside CMS' "Hospital Condition of Participation: Prohibiting Sex-Rejecting Procedures for Children" (Hospital COP) proposed rule, the HHS Office for Civil Rights' "Nondiscrimination on the Basis of Disability in Programs or Activities Receiving Federal Financial Assistance" (OCR) proposed rule, the Food and Drug Administration's warning letters to manufacturers and retailers for illegal marketing of breast binders to children for the purposes of treating gender dysphoria, HHS Secretary Robert F. Kennedy, Jr.'s Declaration of the Department of Health and Human Services "RE: Safety, Effectiveness, and Professional Standards of Care for Sex-Rejecting Procedures on Children and Adolescents" (the Kennedy Declaration), Department of Justice subpoenas requesting personal health information of minor patients receiving sex-rejecting procedures, and the press conference announcing the proposed rule, demonstrated a targeted campaign against gender-dysphoric youth. A few commenters suggested that CMS failed to provide sufficient explanation as to how this rule, the proposed Hospital COP rule, the OCR rule, and the Kennedy Declaration would interact.

Response: We acknowledge that this rule is one of several recent actions addressing sex-rejecting procedures for children. Each of those actions rests on independent legal authority appropriate to the program or regulatory context it addresses. This rule is grounded in sections 1902(a)(19) and 1902(a)(30)(A) of the Act for Medicaid, and section 2101(a) of the Act for CHIP, and it is independent from other actions addressing sex-rejecting procedures for children. It does not rely on the Kennedy Declaration, the Hospital COP proposed rule, the OCR proposed rule

regarding the Rehabilitation Act, or any other concurrent Federal action.

We also affirm, consistent with the statement in the proposed rule, that this rule does not rely on the enjoined provisions of EOs 14168 and 14187. We made this proposal independently of the EOs, based on the legal authorities identified above and on our substantive assessment of the evidentiary record regarding sex-rejecting procedures for children. This rule will not be implemented in contravention of any court orders. Any regulatory provisions on this issue will not become effective until the specified effective date of the final rule.

We recognize that the concurrent issuance of multiple actions related to sex-rejecting procedures for children raises legitimate questions about how those actions interact, what their cumulative effect may be for States, providers, and beneficiaries, and whether apparent tensions in the characterization of sex-rejecting procedures across different actions have been adequately addressed. We will provide clear, consistent guidance to assist States, providers, and other interested parties in understanding the scope and interaction of applicable Federal requirements.

Lastly, as we discuss in more detail in other responses to comments, we do not agree with commenters who characterize this rule as a campaign against gender-dysphoric youth. While the commenters may disagree with the policy reflected in this rule, that policy is based on real concern about the safety of sex-rejecting procedures for children and the need to protect children.

Comment: Many commenters articulated other legal concerns regarding the proposed rule. Many commenters indicated the proposed rule violated Tribal rights/sovereignty because many Tribes acknowledged non-binary and transgender identities (often called "Two-Spirit"), with one of those commenters indicating the proposed rule violated the Snyder Act of 1921 (25 U.S.C. 13) and the permanent reauthorization of the Indian Health Care Improvement Act (enacted in 2010 as part of the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111–148)). A few commenters stated the proposed rule violated the Mental Health Parity and Addiction Equity Act by creating an imbalance in terms of the access to and recognition of care between a mental health condition [gender dysphoria] and other physical conditions, violating States' rights to define additional mental health conditions to be covered, and limiting the treatment of gender

dysphoria to psychotherapy. A few commenters suggested that in the proposed rule, CMS claimed authority under section 1861(e)(9) of the Act (SSA) to establish requirements "in the interest of the health and safety of individuals" and that by prohibiting an entire category of medically recognized treatment, CMS exceeded its statutory authority. A few commenters believed the proposed rule raised privacy concerns under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). A commenter believed CMS failed to outline how sensitive, patient-specific records would be used, violating the Privacy Act of 1974. A commenter stated that the proposed rule was contrary to the Medicaid Act because it would deny medically necessary care to the individuals the program was meant to support. A commenter indicated that the proposed rule failed to outline how the requirements would interact with the Emergency Medical Treatment & Labor Act. A commenter stated that the proposed rule violated the Unfunded Mandates Reform Act of 1995 by forcing providers to absorb the cost of care. A commenter indicated the proposed rule violated the Rural Development Act of 1972 by disproportionately affecting providers in rural areas. A comment stated that the proposed rule violated E.O. 13132 because CMS did not consult with State and local officials when developing the proposed rule. A commenter indicated that the proposed rule violated HHS' fiduciary duty under 42 U.S.C. 1320a–7(b)(6)(B). A commenter stated that the proposed rule violated the International Covenant on Economic, Social and Cultural Rights and Article 26 of the International Covenant on Civil and Political Rights, which protect against discrimination. A commenter indicated that the proposed rule violated the Foster Care Bill of Rights. A commenter stated that the proposed rule violated Article 3 and 39 of the International Convention on the Rights of the Child. A commenter indicated the proposed rule conflicted with previous rulemaking (86 FR 63458 and 63672) around the inpatient-only list for hospital services, which specified that there are numerous safeguards to ensure safe care without specifying that certain procedures had to be provided on an inpatient basis, which rendered the proposed rule unnecessary. A commenter stated the proposed rule introduced legal risk for safety-net providers by potentially conflicting with accreditation and quality reporting expectations. A commenter believed the proposed rule

deprived judges of their ability to hear case-specific facts and render best interest decisions in cases about medical decision-making rights. A commenter stated that the proposed rule violated section 1102 of the Act because the Secretary's delegation to CMS was limited to regulations that are "necessary to the efficient administration of the functions with which [the Secretary] is charged" and "not inconsistent" with the Medicaid Act, and the commenter believed the proposed rule violated both principles. A commenter stated the proposed rule violated the Affordable Care Act generally. A commenter believed CMS could face prosecution under 42 U.S.C. 1983, 18 U.S.C. 241, and 18 U.S.C. 242 by finalizing the proposed rule. A commenter believed the proposed rule constituted "medical malpractice" on the part of the agency. A commenter stated they believed the proposed rule was "child abuse" and could be prosecuted as such.

Response: We have carefully considered each of the additional legal concerns raised by commenters. We address the most significant challenges below.

Tribal rights and sovereignty. We are committed to fulfilling our legal responsibilities to Tribal nations and to the American Indian and Alaska Native people who rely on Indian Health Service and Tribal health programs. We will engage in government-to-government consultation with Tribal nations regarding implementation of this rule, consistent with our Tribal consultation policy. We will ensure that the rule's implementation is consistent with applicable Federal Indian health law, including the Indian Health Care Improvement Act.

Mental Health Parity and Addiction Equity Act (MHPAEA). This rule does not restrict Medicaid or CHIP coverage of mental health services for individuals with gender dysphoria. Mental health services, including psychotherapy, which multiple health authorities have identified as an appropriate first-line treatment for gender dysphoria in children, remain federally matchable under Medicaid and CHIP. The definition of sex-rejecting procedures in this rule is limited to pharmaceutical and surgical interventions provided for specific purposes; it does not encompass mental health counseling, psychotherapy, or other mental health treatment. We do not believe this rule creates any inconsistency with applicable MHPAEA requirements.

E.O. 13132 and Federalism. We have complied with the directives in E.O. 13132 through the **Federal Register**

rulemaking process, which provided notice to State and local officials and an opportunity to comment. The proposed rule acknowledged that the rule will have a substantial direct effect on States' ability to receive Federal Medicaid and CHIP funds for sex-rejecting procedures, consistent with E.O. 13132's disclosure requirements. We have considered the concerns of State officials expressed through the comment process and addressed them throughout this rule.

HIPAA, Privacy Act, and other information law concerns. This rule does not require the collection of protected health information beyond what is already collected through the existing Medicaid and CHIP claims processes. The HIPAA Privacy Rule permits use and disclosure of protected health information by a covered entity without authorization for purposes of payment, subject to the minimum necessary standard. Implementation of the FFP prohibition established by this rule will require States to develop utilization management processes that may involve prior authorization, which inherently involves some collection of clinical information, which is permitted by HIPAA and other health care privacy statutes.

International law, and other challenges. For arguments based on international human rights conventions and other legal frameworks not directly applicable under domestic law, we note that this rule is grounded in and consistent with applicable United States Federal law. International human rights instruments do not independently govern our regulatory authority under the Medicaid and CHIP statutes.

Other claims. The remaining miscellaneous legal claims raised by commenters, including arguments under the Unfunded Mandates Reform Act, the Emergency Medical Treatment and Labor Act, the Foster Care Bill of Rights, and various other legal theories, do not provide a basis for withdrawing or modifying this rule. Our determination under sections 1902(a)(19), 1902(a)(30)(A), and 2101(a) of the Act is grounded in applicable law and an evidence-based assessment of the risk/benefit profile of sex-rejecting procedures for children, and it is not undermined by the additional legal arguments commenters have raised.

Comment: A few commenters provided other legal arguments in support of the proposed rule. A commenter agreed with CMS' rationale in the proposed rule that purpose-based definitions have been used before to identify medical procedures not eligible for Federal funding, such as for sterilizations under 42 CFR 441.251. A

commenter indicated that the proposed rule aligned with the principles underscoring the Hyde Amendment, which bars the use of Federal funds for most abortions. A commenter suggested there would be eventual class action lawsuits for sex-rejecting procedures. A commenter stated that the rule aligned with EOs on regulatory review and cost containment, and suggested CMS coordinate with the Office of Management and Budget (OMB) and Office of Information and Regulatory Affairs (OIRA) for confirmation. This commenter also suggested that HHS Office of Inspector General (OIG) and Government Accountability Office (GAO) review prior Medicaid and CHIP expenditures related to sex-rejecting procedures.

Response: We appreciate the support by commenters who recognized that this rule is consistent with our statutory authority and with the principles underlying other Federal payment restrictions, including the Hyde Amendment's longstanding limitation on Federal financing of certain abortion services. We appreciate suggestions from commenters regarding coordination with OMB, OIRA, HHS, and GAO regarding the implementation of this rule, and will consider those recommendations in the context of ongoing program oversight activities.

Comment: Many commenters indicated that the HHS Review accurately assessed the current credible medical science regarding sex-rejecting procedures in children. Several commenters stated evidence for improved mental health, reduced suicidality, or durable functioning gains from puberty blockers, hormones, or surgeries in children was "very low" quality so claimed benefits were not scientifically established. Several commenters reinforced the HHS Review findings that emphasized the risk of serious and irreversible harms (for example, infertility/sterility, sexual dysfunction, bone density and cardiometabolic risks, neurodevelopmental effects, surgical complications, regret/detransition). A few commenters supported our restricting Medicaid and CHIP coverage and shifting toward noninvasive approaches like psychotherapy to treat gender dysphoria in children.

Response: We appreciate the commenters who support the HHS Review and the proposed rule. As discussed in the proposed rule and this final rule, the HHS Review conducted an umbrella review of existing systematic reviews to evaluate the evidence regarding the benefits and

harms of hormonal and surgical interventions for children and adolescents diagnosed with gender dysphoria. The HHS Review found that the overall quality of evidence concerning the effects of sex-rejecting procedures on psychological outcomes, quality of life, regret, or long-term health is very low. We agree with commenters that this evidentiary landscape, characterized by weak evidence of benefit and plausible risk of significant and sometimes irreversible harm, supports the basis for the prohibition on FFP for sex-rejecting procedures furnished to children. We also agree with commenters who noted that psychotherapy and other non-invasive mental health services offer a more evidence-supported first-line approach to treating gender dysphoria in children, and we emphasize that such services remain covered under Medicaid and CHIP and will not be affected by this rule.

Comment: Many commenters challenged both the validity and the application of the HHS Review. Several stated that the HHS Review did not support a total ban, stating that it acknowledged uncertainty regarding both benefits and harms, and that the European countries it referenced have generally narrowed or centralized access within research frameworks rather than prohibited care outright. Many commenters stated that the HHS Review was politically motivated and scientifically flawed, arguing that it was written to justify a predetermined policy outcome, that its authors lacked relevant clinical expertise or held publicly anti-transgender positions, that the panel excluded experts who provided gender-affirming care, and that the review process may have violated the Federal Advisory Committee Act. Many commenters also raised objections, including that the HHS Review ¹⁵³ misapplied the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) ¹⁵⁴ framework by conflating low-certainty evidence with proof of ineffectiveness, applied asymmetric evidentiary standards by dismissing evidence of benefit while accepting speculative evidence of harm, and did

not meet accepted standards for umbrella reviews. Several commenters further stated that the HHS Review did not provide equivalent evidence that psychotherapy alone resolves gender dysphoria, and that it departed from the positions of major medical organizations.

Response: As discussed in the proposed rule and this final review, the HHS Review conducted an umbrella review of existing systematic reviews to evaluate the evidence regarding the benefits and harms of hormonal and surgical interventions for children and adolescents diagnosed with gender dysphoria. The HHS Review found that the overall quality of evidence concerning the effects of sex-rejecting procedures on psychological outcomes, quality of life, regret, or long-term health is very low. This evidentiary landscape, characterized by weak evidence of benefit and plausible risk of significant and sometimes irreversible harm, supports the basis for the prohibition on FFP for sex-rejecting procedures furnished to children. Psychotherapy and other non-invasive mental health services offer a more evidence-supported first-line approach to treating gender dysphoria in children, and such services remain covered under Medicaid and CHIP and will not be affected by this rule.

We do not agree with commenters who state that the HHS Review does not support the prohibition finalized in this rule. We acknowledge that the HHS Review states it is not a clinical practice guideline and does not itself mandate any particular policy outcome. However, the HHS Review's findings—specifically, that the evidence base for the effectiveness of sex-rejecting procedures in improving mental health or reducing gender dysphoria symptoms is of very low certainty, while the plausible evidence for risk of significant harms is comparatively less uncertain—provide support for our independent policy determination that Federal Medicaid and CHIP funds should not be used to pay for these procedures for children. The statutory authorities cited in this rule require that Medicaid-covered services be provided in a manner consistent with the best interests of recipients and that payments be consistent with quality of care, and the provision of CHIP in a manner that is effective and efficient and coordinated with other sources of health benefits coverage for children. Given the evidence base and plausible evidence of risk of significant, irreversible harm, we have determined that these statutory obligations are not satisfied by covering

sex-rejecting procedures for children with Federal funds.

We acknowledge commenters' observations that some of the European countries referenced in the proposed rule have not adopted blanket bans, but have instead narrowed access within research frameworks or restricted certain interventions. We note that the policy approaches of Sweden, Finland, and the United Kingdom—while certainly not binding on the administration of the Medicaid and CHIP programs operated by the U.S.—are nonetheless meaningfully more restrictive than prior practice in those countries and reflect independent governmental determinations, consistent with the HHS Review, that the risk-benefit profile of these interventions is unfavorable for the pediatric population at the population level. The fact that those countries have not adopted identical policies to this rule does not undermine the validity of our independent determination that Federal funds should not support these procedures for children enrolled in Medicaid and CHIP.

We do not agree with commenters who characterize the HHS Review as politically motivated or scientifically invalid. The HHS Review was published by HHS's Office of Population Affairs and underwent a formal peer review process consistent with applicable information quality guidelines, with the final version published in November 2025 following conclusion of that process. The review employed an umbrella review methodology, a widely accepted approach for synthesizing systematic reviews, and assessed the methodological quality of existing systematic reviews using established appraisal tools. We acknowledge that commenters raised concerns about the perspectives of the review's contributors and their alleged affiliations; however, the validity of a scientific review is assessed by its methodology and the quality of the evidence it synthesizes, not solely by the prior positions of its authors. We reviewed the HHS Review alongside other available evidence and, consistent with our statutory responsibilities, formed an independent policy judgment.

We also do not agree that the HHS Review is scientifically invalid on methodological grounds. We acknowledge commenters' concerns about the application of the GRADE framework and alleged asymmetric evidentiary standards. However, the HHS Review's central finding, that the evidence for benefit is of very low certainty while evidence of certain physiological harms (such as those

¹⁵³ “HHS Releases Peer-Reviewed Report Discrediting Pediatric Sex-Rejecting Procedures,” U.S. Department of Health and Human Services, released November 19, 2025, <https://www.hhs.gov/press-room/hhs-releases-peer-reviewed-report-discrediting-pediatric-sex-rejecting-procedures.html>.

¹⁵⁴ Ignacio Neumann et al., “Overview of the GRADE approach,” in *The GRADE Book version 1.0*, ed. I. Neumann and H. Schünemann, The GRADE Working Group, (updated September 2024), <https://book.grade.pro.org>.

related to bone density, fertility, and endocrine function) is grounded in established biological mechanisms, is a reasonable and defensible evidentiary conclusion. We acknowledge that umbrella reviews are limited by the quality of the underlying systematic reviews they synthesize, and that the HHS Review itself is transparent about these limitations. The statutory standards do not require certainty of harm; they require that covered services be consistent with the best interests of recipients and with quality of care. Given the weak and uncertain evidence base for benefit, we have determined that funding these procedures for children with Federal Medicaid and CHIP dollars does not satisfy those statutory standards at this time. Nothing in this rule prevents further research into these interventions, and we encourage the development of more robust, long-term evidence on the outcomes associated with treatment of gender dysphoria in children.

We note that concerns about the terminology used in the proposed rule, such as “sex-rejecting procedures”, are addressed separately in our later responses to comments on the definitions. We recognize that this terminology differs from the language adopted by major medical associations; however, its use reflects the purpose-based nature of the prohibition, as discussed further in the definitional responses.

Comment: Several commenters supported the use of the Cass Review as evidence to support the proposed rule, noting that the study demonstrated that treating a mental condition like gender dysphoria with cross-sex hormones and irreversible surgery has not been shown to be safe or effective long term, and that the report provided evidence of the danger of this approach, as well as the potential of detransitioning. A few commenters stated that the Cass Review made it clear that there were no scientific bases for the claimed mental health benefits of these interventions. A few commenters believed that Medicaid and CHIP should not be spending its limited funding on procedures that have not shown to have scientific rigor nor proven effect, as demonstrated by the Cass Review. A commenter, after reading the Cass Review, believed that sex-rejecting behavior was a maladaptive coping mechanism, and another commenter supported the Cass Review and stated that sex-rejecting procedures are homophobic. A commenter believed the United Kingdom took the correct ethical step by banning puberty blockers for children.

Response: We appreciate the commenters who state support for our reliance on the Cass Review. As discussed in the proposed rule and this final rule, the Cass Review was a four-year independent evaluation of pediatric gender medicine commissioned by the United Kingdom’s National Health Service. Its findings, including the lack of robust evidence for the long-term effectiveness of puberty suppression and cross-sex hormones for gender dysphoria in children, are consistent with the conclusions of other systematic reviews cited in the rule and with the HHS Review’s umbrella review. We did not rely solely on the Cass Review but considered it as one element of a broader body of international evidence that informed our determination that Federal Medicaid and CHIP funds should not be used for sex-rejecting procedures furnished to children.

Comment: Many commenters indicated that CMS’ reliance on the Cass Review was misplaced and that the Cass Review did not support the proposed rule. These commenters stated that the Cass Review did not support a total ban on funding for gender-affirming medical care for adolescent gender dysphoria, and instead supported additional research, clinical care on a case-by-case basis, and puberty blockers and hormone therapy for certain gender-dysphoric adolescents. A few commenters stated that the Cass Review made statements consistent with models of gender-affirming care described by WPATH and the Endocrine Society. A few commenters highlighted that the Cass Review cited evidence suggesting hormones are associated with improvements in depression, anxiety, and other mental health difficulties. A commenter stated that the Cass Review did not address surgical interventions and therefore could not be used to justify proposals limiting surgical interventions.

Many commenters also questioned the scientific validity of the Cass Review, stating that it was based on unsound science and misinterpreted evidence, had been heavily criticized, and did not follow established standards for evaluating evidence quality. Several commenters pointed to peer-reviewed studies from BMC Medical Research Methodology, Yale (Noone, et al.),¹⁵⁵ and the New England Journal of

Medicine,¹⁵⁶ which alleged challenges with the Cass Review’s methodology, unsubstantiated claims, and misrepresentation of data. Several commenters remarked on the backgrounds and qualifications of the Cass Review authors, asserting that the review was led by researchers with no experience working with gender dysphoric children, and that the research team included individuals they characterized as openly anti-transgender advocates. A few commenters stated the Cass Review had been criticized by major U.S. medical organizations, including the Endocrine Society, the American Academy of Pediatrics, and the American Psychological Association, as well as the World Health Organization and the WPATH. A few commenters also indicated that the Cass Review was not a peer-reviewed study and raised concerns about biased language and political motivation underlying its findings.

Response: We do not agree with commenters who characterized the Cass Review as scientifically unsound or as not supporting the policy approach finalized in this rule. The Cass Review was commissioned by NHS England, conducted over four years by an independent team, and included a series of systematic reviews assessed using established appraisal criteria. We acknowledge that some medical organizations and researchers have criticized aspects of the Cass Review’s methodology and conclusions. Scientific debate is a normal and healthy feature of evidence development, particularly in an evolving clinical field. However, the methodological criticisms cited by commenters do not invalidate the Cass Review’s central findings regarding the low certainty of the evidence base for sex-rejecting procedures in the pediatric population—findings that are consistent with other independent systematic reviews cited in the proposed rule.

We also acknowledge that the Cass Review does not recommend a categorical ban on all medical interventions and continues to recognize that some individuals may ultimately benefit from transition-related care. However, the Cass Review’s core findings, that the evidence base for puberty suppression and cross-sex hormone therapy is of insufficient quality to support confident clinical recommendations, and that the existing model of care had significant

¹⁵⁵ Chris Noone et al., “Critically Appraising the Cass Report: Methodological Flaws and Unsupported Claims,” *BMC Medical Research Methodology* 25 (2025): 128, <https://doi.org/10.1186/s12874-025-02581-7>.

¹⁵⁶ Diane Chen et al., “Psychosocial Functioning in Transgender Youth after 2 Years of Hormones,” *New England Journal of Medicine* 388 (2023): 3, <https://www.nejm.org/doi/full/10.1056/NEJMoa2206297>.

deficiencies, are fully consistent with our determination that Federal funds should not support these procedures for children. We reviewed the Cass Review as part of a broader evidentiary record and did not rely upon it as the sole or determinative basis for this rule. Our independent policy determination reflects the cumulative weight of international systematic reviews and the HHS Review, all of which identify significant uncertainties in the evidence for benefit alongside plausible risks of irreversible harm. This evidentiary foundation is sufficient to support the policy approach finalized in this rule.

We also note that surgical interventions, addressed only in passing by the Cass Review, are included in this rule's prohibition because surgical sex-rejecting procedures for children raise the same or greater concerns regarding irreversibility, lack of robust evidence, and potential for significant harm.

Comment: Many commenters provided additional research, citations, or details on sex-rejecting procedures for CMS' consideration in support of the proposed rule. Several commenters provided research or documentation indicating that WPATH standards of care lacked reliable evidence and were influenced by advocacy. Several commenters noted research, including from countries such as Finland, Sweden, Denmark, and the United Kingdom, showing that sex-rejecting procedures were restricted after finding insufficient evidence and that the risks outweighed the benefits. Several commenters noted that few publicly available systematic reviews existed on puberty blockers, hormones, and surgeries for children, making it difficult to assess the reliability and safety of this care. A few commenters provided references to research or databases highlighting children's vulnerability to influence and the widespread use of irreversible sex-change procedures in the U.S. A commenter indicated that since the proposed rule was published in December 2025, there have been court decisions against providers of sex-rejecting procedures. This commenter also expressed a belief that the American Society of Plastic Surgeons and the American Medical Association had recently altered their position statements on sex-rejecting procedures.¹⁵⁷ A commenter stated that hospitals and health systems have

responded to "new evidence" on sex-rejecting procedures by choosing to suspend sex-rejecting procedures for children.

Response: We appreciate the additional research and documentation submitted by commenters in support of the proposed rule. We have reviewed these materials, and they are consistent with and reinforce the evidentiary record discussed in the proposed rule and this final rule, including the conclusions of the HHS Review and the international systematic reviews cited therein. We are aware that some medical professional organizations have recently updated their positions on surgical interventions for gender-dysphoric youth, and we note that evolving professional consensus in this area is itself indicative of the genuine uncertainty regarding the risk-benefit profile of these procedures for children—an uncertainty that is central to our determination that Federal funds should not support them under Medicaid and CHIP.

Comment: Many commenters shared additional resources for CMS to consider in opposition to the provisions of the proposed rule. Many commenters cited research and stated that sex-rejecting procedures were a medically necessary standard of care endorsed by major medical and professional organizations, including the American Medical Association, American Academy of Pediatrics, Endocrine Society, American Psychological Association, and the World Health Organization. Many commenters shared studies asserting that access to sex-rejecting procedures reduced depression, anxiety, self-harm, and suicide, and specifically stated that hormones and puberty blockers were safe and medically necessary rather than elective or cosmetic.

Many commenters also discussed international policies and studies referenced in the proposed rule from Australia, Brazil, Denmark, Finland, Italy, New Zealand, Norway, Sweden, and the United Kingdom, arguing that CMS misrepresented foreign developments as evidence for bans when sex-rejecting procedures remain lawful, medically indicated, and often publicly funded in those countries. Several commenters stated that the proposed rule selectively cited outlier scenarios within each country and that the policies of those countries did not align with the proposed rule. Several commenters referenced additional international policies from countries not cited in the proposed rule, stating that those countries defined sex-rejecting procedures as medically necessary,

treated access as a constitutional right, and framed denials as unlawful discrimination.

Many commenters also cited the University of Utah College of Pharmacy's Drug Regimen Review Center report¹⁵⁸ ("Utah Study"), commissioned by the Utah State Legislature, which reviewed several hundred studies on hormone therapy and related treatments. These commenters stated that the Utah Study found hormone therapy for gender-dysphoric youth to be safe, effective, and well supported by evidence, and that policies banning or restricting this care could not be justified on scientific grounds. A few commenters specifically stated that the Utah Study found hormone treatments to be safe for bone density, cardiovascular risk factors, metabolic changes, and cancer.

Response: We have carefully reviewed the studies, international policy materials, and other resources submitted by commenters opposing the proposed rule. We acknowledge that a number of studies, including those cited by commenters and those reviewed in the Utah Study, report positive outcomes associated with gender-affirming care, including reductions in depression, anxiety, and suicidal ideation. We have reviewed these studies, but we note that the HHS Review and other systematic reviews have identified significant methodological limitations in the existing evidence base, including lack of control groups, short follow-up periods, small sample sizes, and high rates of study attrition, that substantially limit the conclusions that can be drawn regarding long-term effectiveness and safety. The Utah Study itself acknowledges these methodological limitations, including the absence of randomized controlled trials and the generally short duration of follow-up in available studies. The existence of studies reporting positive short-term outcomes does not establish that the overall risk-benefit profile is favorable, particularly given the potential for irreversible harms such as infertility, impaired bone density accrual, and sexual dysfunction. Our role is to make a reasonable policy determination based on the overall weight of available evidence, which, for the reasons stated in the proposed rule and this final rule, does not support Federal Medicaid and CHIP funding for sex-rejecting procedures furnished to children.

¹⁵⁷ Subsequent to the submission of this comment the AMA issued a statement clarifying that "AMA policy on gender-affirming care is unchanged." See "AMA Board Newsletter," American Medical Association (March 2026), <https://cloud.e.ama-assn.org/newsletter>.

¹⁵⁸ "Gender-Affirming Medical Treatments for Pediatric Patients with Gender Dysphoria," University of Utah College of Pharmacy, Drug Regimen Review Center, August 6, 2024, <https://le.utah.gov/AgencyRP/reportingDetail.jsp?rid=636>.

We also do not agree with commenters who contend that we misrepresented international policy developments. As discussed in the proposed rule, Sweden, Finland, and the United Kingdom have each conducted independent systematic reviews and, based on the findings of those reviews, meaningfully restricted access to sex-rejecting procedures for children in their public health systems. We acknowledge that these countries have not adopted policies identical to this rule and that these procedures remain available in some circumstances. However, the directional shift in those countries away from broad access to puberty suppression and cross-sex hormones for children is directly relevant to our assessment of the evolving international evidence base and is appropriately cited in the proposed rule. We also acknowledge that other countries continue to provide broader access to these interventions, and we do not claim that international policy uniformly supports our approach. Rather, the international evidence is one element of a broader evidentiary record, and our determination is independently grounded in the statutory requirements of sections 1902(a)(19), 1902(a)(30)(A), and 2101(a) of the Act.

Finally, we note that this rule does not prohibit the provision of sex-rejecting procedures with State-only funds, prevent researchers from studying these interventions, or restrict providers from offering them consistent with applicable law. This rule is narrowly focused on the use of Federal Medicaid and CHIP dollars, consistent with our statutory authority.

B. Prohibition on Medicaid Payment for Sex-Rejecting Procedures (§ 441.800)

We proposed to add a new subpart N to 42 CFR part 441 to ensure care and services are provided consistent with the best interests of Medicaid recipients and ensure Medicaid payments are consistent with quality of care by prohibiting Federal Medicaid payments to States for sex-rejecting procedures provided to children under the age of 18. The basis and purpose of proposed subpart N (as described previously in this final rule) is reflected in proposed § 441.800.

Within new subpart N, we proposed at § 441.802(a) that State Medicaid plans must provide that the Medicaid agency will not make payment under the plan for sex-rejecting procedures for children under the age of 18. Per 42 CFR 430.10, the State plan is the vehicle through which States assure that their Medicaid programs will be administered in

conformity with title XIX of the Act (including sections 1902(a)(19) and 1902(a)(30)(A) of the Act) and CMS' implementing regulations, and the State plan must also contain all information necessary for CMS to determine whether the plan can serve as a basis for FFP. Proposed § 441.802(a) would not preclude States from covering sex-rejecting procedures with State-only funding outside of their Federally-matched Medicaid programs. We proposed at § 441.802(b) that FFP would not be available in State expenditures for sex-rejecting procedures for children under the age of 18.

Proposed § 441.801 would define sex-rejecting procedures as any pharmaceutical or surgical intervention that attempts to align a child's physical appearance or body with an asserted identity that differs from the child's sex either by: (1) intentionally disrupting or suppressing the normal development of natural biological functions, including primary or secondary sex-based traits; or (2) intentionally altering a child's physical appearance or body, including amputating, minimizing, or destroying primary or secondary sex-based traits such as the sexual and reproductive organs. However, our definition also provided that the term sex-rejecting procedures would not include procedures undertaken: (1) to treat a child with a medically verifiable disorder of sexual development; (2) for purposes other than attempting to align a child's physical appearance or body with an asserted identity that differs from the child's sex; or (3) to treat complications, including any infection, injury, disease, or disorder that has been caused by or exacerbated by the performance of sex-rejecting procedure(s).

Given States' obligations under sections 1902(a)(19) and 1902(a)(30)(A) of the Act to assure care and services are provided consistent with the best interests of Medicaid recipients and that payments are consistent with quality of care, respectively, we believed that our proposed prohibition of FFP for sex-rejecting procedures for children under age 18 was necessary given the lack of an adequate evidence base for the effectiveness of these treatments for the purposes that would be included in our definition and the significant potential for negative and irreversible side effects.

We noted that CMS has imposed age limitations on the availability of Federal funding for certain procedures in the Medicaid program before. CMS has long prohibited, at § 441.253, Federal funding for permanent sterilizations furnished to individuals under age 21, motivated by concerns about potential

coercion, informed consent, and patient regret that were based on data specifically related to permanent sterilizations (see preamble discussion at 43 FR 52146, 52151 through 52153). In this context, our concerns about the effectiveness of sex-rejecting procedures and the plausible evidence for risk of irreversible harm motivated our proposal to prohibit Federal funding for sex-rejecting procedures for children under the age of 18. Specifically, the proposed rule recognized that the more cautious approach of psychosocial support to treat individuals diagnosed with gender dysphoria prior to age 18, which is the legal age of majority in nearly all U.S. States and Territories,¹⁵⁹ ¹⁶⁰ better protects children and youth from adverse effects of any such procedures.

Three states have a different, higher age of majority. Alabama and Nebraska's age of majority is 19 and Mississippi has the highest age of majority at 21.¹⁶¹ We noted that this rule would not conflict with the age of majority in Alabama, Nebraska and Mississippi because these States recognize higher ages of majority than this final rule. Under this rule, FFP for sex-rejecting procedures would be available for Medicaid coverage at age 18, which is a lower age than the age of majority in these States. Additionally, nothing in this rule preempts State authority to regulate the age of majority in their State, nor does it interfere with a State's ability to fund these services with State-only funds. The rule makes age 18 as the minimum age for Federal payment of sex-rejecting procedures under the Medicaid program, should a State include such procedures in their program.

We originally considered establishing the prohibition on Federal reimbursement of sex-rejecting procedures to individuals under age 19

¹⁵⁹ CMS is aware that 3 States—Alabama, Nebraska, and Mississippi—recognize higher ages as the age of majority. See "Age of Majority by State 2025," World Population Review, accessed August 11, 2025, <https://worldpopulationreview.com/state-rankings/age-of-majority-by-state>. CMS proposed to prohibit FFP in State expenditures within the Medicaid program for sex-rejecting procedures for children under the age of 18 to correspond to the legal age of majority used by the overwhelming majority of States and Territories. Because section 2110(c)(1) of the Act defines "child" for purposes of CHIP as an individual under age 19, CMS proposed to prohibit FFP in State expenditures within CHIP for sex-rejecting procedures for children under age 19.

¹⁶⁰ "Age of Majority by State 2025," World Population Review, accessed September 9, 2025, <https://worldpopulationreview.com/state-rankings/age-of-majority-by-state>.

¹⁶¹ "Age of Majority by State 2025," World Population Review, accessed September 9, 2025, <https://worldpopulationreview.com/state-rankings/age-of-majority-by-state>.

as we proposed for CHIP. However, age 19 had no specific meaning for the Medicaid program and, as stated, was a year older than the legal age of majority in nearly all U.S. States and Territories. By comparison, this is not true under CHIP, as the statutory definition of a child in CHIP under section 2110(c)(1) of the Act is an individual under 19 years of age. In addition to other issues, we solicited comment on the operational feasibility of States in implementing the under-age 18 prohibition in Medicaid and the under-age 19 prohibition in CHIP. A summary of the comments and our responses are at the end of this section.

As discussed previously, States have obligations under sections 1902(a)(19) and 1902(a)(30)(A) of the Act to ensure that Medicaid-covered care and services are provided in a manner consistent with the best interests of beneficiaries and that payments for Medicaid-covered care and services are consistent with quality of care. For the reasons discussed in the proposed rule and this final rule, CMS believes prohibiting Federal Medicaid funding for sex-rejecting procedures for children under the age of 18 is warranted to help ensure that States meet these statutory obligations.

We believe that the definition of sex-rejecting procedures provides an appropriate degree of clarity and certainty regarding which sex-rejecting procedures would and would not be subject to the prohibitions at proposed § 441.802. We believe the definition is narrowly tailored and appropriate to exclude only FFP for treatments CMS has determined to lack sufficient evidence of safety and effectiveness for their intended purposes. Examples such as procedures to treat precocious puberty, therapy subsequent to a traumatic injury, or the use of hormone replacement therapy to treat a growth hormone deficiency would not fall under the definition of sex-rejecting procedures, and Federal Medicaid payment for such procedures would therefore not be prohibited for individuals under the age of 18, when medically necessary. As the HHS Review explains, central precocious puberty and gender dysphoria are distinct clinical conditions. In addition, because the definition is narrowly tailored in this way, we believe that States will be able to administer Medicaid coverage for drugs in a manner that is consistent with both the rule and the requirements in section 1927 of the Act. Section 1927 of the Act governs the Medicaid Drug Rebate Program and payment for covered outpatient drugs (CODs), which are

defined in section 1927(k)(2) of the Act. In general, if manufacturers enter into a National Drug Rebate Agreement (NDRA) as set forth in section 1927(a) of the Act, payment is available for the CODs covered under that NDRA for medically accepted indications.¹⁶² As defined in section 1927(k)(6) of the Act, “medically accepted indications” mean use for a COD approved under the Federal Food, Drug, and Cosmetic Act or approved for inclusion in any of the compendia described in subsection 1927(g)(1)(B)(i) of the Act. There is no pharmaceutical that is approved for these sex-rejecting procedures; the pharmaceuticals that are used for these procedures are approved for other indications. Thus, these pharmaceuticals will continue to be coverable by Medicaid programs for other indications in accordance with section 1927 of the Act to the extent that the manufacturer of these pharmaceuticals participates in the Medicaid Drug Rebate Program and complies with other requirements set forth in section 1927 of the Act, as discussed earlier in this Preamble. In addition, we note that the rule only applies to pharmaceuticals that are used in the definition of sex-rejecting procedures and would not apply to other pharmaceuticals that are prescribed to a child.

As noted previously, the definition of sex-rejecting procedures categorically excludes procedures undertaken (1) to treat a child with a medically verifiable disorder of sexual development; (2) for purposes other than attempting to align a child’s physical appearance or body with an asserted identity that differs from the child’s sex; or (3) to treat complications, including any infection, injury, disease, or disorder that has been caused by or exacerbated by the performance of sex-rejecting procedure(s). We reiterate that these regulatory changes do not prohibit the use of Federal Medicaid dollars for mental health treatments for conditions such as gender dysphoria.

In addition, to further explain the meaning of terms used in the sex-rejecting procedures definition, we also proposed definitions at new § 441.801 that would apply to subpart N of part 441. We define FFP for purposes of subpart N of part 441 as Federal financial participation, recognizing the longstanding term used in the Medicaid program to describe the Federal Government’s matching arrangement

¹⁶² The NDRA does not have a specific OMB number, however the OMB package that contains all of the information a manufacturer has to report once entering into an NDRA is included in CMS 367a–367e.

with States and Territories. We also define “female” as a person of the sex characterized by a reproductive system with the biological function of (at maturity, absent disruption or congenital anomaly) producing eggs (ova). We define “male” as a person of the sex characterized by a reproductive system with the biological function of (at maturity, absent disruption or congenital anomaly) producing sperm. We define “sex” as a person’s immutable biological classification as either male or female.

A landmark study of and model for anisogamy established that differences in gamete size, and the associated differences in gamete production time, lead to stable sexual dimorphism and the establishment of two sexes: ovum producers (females) and sperm producers (males).¹⁶³ Additionally, more recent literature acknowledges differences in sex roles but maintains that such differences can still be traced to the concept of anisogamy and the resultant sexual dimorphism that remain the root cause of sex specific selection, the sex roles, and the biological determination of sex.¹⁶⁴ We believe our definitions of female, male, and sex are appropriately rooted biological concepts. In addition to other issues, we solicited comments on whether these proposed definitions of “sex”, “male”, and “female” could pose challenges to States in operationalizing this proposed prohibition on Federal reimbursement of sex-rejecting procedures or other aspects of the Medicaid program or CHIP.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposed rule, specifically the proposed definitions of “male,” “female,” and “sex,” because they believed that sex is innate and cannot be changed. These commenters stated that DNA is not changed by sex-rejecting procedures and that no individual can be born in the wrong body. Many commenters supported the proposed rule because of their religious beliefs that attempting to change one’s sex goes against God’s design. Many commenters supported the proposed rule because they believed that

¹⁶³ G.A. Parker et al., “The origin and evolution of gamete dimorphism and the male-female phenomenon,” *Journal of Theoretical Biology* 36, no. 3 (1972): 529–553, [https://doi.org/10.1016/0022-5193\(72\)90007-0](https://doi.org/10.1016/0022-5193(72)90007-0).

¹⁶⁴ Lukas Schärer et al., “Anisogamy, chance and the evolution of sex roles,” *Trends in Ecology & Evolution* 27, no. 5 (2012): 260–264, <https://doi.org/10.1016/j.tree.2011.12.006>.

attempting to change one's sex is an unethical, scientifically incorrect, harmful, or medically unnecessary practice that should be stopped. Several commenters stated that only psychological care should be offered to children for the treatment of gender dysphoria. Several commenters indicated they believed providing sex-rejecting procedures to children and youth pathologizes normal struggles that many children have with their body image as they mature. Several commenters stated that these procedures interrupted or interfered with normal adolescent development and several commenters characterized these interventions as unnecessary because they expected gender dysphoria to resolve without the need for medical intervention.

Response: We appreciate commenters who stated support for the proposed definitions of “sex,” “male,” and “female” set forth in the proposed regulatory text at § 441.801. As stated in the preamble of the rule, these definitions are rooted in the biological concept of anisogamy and the resulting sexual dimorphism that underlies the two sexes.

For comments noting support on religious grounds, we note that this regulation is not based on, nor does it endorse, any specific religious doctrine or belief. Rather, it is grounded in sections 1902(a)(19), 1902(a)(30)(A), 2101(a), and 2102(a)(7)(A) of the Act and in the current state of the medical evidence regarding the risk/benefit profile of sex-rejecting procedures for children. We recognize that concerns about protecting children from potentially harmful and irreversible medical interventions are shared across communities for a variety of reasons.

For comments stating that gender dysphoria should be addressed exclusively through psychological treatment, CMS notes that the regulation does not affect the continued use of Federal Medicaid and CHIP funds for mental health treatment and psychotherapy. As discussed in Section I.D. of the preamble of the rule, psychotherapy represents a noninvasive intervention that has been proven effective for many mental health conditions that frequently co-occur with gender dysphoria, and multiple countries that have independently reviewed the evidence on these procedures have similarly recommended psychosocial support as the first line of treatment. We believe that the prohibition on FFP for sex-rejecting procedures reflects our determination that Federal funds should be directed toward interventions with a

more favorable and better-established evidence base.

Comment: Commenters offered a range of views on the definitions in the proposed rule. A commenter stated support, stating that the definitions were medically and scientifically accurate. A few commenters offered suggestions, including adding a definition of meaningful informed consent and harmonizing definitions across the 42 CFR part 441 and 42 CFR part 482 rules. A few commenters did not agree with the definitions, stating that they were overly broad, unclear, difficult to operationalize, not authorized by the governing statutes, or that the language demonized gender-affirming care and those involved in providing it.

Response: We appreciate the commenter who supported the definitions in this rule and agree that biologically grounded, clear definitions are important for the administrability of the policy finalized here. In response to the commenter who suggested that we include a definition of meaningful informed consent, we note that the rule does not alter existing State requirements for informed consent, which continue to govern the provision of medical care to children. We do not agree with commenters who stated that the definitions are overly broad, unclear, or not authorized by the governing statutes. The definitions of “sex,” “male,” and “female” are grounded in biology and are necessary to give meaning to the purpose-based definition of “sex-rejecting procedure.”¹⁶⁵ This purpose-based approach is more precise and less sweeping than a categorical exclusion of specific drugs or procedures, and it reflects our careful consideration of the range of medical uses for the interventions addressed in this rule.

Comment: Several commenters did not agree with the definitions of female and male in the proposed rule. A few commenters stated that they did not agree with both definitions because they ignored the role of gender identity in individual human experience and biology. A commenter believed the definitions of female and male were circular because each relied on the definition of sex, while the definition of sex in turn relies on the definitions of female and male. Several commenters stated that the definitions were too narrow and ideologically based.

Response: We do not agree with commenters who stated that the proposed definitions of female and male are inadequate, circular, or scientifically inaccurate. The definitions adopted in this rule—that “female” means a person of the sex characterized by a reproductive system with the biological function of (at maturity, absent disruption or congenital anomaly) producing eggs (ova), and that “male” means a person of the sex characterized by a reproductive system with the biological function of (at maturity, absent disruption or congenital anomaly) producing sperm—are grounded in established biological science regarding sexual dimorphism and gamete production. These definitions are consistent with the definition of “sex” in this rule and with similar definitions used in other recent Federal regulatory actions.

We also acknowledge that the definitions do not incorporate concepts of gender identity. This is intentional. The definitions in this rule are intended to reflect sex, based on biology, as relevant to the purpose of the prohibition on sex-rejecting procedures, which is aligning a child's physical appearance or body with an asserted identity that differs from the child's sex.

Comment: Many commenters stated concern that CMS' proposal did not provide adequate protections for individuals with intersex conditions. Some commenters estimated that there are approximately 6 million individuals who are intersex. Commenters stated that these conditions are complex and may involve multiple sets of gonads, not be detectable at birth, involve extra chromosomes or differences in hormone levels, and asserted that these conditions would require high-cost efforts like karyotyping to determine treatment paths to align with the proposed regulations. A commenter suggested that the “anomaly” language in each definition would not include such individuals because such conditions are a natural variation of human experience rather than an anomaly. The commenters also argued that CMS' proposed examples of conditions where a child's “reproductive or sexual anatomy does not develop in typical ways due to genetic, hormonal, or other factors that can be medically verified” excluded such individuals and did not sufficiently address how they must navigate the proposed regulations when receiving care. Several commenters stated concerns that these individuals may face care delays if their care involved interventions considered to meet the proposed definition of a “sex-

¹⁶⁵ Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government, Exec. Order No. 14168, 90 FR 8615 (January 30, 2025), <https://www.govinfo.gov/content/pkg/FR-2025-01-30/pdf/2025-02090.pdf>.

rejecting procedure”, including testosterone or estrogen therapy. Finally, commenters argued that CMS created a double standard in allowing the continuation of medical interventions for patients with disorders of sexual development without their informed consent. Many commenters requested CMS prohibit funding for procedures conducted on children with these conditions who may receive non-consensual corrective surgeries that may negatively impact their physical, sexual, and psychosocial well-being. Commenters stated that these were non-medical interventions that could be delayed until later in life. Several commenters also highlighted public statements from professional organizations, governing bodies, government leaders, and other countries’ approaches along with peer-reviewed publications that similarly concluded that non-consensual procedures on such infants should be prohibited. A commenter questioned why CMS departed in the proposed rule from the 2025 HHS report urging the protection of informed consent rights of such patients.

Response: We appreciate commenters raising concerns about individuals with disorders of sexual development and the adequacy of protections in this rule. We acknowledge commenters’ observations that the boundaries between disorders of sexual development and other conditions may not always be clear-cut and that the definition of “medically verifiable disorder of sexual development” gives discretion to the reasonable medical judgment of qualified providers to make such assessments in accordance with standard medical practice. We want to be clear that individuals with medically verifiable disorders of sexual development are excluded from the prohibition on FFP for sex-rejecting procedures. This exception is specifically intended to ensure that medical care for children with disorders of sexual development, including surgical and pharmaceutical interventions that may be appropriate for such conditions, is not disrupted by this rule. While we acknowledge that some individuals may not view themselves as having a disorder of sexual development, and may prefer the term “intersex,” we clarify here that these individuals do not fall under the FFP prohibition for sex-rejecting procedures.

We acknowledge commenters’ concerns about non-consensual surgical interventions on infants and children with disorders of sexual development. Those concerns are outside the scope of

this rule, which addresses Federal Medicaid and CHIP funding for a defined category of procedures. This rule neither mandates nor endorses surgical or any other interventions on individuals with disorders of sexual development.

Comment: A few commenters provided suggested revisions to the definitions of both female and male. For female, a commenter recommended CMS finalize a definition aligned with that in the Chloe Cole Act: “Female is a person who naturally has, had, will have, or would have but for a congenital anomaly or intentional or unintentional disruption, the reproductive system that produces, transports, and utilizes the large gamete (ova) for fertilization.” For male, a commenter recommended CMS finalize a definition aligned with the Chloe Cole Act: “Male is a person who naturally has, had, will have, or would have but for a congenital anomaly or intentional or unintentional disruption, the reproductive system that produces, transports, and utilizes the small gamete (sperm) for fertilization.” Commenters for both definitions also suggested including references to XX and XY chromosomes in the respective definitions.

Response: We appreciate commenters who offered suggested revisions to the definitions of female and male. We have considered the alternative formulations proposed, including language modeled on the Chloe Cole Act and proposals to incorporate chromosomal references. After careful consideration, we are retaining both definitions as proposed. We believe the definitions as finalized, grounded in reproductive system function and gamete production, are biologically accurate, administrable, and appropriate for the purposes of this rule. The definitions’ reference to “absent disruption or congenital anomaly” provides sufficient flexibility to account for individuals whose reproductive development has not followed a typical course.

Comment: A few commenters supported CMS’ definition of sex outlined in the proposed rule. A commenter agreed that sex is unchangeable and determined by objective biology. A commenter appreciated that the definitions aligned with the Hospital COP rule. A commenter stated that clear definitions reduce public confusion between sexuality and gender identity.

Response: We appreciate the commenters who support the definition of sex in this rule. We agree that clear and biologically grounded definitions are important for the administrability of the policy finalized in this rule and for

providing clarity to States, providers, and beneficiaries.

Comment: Many commenters did not agree with CMS’ definition of sex outlined in the proposed rule. Many commenters asserted that science demonstrated that sex is not binary, sex is complicated and the proposed rule fails to account for intersex individuals. Several commenters stated that the definition of sex was discriminatory and politically and ideologically motivated. Several commenters stated that sex and gender are not the same thing, and that they do not always correlate. A commenter stated that the Federal government should not be in the business of or have the right to “reduce human beings to producers of reproductive cells.”

Response: We do not agree with commenters who state that the definition of sex in this rule is scientifically inaccurate or fails to account for biological complexity. The definition—that “sex” means a person’s immutable biological classification as either male or female—reflects the established biological understanding that sexual reproduction involves two distinct reproductive strategies associated with the production of large gametes (ova) and small gametes (sperm), giving rise to a stable sexual dimorphism. This understanding is well-established in the scientific literature, as discussed in the preamble to the rule.

In humans, it is not possible for a person to have two fully functional reproductive systems capable of producing both eggs and sperm. At the moment of fertilization, a human embryo receives a fixed set of chromosomes from the egg and sperm. That genetic blueprint contains all the information that will ultimately guide whether the unborn child develops along the male or female pathway. Human sexual development is organized in such a way that once the embryo begins differentiating along either the male or female pathway, the other pathway is actively suppressed. Once this developmental pathway is initiated, it proceeds in one direction and does not reverse.

We acknowledge that biological sex development is not always typical and that a small number of individuals have conditions affecting the development of their sexual organs. These cases do not disprove the binary nature of sex reflected in the definitions of male or female. For example, there are rare developmental conditions, sometimes grouped under disorders (or differences) of sexual development, in which tissue from both testes and ovaries is present

(for example, ovotesticular disorders of sexual development). In such cases, small amounts of tissue from both pathways can exist in the same individual. However, only one set of reproductive structures is ever dominant and functional in producing gametes. There are no documented cases in humans of an individual with both a fully functional set of testes and a fully functional set of ovaries.

As discussed in the proposed rule and in our responses regarding the definitions of male and female, individuals with medically verifiable disorders of sexual development are expressly excluded from the prohibition on FFP for sex-rejecting procedures. The definition of sex in this rule does not eliminate or invalidate the medical recognition of such conditions; it provides a biological reference point for the purposes of the prohibition finalized in this rule.

We acknowledge that unlike sex, which has a definite and established meaning, gender identity is a distinct but internally inconsistent concept that diminishes sex as an identifiable or useful category but nevertheless maintains that it is possible for a person to be born in the wrong sexed body. The definitions in this rule address sex, as biologically understood and defined, because the prohibition on sex-rejecting procedures is defined in relation to interventions that attempt to align a child's physical appearance or body with an asserted identity that differs from the child's sex.

Comment: A few commenters proposed alternatives to the definition of sex. A commenter recommended CMS finalize a definition of sex that aligned with that in the Chloe Cole Act. A commenter suggested including references to XX and XY chromosome to the definitions of sex.

Response: We appreciate commenters who offered suggested revisions to the definition of sex. For the reasons discussed in our response to other comments related to the definition of sex, we are retaining the definition as proposed. We believe the finalized definition is scientifically grounded, consistent with other recent Federal regulatory definitions, and appropriate for the purposes of this rule.

Comment: Several commenters supported the use of the proposed term “sex-rejecting procedure.” The commenters believed that this term was appropriate for distinguishing between procedures conducted to treat sexual development disorders, and those procedures performed to align an individual's body with an identity that differs from an individual's sex. A

commenter suggested that 42 CFR 440.230 be amended as well to prohibit specifically defined sex-rejecting procedures, require providers to conduct time-defined evaluations and prioritize psychotherapy, define specific exceptions and restrictions, and conduct enforcement through auditing measures. The commenter suggested that parallel amendments be made to CHIP at 42 CFR 457.53, TRICARE at 32 CFR 199.4 and FEHB at 5 CFR 890.203.

Response: We appreciate commenters who support the term “sex-rejecting procedure” and for the purpose-based approach to defining the prohibited category of interventions. We agree that a purpose-based definition, which allows payment of the same pharmaceutical or surgical interventions for other medically indicated purposes, is an appropriate approach that reflects the targeted nature of this prohibition. However, we are declining to additionally modify Medicaid or CHIP regulations and note that amendments to TRICARE or FEHB regulations are outside of our purview.

Comment: Many commenters did not agree with the proposed rule's use of the term “sex-rejecting procedures,” stating that it was ideologically driven, scientifically imprecise, and not recognized in medical practice, peer-reviewed literature, insurance coding standards, or major medical association guidelines. Commenters stated that “gender-affirming care” was the appropriate clinical term and should be reflected in Federal regulations. Several commenters stated that the term was absent from billing codes, procedure categories, and other State and Federal statutes, and expressed concern that its ambiguity would create confusion in claims adjudication and compliance, particularly for Medicaid managed care organizations. A commenter stated that CMS used different terminology (“specified sex-trait modification procedure”) in the 2025 Marketplace Integrity and Affordability Final Rule without explaining the distinction. Another commenter indicated that the inclusion of “intentionally” in the definition imposed an unrealistic requirement for payors to determine a provider's intent at the time of treatment. A commenter requested that CMS clarify the role of diagnosis and procedure codes in implementing the rule to reduce inconsistent coverage determinations and appeals. Several commenters also raised concern that CMS' terminology departed from the HHS Review's own use of “pediatric medical transition” and overrode clinical determinations made by

licensed providers and established standards of care.

Response: We acknowledge commenters' concerns regarding the term “sex-rejecting procedures” and recognize that this term is not currently part of the standard clinical lexicon used by major medical organizations, which generally use the term “gender-affirming care.” However, we believe the term “gender-affirming care” inaccurately describes and characterizes the grave and possibly irreversible nature of these interventions, and biases treatment in favor of hormonal and surgical interventions. As the HHS Review explains, “In this context, the understandable desire to avoid exclusionary or pathologizing language—combined with beliefs firmly embedded in the field—has led to a vocabulary and a mode of communicating that is scientifically ungrounded, that presupposes answers to ethical controversies, and that is in other ways misleading.”¹⁶⁶ The HHS Review continues: “‘Affirming’ has a positive connotation, and someone who objects to ‘gender-affirming surgery’ sounds lacking in compassion. The euphemisms ‘chest surgery’ and ‘top surgery’ gloss over the relevant fact that breasts are removed.”¹⁶⁷ The term used in this rule is not intended to function as a clinical descriptor; rather, it describes a defined set of pharmaceutical and surgical interventions for the specific purpose of this rule, namely, interventions that attempt to align a child's physical appearance or body with an asserted identity that differs from the child's sex and which do not fall within an exception. The definition of “sex-rejecting procedure” in this rule is purpose-based, meaning that the same pharmaceutical or surgical intervention may or may not constitute a sex-rejecting procedure depending on the purpose for which it is provided.

We acknowledge that commenters raised concerns about the operational feasibility of a purpose-based definition, including how payors would determine the purpose behind a provider's claim. We address those operational concerns in our response to comments on administrative and operational challenges above.

We also acknowledge that the term used in this rule differs from the term “specified sex-trait modification procedure” used in the 2025 Marketplace Integrity and Affordability Final Rule. The shift in terminology follows input the agency received in

¹⁶⁶ HHS Review, 31.

¹⁶⁷ HHS Review, 31–32.

comments received for the 2025 Marketplace Integrity and Affordability Proposed rule that the term “sex-trait modification” is on its face overbroad and imprecise by lacking an explicit purpose-based element, while “sex-rejecting procedure” is a more consistent, succinct, accurate, and precise term to refer to the hormonal and surgical interventions at issue. Additionally, a recent State Department regulation used the term “sex-rejecting procedures” in prohibiting recipients of foreign assistance to provide such procedures.¹⁶⁸ We do not believe the use of different terminology in different regulatory contexts creates inconsistency, as each rule operates within its own statutory framework and applies to a different set of programs and populations.

Comment: A few commenters recommended revisions to the definition of sex-rejecting procedures. A commenter did not agree with the term “sex-rejecting procedures” and believed that “transition-related healthcare” should be used as an alternative term. A commenter indicated that “disorders of sexual development” include defined conditions, such as atypical development of sex chromosomes or genitalia or androgen insensitivity syndrome, that should receive Federal coverage for healthcare interventions addressing such conditions. The commenter indicated that covered healthcare interventions would be inclusive of reconstructive procedures aimed at restoring form and function to be consistent with an individual’s genetic profile. A commenter indicated that CMS should be more definitive in the rule language that psychotherapy for gender dysphoria is not a prohibited procedure. Alternatively, another commenter requested CMS clarify that gender-affirming mental health counseling and psychotherapy are prohibited procedures. A commenter suggested revising the definition of sex-rejecting procedures to allow for coverage when a patient had a history of attempted suicide or suicidal ideation or was likely to experience such as a result of losing care.

Response: We appreciate commenters who offered suggestions related to the definition of sex-rejecting procedures. After careful consideration, we are retaining the definition as proposed (with a change that replaces “child” with “individual” noted below). We believe the purpose-based definition provides the appropriate degree of precision while allowing payment of the same pharmaceutical or surgical

interventions for other medically indicated purposes. As indicated above, procedures to treat disorders of sexual development are excluded from the prohibition on federal funding for sex-rejecting procedures.

In response to commenters who recommended that we be more explicit that psychotherapy and mental health counseling for gender dysphoria are not prohibited by this rule, we affirm that these services are not sex-rejecting procedures as defined in this rule and remain federally matchable under Medicaid and CHIP. Federally matched Medicaid and CHIP coverage for mental health services, including psychotherapy, remains available to all eligible children, including those diagnosed with gender dysphoria.

In response to commenters who suggested that the prohibition should include an exception for patients with a history of attempted suicide or suicidal ideation, we note that the prohibition on FFP for sex-rejecting procedures does not eliminate coverage of other medically necessary services, including mental health interventions, for children at risk of self-harm.

We are finalizing the definitions in Subpart N as proposed, with the exception of revising references to “child” in the definition of “sex-rejecting procedure” to “individual”. The procedures themselves are not differentiated between children and adults; however, the prohibition on FFP for these procedures applies only to individuals under the age of 18 in Medicaid and under the age of 19 in CHIP. We have also added a new § 441.802(c) to specify in regulation text the availability of FFP for cross-sex hormone therapy during a tapering period of up to 6 months from the effective date of this final rule for individuals receiving such therapy as of the effective date of the rule.

C. Prohibition on CHIP Payment for Sex-Rejecting Procedures

We proposed to revise subpart D in 42 CFR part 457 to prohibit Federal CHIP payments to States for sex-rejecting procedures provided to children. The purpose of this section was to ensure that CHIP is operated in an effective and efficient manner that is coordinated with other sources of health benefits coverage, including Medicaid, for children consistent with section 2101(a) of the Act by prohibiting Federal financial participation in payments by States for sex-rejecting procedures for a child under the age of 19. This would promote consistency between CHIP and Medicaid.

The prohibition on FFP for payments by States for sex-rejecting procedures for children applies in the same manner described in Medicaid at § 441.802 to a State administering a separate CHIP except that it applies to children under the age of 19 in accordance with the definition of a targeted low-income child at § 457.310. This prohibition would apply to CHIP regardless of the type of health benefit coverage option described at § 457.410. The definitions applied under Medicaid at § 441.801 would apply equally to a separate CHIP.

We believe that our prohibition of Federal CHIP payment for sex-rejecting procedures is necessary given the policy goal of aligning CHIP payment with Medicaid, the lack of scientific evidence regarding the effectiveness of these treatments, and the plausible risks of negative and often irreversible side effects when used for the purposes included in our definition in children.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters believed that the rule did not cite a relevant authority under CHIP to make Federal determinations about what kind of care may be included in CHIP programs in each State. These commenters stated that the Congress allowed standalone CHIP plans to cover any State-recognized medical services provided by licensed physicians and other professionals in accordance with State-determined standards and scopes of practice, even those not specifically enumerated in the CHIP statute. Several commenters believed that the proposed rule would compromise the intent that CHIP funds help States provide care to a select population in an “effective and efficient” manner (referring to manner of administration, initiation and expansion of coverage). They suggested that using the “effective and efficient manner” phrase to justify this rule was inconsistent with CHIP’s statutory framework, as the phrase functioned as administrative directive and not a mechanism for excepting certain medical care from coverage. A commenter stated that section 2101(a) of the Act concerns the administration of the CHIP program and does not require States to align the scope of benefits provided in the various sources of health coverage for children. A commenter cited section 2103 of the Act, stating that the provision gives States flexibilities in creating a CHIP benefit plan, and does not limit States to a specific set of benefits.

Response: We do not agree with commenters who state that we lack

¹⁶⁸ 2 CFR pt. 603 (2026).

authority to prohibit FFP for sex-rejecting procedures under CHIP. While the Congress afforded States considerable flexibility in designing their CHIP benefit packages, including authority under section 2110(a)(24) of the Act to cover services recognized by State law, that flexibility has some specified restrictions. We have a responsibility to ensure that CHIP operates consistently with its statutory purpose

Section 2101(a) of the Act establishes that CHIP funds are provided to enable States “to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner that is coordinated with other sources of health benefits coverage for children.” This provision imposes substantive requirements on how CHIP is administered, not merely procedural requirements. Our authority to oversee CHIP to ensure consistency with the “effective and efficient” standard and the coordination requirement supports the prohibition established in this rule. This authority is reinforced under regulations at § 457.50, which states that we have the ability to determine whether the plan “can be approved to serve as a basis for Federal financial participation in the State program,” and § 457.60, which specifies that a State must amend its State plan whenever necessary to reflect “changes in Federal law, regulations, policy interpretations, or court decisions that affect provisions in the approved State plan.”

With respect to the authority provided under sections 2103 and 2110(a)(24) of

the Act for States to cover services recognized by State law, we acknowledge that these provisions provide States flexibility to cover and provide these services in alignment with State law, but we do not read that provision as compelling FFP for any service a State recognizes. These sections must be read in context with section 2102(a)(7)(A) of the Act, which requires that State CHIP plans describe how the plan will “assure the quality and appropriateness of care, particularly with respect to . . . well-child care.” We do not believe that it would be possible for a State to include such a description in its plan in light of our conclusion that there is insufficient evidentiary support for the medical necessity of sex-rejecting procedures. The flexibility that the State-recognized services provision provides, like other State flexibility under CHIP, is conditioned on compliance with applicable Federal standards. We have determined that FFP for sex-rejecting procedures described in this rule is not consistent with those standards, based on the current evidentiary record. States that wish to cover these services in their CHIP programs may do so using State-only funds.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501–3520, we are required to provide notice in the **Federal Register** and solicit public comment before a “collection of information” as defined under 5 CFR 1320.3(c) of the PRA’s implementing

regulations, requirement is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB, 44 U.S.C. 3506(c)(2)(A) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Our December 19, 2025 (90 FR 59441) proposed rule (CMS–2451–P; RIN 0938–AV73) solicited public comment on each of these issues for that rule’s proposed collection of information requirements. Such comments were received. A summary of the comments and our responses are set out below under each collection of information requirement section.

A. Wage Data

To derive average costs, we used data from the U.S. Bureau of Labor Statistics’ May 2025 National Occupational Employment and Wage Statistics for all salary estimates (<https://www.bls.gov/oes/tables.htm>). Table 1 presents BLS’ mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage.

TABLE 1: National Occupational Employment and Wage Estimates

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefits and Other Indirect Costs (\$/hr)	Adjusted Hourly Wage (\$/hr)
Business Operations Specialist	13-1000	44.63	44.63	89.26
General and Operations Manager	11-1021	64.87	64.87	129.74

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessary, both because fringe benefits and other indirect costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate the total cost is a reasonably accurate estimation method.

B. Collection of Information Requirements (ICRs)

1. ICRs Regarding Definitions (§ 441.801)

The following changes will be made available for public review/comment under OMB control number 0938–1148 (CMS–10398 #97) via the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, the following discussion scores the potential impact of the finalized provisions. We will revisit these

preliminary estimates during the 60-/30-day PRA process and revise if needed.

We anticipate that the definitions (adding and defining “female”, “male”, “sex”, and “sex-rejecting procedure”) may result in the need for some States to amend existing policy/manual documents where those items are inconsistent with the provisions of this final rule. However, we do not anticipate that this would impact any active claims/billing forms or instructions.

We estimate a potential of 56 Medicaid respondents and 56 CHIP respondents consisting of 50 States, the District of Colombia, American Samoa, Commonwealth of the Mariana Islands, Guam, Puerto Rico, and the US Virgin Islands. Based on research discussed in section I.1.C. (United States' State Bans of and Coverage of Sex-Rejecting Procedures) of this final rule, we further estimate that approximately 27 States and one Territory have laws enacted restricting some or all of the sex-rejecting procedures that are covered by this final rule. For these States and Territories, we do not anticipate State staff will need to conduct a review of policy documents for Medicaid or CHIP as these procedures are currently banned (or will be banned).

For the remaining 28 States and Territories, we assume that State staff will review and amend their State's Medicaid and CHIP policy documents to be compliant with the provisions of this final rule. We estimate it will take 3 hours at \$89.26/hr for a Business Operations Specialist to review existing State policy documents to ensure consistency with the definitions and 1 hour at \$129.74/hr for a General and Operations Manager to review and approve the necessary State policy document changes.

In aggregate we estimate a one-time State burden of 112 hours (28 States $\times$ 4 hr/response) at a cost of \$11,131 [(3 hr $\times$ \$89.26/hr $\times$ 28 States) + (1 hr $\times$ \$129.74/hr $\times$ 28 States)]. When taking into account the Federal administrative match of 50 percent, we estimate a one-time State cost of \$5,566 (\$11,131 $\times$ 0.5). We assumed all services meeting the definition will no longer be covered by Medicaid nor CHIP, and thus will not be eligible for Federal matching funds.

With regard to the rule's public comments:

Comment: Several commenters state that CMS underestimated the administrative burden associated with the rule's information collection requirements, contending that our proposed burden estimates failed to account for the full scope of work required by States and territories (including those that have already implemented bans) to review and align policy documents, update State Plan Amendments, engage external interested parties such as managed care plans, providers, and State legislatures, and obtain necessary legal and leadership review. Another commenter, by contrast, supported the rule's approach to information collection, stating that it aligns with PRA objectives and administration directives to reduce administrative burden, clarify regulatory

scope, and prevent the misuse of Federal funds.

Response: We acknowledge commenters' concerns that the burden estimates may not fully capture the scope of administrative work required of all States and territories. We recognize that States may need to engage a range of internal and external interested parties (including managed care plans, providers, and legislative staff) and that review processes may require participation from legal counsel and senior leadership beyond the roles specifically identified in our estimates. We will revisit and refine these estimates as part of the aforementioned standard PRA process. As we indicated in the proposed rule, the estimates provided are preliminary, and we are committed to revising them if/as and when needed.

We note that for States and territories that have already enacted laws restricting some or all of the procedures covered by the rule, we continue to believe that the administrative burden for those jurisdictions will be limited, as the rule largely aligns with existing State policy. However, we acknowledge that even these States may need to conduct some degree of review to confirm consistency with the Federal requirements being established here. We will take this into account in our 60- and 30-day **Federal Register** notices.

We also acknowledge and appreciate the commenter(s) who support the rule's information collection approach and its alignment with PRA objectives and administration directives to reduce administrative burden, clarify regulatory scope, and ensure the appropriate stewardship of Federal funds. We share these goals, and we believe the administrative requirements associated with this rule are proportionate to and necessary for their achievement.

2. ICRs Regarding the Prohibition on Payment for Sex-Rejecting Procedures (§ 441.802)

The following changes and associated SPA template will be made available for public review/comment under OMB control number 0938–1148 (CMS–10398 #97) via the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, the following discussion scores the potential impact for preparing and submitting the SPA. We will revisit these preliminary estimates during the standard PRA process and revise if needed.

Under this rule's finalized provisions, States and Territories will be required to submit SPAs that indicate adherence to the prohibition on claiming Federal

funding of sex-rejecting procedures for individuals under the age of 18 for Medicaid and for individuals under the age of 19 for CHIP. The content of the SPA will be a simple recitation of the prohibition. We intend to require all States and Territories to submit this template for approval as part of their State plan.

We estimate a potential of 56 Medicaid and CHIP respondents consisting of 50 States, the District of Colombia, American Samoa, Commonwealth of the Mariana Islands, Guam, Puerto Rico, and the US Virgin Islands. We estimate it will take 2 hours at \$89.26/hr for a Business Operations Specialist to prepare an initial SPA and 1 hour at \$129.74/hr for a General and Operations Manager to review and approve the SPA for submission to CMS.

In aggregate, we estimate a one-time State burden of 168 hours (56 States $\times$ 3 hr/response) at a cost of \$17,263 [(2 hr $\times$ \$89.26/hr $\times$ 56 States) + (1 hr $\times$ \$129.74/hr $\times$ 56 States)]. When taking into account the Federal administrative match of 50 percent, we estimate a one-time State cost of \$8,632 (\$17,263 $\times$ 0.5). We assumed all services meeting the definition will no longer be covered by Medicaid nor CHIP, and thus not eligible for Federal matching funds.

With regard to the rule's public comments:

Comment: Several commenters state that CMS underestimated the administrative burden associated with the rule's information collection requirements, contending that our proposed burden estimates failed to account for the full scope of work required by States and territories (including those that have already implemented bans) to review and align policy documents, update State Plan Amendments, engage external interested parties such as managed care plans, providers, and State legislatures, and obtain necessary legal and leadership review. A commenter, by contrast, supported the rule's approach to information collection, stating that it aligns with PRA objectives and administration directives to reduce administrative burden, clarify regulatory scope, and prevent the misuse of Federal funds.

Response: We acknowledge the commenters' concerns that our burden estimates may not fully capture the scope of administrative work required of all States and territories. We recognize that States may need to engage a range of internal and external interested parties (including managed care plans, providers, and legislative staff) and that review processes may require

participation from legal counsel and senior leadership beyond the roles specifically identified in our estimates. As indicated in our proposed rule and again in this final rule, our burden estimates are preliminary and we are committed to revisiting them in our 60- and 30-day **Federal Register** notices.

For States and territories that have already enacted laws restricting some or all of the procedures covered by this final rule, we continue to believe that

the administrative burden for those jurisdictions will be limited, as they largely align with existing State policy. However, we acknowledge that even these States may need to conduct some degree of review to confirm consistency with the Federal requirements being established here. We will take this into account in our revised estimates.

We also acknowledge and appreciate the commenter(s) who support the rule’s information collection approach and its

alignment with PRA objectives and administration directives to reduce administrative burden, clarify regulatory scope, and ensure the appropriate stewardship of Federal funds. We share these goals, and we believe the administrative requirements associated with this rule are proportionate to and necessary for their achievement.

C. Summary of Requirements and Burden Estimates

TABLE 2: Requirements/Preliminary Burden Estimates
CMS-10398 #97 (OMB 0938-1148)

Regulation Section(s) under Title 42 of the CFR	Respondent s	Frequency	Total Responses	Time per Response (hr)	Total Time (hr)	Labor Costs (\$/hr)	Total Cost (\$)	Cost to the Fed Gov’t (\$)	State Share (\$)
§ 441.801	28 States and Territories	one time	28	4	112	Varie s	11,131	5,566	5,566
§ 441.802	56 States and Territories	one time	56	3	168	Varie s	17,263	8,632	8,632
Total	56	--	84	Varies	280	Varie s	28,394	14,198	14,198

IV. Regulatory Impact Analysis

A. Statement of Need

Throughout the U.S., thousands of children are receiving sex-rejecting procedures for the purpose of attempting to align their bodies with an asserted identity that differs from their sex. As outlined in this final rule, however, the current medical evidence does not conclusively demonstrate the effectiveness of these interventions and suggests that there are plausible health and safety risks. To help ensure that Medicaid services are provided in a manner consistent with the best interests of the recipients and that Medicaid payments are consistent with quality of care, we proposed a prohibition on State Medicaid Agencies from providing payment under the plan for sex-rejecting procedures for children under the age of 18 and proposed a prohibition on State CHIPs from providing payment under the plan for sex-rejecting procedures for children under the age of 19.

B. Overall Impact

We have examined the impacts of this final rule as required by E.O. 12866, “Regulatory Planning and Review”; E.O. 13132, “Federalism”; E.O. 13563,

“Improving Regulation and Regulatory Review”; E.O. 14192, “Unleashing Prosperity Through Deregulation”; the Regulatory Flexibility Act (RFA) (Pub. L. 96–354); section 1102(b) of the Social Security Act; and section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

E.O.s 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select those regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts). Section 3(f) of E.O. 12866 defines a “significant regulatory action” as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the

rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, or the President’s priorities.

A RIA must be prepared for a regulatory action that is significant under section 3(f)(1) of E.O. 12866. Based on our estimates, the Office of Management and Budget’s (OMB) Office of Information and Regulatory Affairs (OIRA) has determined this rulemaking is significant per section 3(f). Accordingly, we have prepared a RIA that to the best of our ability presents the costs and benefits of the rulemaking.

C. Detailed Economic Analysis

1. Impacts on Federal Expenditures and Other Transfers

We estimate that this rule will reduce Federal Medicaid spending by about \$175 million from fiscal year 2027 through fiscal year 2036 (in real 2027 dollars). To estimate the impact of this rule, we analyzed data from T–MSIS TAF v8.0 for 2023. We selected all claims with a gender dysphoria diagnosis and in the following claims categories: inpatient hospital with surgical procedure; outpatient hospital with surgical procedure; and professional services and prescription drugs with hormone therapy. We

included fee-for-service and managed care encounter data. We only counted claims with one of the following ICD-10 diagnosis codes: F64.0 (transsexualism); F64.1 (gender identity disorder in adolescence or adulthood); F64.2 (gender identity disorder in childhood); F64.8 (other gender identity disorders); F64.9 (gender identity disorder, unspecified); and Z87.890 (personal history of sex reassignment).

We also analyzed this data by beneficiary age group and counted only spending for individuals ages 17 and younger. We note that the policy will not prohibit payment by a State Medicaid agency for these services for those age 18, and those individuals and costs are not included as part of the estimates. This data also includes CHIP expenditures for these services.

For 2023, we identified about \$31 million in total computable (Federal and State shares) Medicaid and CHIP spending for these services and individuals. States that had not banned gender dysphoria treatments for children as of 2023 accounted for 76 percent of spending, including 92 percent of inpatient treatment with surgery and 87 percent of outpatient treatment with surgery.

TABLE 3: Medicaid Expenditures on Gender Dysphoria Treatment by Category of Service and Age Group, 2023

	Age 6-12	Age 13-14	Age 15-18	Total
Inpatient hospital with surgery	\$0	\$0	\$180,553	\$180,553
Outpatient hospital with surgery	\$15,526	\$23,534	\$2,145,082	\$2,184,142
Professional services hormone therapy	\$482,924	\$1,180,610	\$3,089,948	\$4,753,482
Prescription drug hormone therapy	\$2,566,749	\$6,130,955	\$14,779,884	\$23,477,588
Total	\$3,065,198	\$7,335,099	\$20,195,468	\$30,595,765

Source: Analysis of T-MSIS TAF v8.0.

Note: The T-MSIS data includes enrollment and spending by age groups, which includes ages 15-18 as one group. The policy in this final rule will only affect Medicaid enrollees under age 18 (ages 15-17), but the table above includes spending for individuals age 18. We note that we have adjusted for this when developing the estimates in the RIA.

Total spending on hormone therapy for children ages 6 through 17 was \$23.8 million (assuming that 25 percent of spending for those ages 15 to 18 was for 18-year-olds in the data). Of that amount, we calculated that 88 percent (\$21.0 million) was for GnRH analogues (or puberty blockers). The remaining spending for hormone therapy (\$2.8 million) was for estrogen/anti-androgen and testosterone.

We projected this spending forward from 2023 through 2036 using projected growth in Medicaid and CHIP spending on children from the President's fiscal year 2027 Budget. We assumed all services will not eligible for Federal Medicaid or CHIP matching funds. We solicited comment on whether States that currently cover services will continue to cover these services absent FFP as described in this final rulemaking.

States that currently cover these services under Medicaid will see the largest reductions in Medicaid spending. We have updated the

estimates in this rule to reflect that many States have banned these services since the beginning of 2023. As noted above, about 24 percent of spending on these services for children was in States that have implemented bans on these services. We have excluded spending in those States from these estimates, which results in lower projected savings.

We also assumed about 3 percent of spending will be delayed until individuals reach age 18, reflecting 50 percent of the surgical procedures being paid by Medicaid and CHIP in the future. Absent data or analysis on the impact of prohibitions on these procedures, we assumed some individuals will ultimately receive these services once eligible and believe 50 percent is reasonable (considering that some individuals will no longer be eligible for Medicaid in the future and some individuals may find other sources of coverage). Assuming none or all surgical procedures no longer covered by Medicaid are later performed once the beneficiaries reach age 18

would decrease or increase the estimates presented here by about 2 percent.

Table 4 shows the annual impact of the proposal on total and Federal Medicaid and CHIP spending in millions of dollars. These estimates assume the policies in the final rule will be effective as of October 6, 2026. The estimates also reflect a 6-month transition period for enrollees currently using non-GnRH hormone therapy, which was not included in the estimates in the proposed rule. Total Medicaid and CHIP spending will be reduced by \$235 million over 10 years, Federal spending will be reduced by \$138 million, and State spending will be reduced by \$97 million (in real 2027 dollars). Actual impacts may vary from these estimates. We relied on the most recently available program data for this analysis and projections of future enrollment and spending. Actual future costs may vary if enrollment and spending are higher or lower than projected.

TABLE 4: Projected Impacts of Prohibiting Coverage of Sex-Rejecting Procedures for Individuals under 18 on Medicaid Spending (in millions of real 2027 dollars)

	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2027-2036
Total	-\$20	-\$22	-\$22	-\$22	-\$24	-\$24	-\$24	-\$25	-\$26	-\$26	-\$235
Federal	-\$12	-\$13	-\$13	-\$13	-\$14	-\$14	-\$14	-\$15	-\$15	-\$15	-\$138
State	-\$8	-\$9	-\$9	-\$9	-\$10	-\$10	-\$10	-\$10	-\$11	-\$11	-\$97

We have made reasonable assumptions about how individuals may use these services in the future. A greater or lesser number of individuals may still receive coverage for these services upon reaching age 18 than we have assumed. In addition, it is possible some individuals may find alternative coverage for these services (for example, States covering services without Federal funding, or private insurance). We have also not estimated if there will be any other impacts on Federal expenditures (for example, increases in other healthcare services related to gender dysphoria). We are unable to provide quantitative estimates of these effects. To the extent that States, other healthcare programs, or other payers fund these services in the future, we would expect them to incur costs equivalent to the savings shown here, to the extent they cover these services. (For example, if half of the States were to cover these services using only State funds, those States would have costs approximately equal to about half of the spending reductions shown here.)

2. Costs

In addition, the final rule may result in several costs. States will need to update State plans or waivers to comply with the proposed changes to covered benefits. Those impacts are described in section III. of this final rule. In addition, the changes in this final rule may prevent or delay individuals from receiving these healthcare services.

3. Alternatives

As an alternative to this final rule, we considered taking no action to require that a State Medicaid or CHIP plan must provide that the Medicaid or CHIP agency will not make payment under the plan for sex-rejecting procedures for children in Medicaid under the age of 18 and children in CHIP under the age of 19 and to prohibit the use of Federal Medicaid or CHIP dollars to fund sex-

rejecting procedures for these individuals. On January 28, 2025, President Trump issued E.O. 14187, Protecting Children from Chemical and Surgical Mutilation. Section 5(a) of that order directs the Secretary to take all appropriate actions consistent with applicable law to end what the order refers to as the chemical and surgical mutilation of children, including regulatory and sub-regulatory actions for specific programs, including Medicaid. In alignment with the E.O. and the evidence outlined in section I.B. of this final rule, CMS decided to pursue this policy. These final changes will not prevent States from providing coverage for sex-rejecting procedures with State-only funds outside of the Federally-matched Medicaid program or CHIP.

We acknowledge that alternative actions could have been taken such as issuing sub-regulatory guidance suggesting States refrain from offering these services based on the evidence described in the HHS Review, issuing a regulation to require utilization management in advance of the provision of these services to ensure appropriate State oversight of these services, or simply allowing continued Federal matching for these services. While these actions continue to be possible, they were not considered as alternatives as we concluded that a prohibition of Federal matching funds was warranted in the immediate term in light of the current evidence described in the HHS Review identifying significant risks associated with sex-rejecting procedures, including potentially irreversible harms, and the growing international retreat from the use of puberty blockers, cross-sex hormones, and surgeries to treat gender dysphoria in children.

D. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small

entities, if a rule has a significant economic impact on a substantial number of small entities. The great majority of hospitals and most other healthcare providers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration (SBA) definition of a small business.¹⁶⁹ Individuals and States are not included in the definition of a small entity. Overall, the regulated industry has a high number of firms considering that there are 2,573 hospitals in the United States,¹⁷⁰ Because a great majority of them qualify as a small entity, we deduce by two distinct methods that both the number and proportion of small entities expected to experience significant economic impacts from the rule are limited. For this analysis, HHS uses a change in annual revenue exceeding 3 to 5 percent as its measure of a significant economic impact.

For purposes of the RFA, approximately 96 percent of the small businesses in the health care industries impacted are considered small businesses according to the Small Business Administration's size standards. According to the SBA's website at <http://www.sba.gov/content/small-business-size-standards>, the health care industries impacted fall in the North American Industrial Classification System (NAICS) 446110 Pharmacies and Drug Stores; 621111 Offices of Physicians (except Mental Health Specialists); 621112 Offices of Physicians, Mental Health Specialists; 621493 Freestanding Ambulatory Surgical and Emergency Centers; 621498 All Other Outpatient Care Centers; and 622110 General Medical and Surgical Hospitals. Table 5 shows the industry size standards for each of these health care industries.

¹⁶⁹ See U.S. Small Bus. Admin., Office of Advocacy, Comment Letter on "Health and Human Services' Request for Information: Ensuring Lawful Regulation and Unleashing Innovation to Make

America Healthy Again," (July 14, 2025): 4, https://advocacy.sba.gov/wp-content/uploads/2025/07/Comment-Letter_Advocacy-Comments-to-HHS-Deregulatory-RFI.pdf.

¹⁷⁰ See Table 11, column "firm count." Sum the total number of small firms and the total number of large firms.

TABLE 5: Health Care Industry Size Standards

NAICS (6-digit)	Industry Subsector Description	SBA Size Standard/ Small Entity Threshold	Total Small Businesses
446110	Pharmacies and Drug Stores	\$37.5 Million	18,461
621111	Offices of Physicians (except Mental Health Specialists)	\$16.0 Million	129,117
621112	Offices of Physicians, Mental Health Specialists	\$13.5 Million	12,325
621493	Freestanding Ambulatory Surgical and Emergency Centers	\$19.0 Million	5,569
621498	All Other Outpatient Care Centers	\$25.5 Million	9,801
622110	General Medical and Surgical Hospitals	\$47.0 Million	1,169

Source: 2022 Statistics of U.S. Businesses, available at <https://www.census.gov/programs-surveys/susb.html>.

Tables 6 through 11 aid in showing the distribution of firms and revenues at their 6 digits NAICS code level. These

tables aim to provide an understanding

of the disproportionate impacts among firms, between small and large firms.

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TABLE 6: NAICS 446110 Pharmacies and Drug Stores (\$37.5 Million Size Standard)

Firm Size (by Receipts)	Firm Count	% of Small Firms	Avg. Revenue
SMALL FIRMS	18,461	100%	\$3,930,615.08
<\$100K	560	3%	\$50,953.57
\$100K - \$499K	1,733	9%	\$292,525.68
\$500 - \$999K	1,764	10%	\$753,448.41
\$1M - \$2.499M	4,810	26%	\$1,760,637.01
\$2.5M - \$4.999M	5,159	28%	\$3,606,681.53
\$5M - \$7.499M	2,137	12%	\$6,079,067.38
\$7.5M - \$9.999M	869	5%	\$8,624,350.98
\$10M - \$14.999M	762	4%	\$11,934,971.13
\$15M-\$19.999M	318	2%	\$16,805,396.23
\$20M-\$24.999M	146	1%	\$21,375,342.47
\$25M-\$29.999M	98	1%	\$26,077,561.22
\$30M-\$34.999M	64	0%	\$27,529,546.88
\$35M-\$39.999M	41	0%	\$30,746,414.63
LARGE FIRMS			
Receipts > \$40M	396	N/A	\$672,827,431.82

Source: 2022 Statistics of U.S. Businesses, available at <https://www.Census.gov/program-surveys/susb.html>.

TABLE 7: NAICS 621111 Offices of Physicians (except Mental Health Specialists) (\$16.0 Million Size Standard)

Firm Size (by Receipts)	Firm Count	% of Small Firms	Avg. Revenue
SMALL FIRMS	129,117	100%	\$1,463,302.41
<\$100K	11,119	9%	\$51,195.79
\$100K - \$499K	44,138	34%	\$296,376.77
\$500 - \$999K	30,224	23%	\$712,231.21
\$1M - \$2.499M	24,522	19%	\$1,559,970.11
\$2.5M - \$4.999M	10,388	8%	\$3,475,423.18
\$5M - \$7.499M	3,799	3%	\$6,048,868.65
\$7.5M - \$9.999M	1,945	2%	\$8,498,150.64
\$10M - \$14.999M	2,003	2%	\$11,844,361.46
\$15M-19.999M	979	1%	\$16,517,796.73
LARGE FIRMS			
Receipts > \$20M	3,782	N/A	\$116,848,659.18

Source: 2022 Statistics of U.S. Businesses, available at <https://www.census.gov/programs-surveys/susb.html>.

TABLE 8: NAICS 621112 Offices of Physicians, Mental Health Specialists (\$13.5 Million Size Standard)

Firm Size (by Receipts)	Firm Count	% of Small Firms	Avg. Revenue
SMALL FIRMS	12,325	100%	\$634,311.40
<\$100K	2,125	17%	\$52,448.00
\$100K - \$499K	6,341	51%	\$261,018.29
\$500 - \$999K	2,092	17%	\$686,686.90
\$1M - \$2.499M	1,206	10%	\$1,496,716.42
\$2.5M - \$4.999M	338	3%	\$3,331,017.75
\$5M - \$7.499M	111	1%	\$5,735,522.52
\$7.5M - \$9.999M	52	0%	\$8,039,461.54
\$10M - \$14.999M	60	0%	\$10,485,850.00
LARGE FIRMS			
Receipts > \$15M	212	N/A	\$14,421,103.77

Source: 2022 Statistics of U.S. Businesses, available at <https://www.census.gov/programs-surveys/susb.html>.

TABLE 9: NAICS 621493 Freestanding Ambulatory Surgical and Emergency Centers (\$19.0 Million Size Standard)

Firm Size (by Receipts)	Firm Count	% of Small Firms	Avg. Revenue
SMALL FIRMS	5,569	100%	\$2,713,466.15
<\$100K	353	6%	\$48,246.46
\$100K - \$499K	1,249	22%	\$287,140.11
\$500 - \$999K	867	16%	\$724,727.80
\$1M - \$2.499M	1,265	23%	\$1,648,132.81
\$2.5M - \$4.999M	845	15%	\$3,602,647.34
\$5M - \$7.499M	413	7%	\$5,999,140.44
\$7.5M - \$9.999M	223	4%	\$8,392,170.40
\$10M - \$14.999M	241	4%	\$11,472,634.85
\$15M-19.999M	113	2%	\$16,496,955.75
LARGE FIRMS			
Receipts > \$20M	610	N/A	\$46,366,978.69

Source: 2022 Statistics of U.S. Businesses, available at <https://www.census.gov/programs-surveys/susb.html>.

TABLE 10: NAICS 621498 All Other Outpatient Care Centers (\$25.5 Million Size Standard)

Firm Size (by Receipts)	Firm Count	% of Small Firms	Avg. Revenue
SMALL FIRMS	9,801	100%	\$2,124,005.00
<\$100K	1,079	11%	\$48,916.59
\$100K - \$499K	2,925	30%	\$283,037.26
\$500 - \$999K	1,832	19%	\$719,524.02
\$1M - \$2.499M	1,990	20%	\$1,545,938.69
\$2.5M - \$4.999M	790	8%	\$3,409,083.54
\$5M - \$7.499M	289	3%	\$5,739,238.75
\$7.5M - \$9.999M	193	2%	\$7,644,943.01
\$10M - \$14.999M	292	3%	\$10,567,616.44
\$15M-\$19.999M	184	2%	\$13,609,652.17
\$20M-\$24.999M	137	1%	\$16,169,890.51
\$25M-\$29.999M	90	1%	\$21,218,188.89
LARGE FIRMS			
Receipts > \$30M	1,008	N/A	\$55,938,203.37

Source: 2022 Statistics of U.S. Businesses, available at <https://www.census.gov/programs-surveys/susb.html>.

TABLE 11: NAICS 622110 General Medical and Surgical Hospitals (\$47.0 Million Size Standard)

Firm Size (by Receipts)	Firm Count	% of Small Firms	Avg. Revenue
SMALL FIRMS	1,169	100%	\$17,598,603.93
<\$100K	59	5%	\$49,491.53
\$100K - \$499K	150	13%	\$270,466.67
\$500 - \$999K	54	5%	\$696,814.81
\$1M - \$2.499M	28	2%	\$1,522,000.00
\$2.5M - \$4.999M	28	2%	\$3,739,428.57
\$5M - \$7.499M	35	3%	\$6,512,657.14
\$7.5M - \$9.999M	51	4%	\$8,550,588.24
\$10M - \$14.999M	124	11%	\$11,777,798.39
\$15M-\$19.999M	132	11%	\$16,993,166.67
\$20M-\$24.999M	121	10%	\$22,389,727.27
\$25M-\$29.999M	100	9%	\$26,686,900.00
\$30M-\$34.999M	99	8%	\$31,329,858.59
\$35M-\$39.999M	66	6%	\$35,617,636.36
\$40M-\$44.999M	122	10%	\$42,184,385.25
\$45M-\$49.999M	1,169	5%	\$17,598,603.93
LARGE FIRMS			
Receipts > \$50M	1,404	N/A	\$884,790,689.46

Source: 2022 Statistics of U.S. Businesses, available at <https://www.census.gov/programs-surveys/susb.html>.

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As shown in Table 12, all the industries combined, according to the 2022 Economic Census, earned approximately \$2,364,153,884,000, while the small firms for all the industries combined earned approximately \$325,819,624,000. Table 13 in section V.E. estimates a \$31.6

million reduction in total annualized monetized transfers from the Federal Government and States to health care providers. This total estimated reduction represents less than 1 percent of the total revenues of the health care industries impacted and the total revenues of the small firms in the health care industries impacted. It also

represents less than 1 percent of the total revenues of each health care industry impacted and the total revenues of the small firms in each health care industry impacted. As a result, this final rule will result in a change in revenue of less than 1 percent for the impacted health care industries.

TABLE 12: Total Revenues, All Firms and Small Firms, by NAICS Classification

NAICS	Total Revenues (All Firms)	Revenue Test*	Total Revenues (Small Firms)	Revenue Test*
446110 Pharmacies and Drug Stores	\$339,002,748,000.00	0.01%	\$72,563,085,000.00	0.04%
621111 Offices of Physicians (except Mental Health Specialists)	\$630,858,846,000.00	0.00%	\$188,937,217,000.00	0.02%
621112 Offices of Physicians, Mental Health Specialists	\$10,875,162,000.00	0.29%	\$7,817,888,000.00	0.40%
621493 Freestanding Ambulatory Surgical and Emergency Centers	\$43,395,150,000.00	0.07%	\$15,111,293,000.00	0.21%
621498 All Other Outpatient Care Centers	\$77,203,082,000.00	0.04%	\$20,817,373,000.00	0.15%
622110 General Medical and Surgical Hospitals	\$1,262,818,896,000.00	0.00%	\$20,572,768,000.00	0.15%
Total	\$2,364,153,884,000.00	0.00%	\$325,819,624,000.00	0.01%

Source: 2022 Statistics of U.S. Businesses, available at <https://www.census.gov/programs-surveys/susb.html>.

* Calculated using an estimated reduction in total annualized monetized transfers of \$31.6 million (as shown in Table 13) as a percentage of total revenues.

As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. According to Table 12, we do not believe that the 3 to 5 percent threshold will be reached by the requirements in this rule for NAICS 446110 Pharmacies and Drug Stores; 622111 Offices of Physicians (except Mental Health Specialists); 621112 Offices of Physicians, Mental Health Specialists; 621493 Freestanding Ambulatory Surgical and Emergency Centers; 621498 All Other Outpatient Care Centers; or 622110 General Medical and Surgical Hospitals.

The \$31.6 million in anticipated transfers from providers is not an economically significant impact compared to the revenues of the healthcare sector. It is small even compared to the revenues of a large hospital. The only way for a substantial number of providers to be significantly affected by \$31.6 million in transfers would be for a substantial number of small providers to bear much of those transfers. That is not the case for the transfers imposed by this rule, which would be disproportionately borne by large academic medical centers.

In a nationally weighted analysis of hospital inpatient and hospital-owned ambulatory surgery data from 2016–2020, 88.4 percent of patients identified as undergoing sex-rejecting surgery were classified as receiving care at urban

teaching hospitals.¹⁷¹ By comparison, urban teaching hospitals are less than 51 percent of the hospital industry by admissions and less than 20 percent by number.¹⁷²

The number of hospitals that had, at the time of Executive Order 14187, been performing pediatric sex-rejecting surgeries is reported to be a few dozen. We reviewed a list of health care provider organizations that reportedly discontinued, or announced plans to phase out, pediatric sex-rejecting care services in anticipation of the final rule.¹⁷³ With 42 organizations, the list is quite a comprehensive sample of all hospitals that had been performing the surgeries. Of the listed organizations, three-fourths were part of academic medical centers or teaching hospitals. The operating scale of the providers in the list is characteristic of some of the largest provider organizations in the industry. Their reported annual revenues average \$8 billion, and 34 of them have revenues above \$1 billion and have revenues above the large-

hospital average shown in Table 11. Despite qualifying as small entities, their revenues are well beyond the revenue categories presented for small hospital organizations in Table 11, showing that affected providers have a large revenue profile. At least 33 of the 42 hospitals could absorb the entire \$31.6 million annual transfer and still have it be below three percent of revenue, which is at the low end of the Department's threshold for economic significance. Therefore, the Secretary has certified that this final rule will not have a significant economic impact on a substantial number of small entities in these industries.

In addition, section 1102(b) of the Act requires us to prepare a RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we defined a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We did not prepare an analysis for section 1102(b) of the Act because we determined, and the Secretary certifies, that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess

¹⁷¹ Jason D. Wright et al., "National Estimates of Gender-Affirming Surgery in the US," *Jama Network Open* 6, no. 8 (2023), doi:10.1001/jamanetworkopen.2023.30348.

¹⁷² "Teaching Hospitals," American Hospital Association, accessed July 28, 2026, <https://www.aha.org/system/files/2018-02/info-teaching.pdf>.

¹⁷³ Theresa Gaffney, "Amid federal pressure, more hospitals stop gender-affirming care for minors," *STAT*, February 5, 2026, <https://www.statnews.com/2026/02/05/hospitals-stop-gender-care-minors-trump-administration-pressure/>.

anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2026, that threshold is approximately \$193 million. The final rule will not mandate significant spending costs on State, local, or Tribal governments in the aggregate, or by the private sector.

E.O. 14192, entitled “Unleashing Prosperity Through Deregulation” was issued on January 31, 2025, and requires that “any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.” This final rule is exempt from otherwise-applicable requirements under E.O. 14192, per footnote 1 of OMB’s Accounting Methods.¹⁷⁴

E.O. 13132 establishes certain requirements that an agency must meet when it issues a rule that imposes substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. This final rule will have a substantial direct effect on the ability of States to receive Federal Medicaid funds for sex-rejecting procedures furnished to children under age 18 and on the ability of States to receive Federal CHIP funds for sex-rejecting procedures furnished to children under age 19.

We received public comment on this RFA analysis. The following is a summary of the comment we received and our response.

Comment: A commenter stated that the proposed rule’s RFA analysis failed to accurately assess the rule’s economic impact on small entities. The commenter asserted that CMS assumed almost all providers are small entities without analyzing which providers actually offer these procedures or whether they meet the definition of a small entity, and that this assumption spread costs across all providers and artificially deflated the estimated change in revenue, inconsistent with HHS guidance that a low average impact should not be used to disguise a significant impact on a subset. The commenter also stated that the analysis relied solely on change in revenue and,

in finding the estimated \$31.6 million reduction fell below the 3 to 5 percent significance threshold, failed to consider that providers offering these procedures often provide unrelated services that patients would no longer receive if the procedures were discontinued. Additionally, the commenter raised concerns that the analysis failed to account for other compliance costs identified in HHS guidance, such as training, new policies and procedures, technology, and insurance, and failed to consider the burden on small practices from sudden increases in patient demand or CMS’ obligation to analyze options for regulatory relief.

Response: In the proposed rule, we estimated the potential economic impact on small entities. After considering the public comments, we continue to conclude that the applicable significance threshold is not reached. Accordingly, the Secretary certifies that this final rule does not have a significant economic impact on a substantial number of small entities. As explained in the proposed rule, for purposes of the RFA, we estimate that the great majority of hospitals and other healthcare providers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration (SBA) size standards, and we identified the specific North American Industrial Classification System (NAICS) codes for the healthcare industries impacted by this rule along with the applicable SBA size standards and the distribution of firms and revenues within each. Using an estimated reduction in total annualized monetized transfers of \$31.6 million, we determined that this reduction represents less than 1 percent of total revenues for each impacted healthcare industry and for the small firms within each such industry. Because HHS uses a change in revenue of more than 3 to 5 percent as its measure of significant economic impact on a substantial number of small entities, and this threshold is not reached for any of the impacted industries, the Secretary has certified that this final rule does not have a significant economic impact on a substantial number of small entities. We note that the estimated reduction in transfers reflects our analysis of T–MSIS TAF data identifying Medicaid and

CHIP spending on the procedures at issue for the affected population, and this final rule does not prohibit States from continuing to cover these procedures with State-only funds outside of the Federally-matched Medicaid program or CHIP. We also reiterate that this final rule does not prohibit providers from continuing to furnish these procedures or from receiving payment for them through other sources, nor would it prohibit Federal Medicaid or CHIP payment for other services these providers furnish, including mental health counseling and psychotherapy for gender dysphoria and procedures falling within the exceptions in the definition of sex-rejecting procedures. To the extent the commenter raises concerns regarding downstream effects on revenue from unrelated services or other compliance costs, we continue to believe that the change in revenue for the impacted healthcare industries is well below the threshold for a significant economic impact. It is unclear what is exactly meant by a “sudden increase in patient demand” or by the asserted “obligation to analyze options for regulatory relief.” We understand the commenter to be referring to the agency’s certification at the proposed rule stage under § 605(b).¹⁷⁵ Under HHS guidance, that certification did not require preparation of an initial regulatory flexibility analysis or an analysis of significant regulatory alternatives.¹⁷⁶

In addition, we identify that urban teaching hospitals provide the majority of sex-rejecting procedures, and therefore they form the smaller subset of small entities disproportionately affected by the final rule. In other words, the final rule establishes that the economic impact is borne by urban teaching hospitals. Per the RFA analysis in the final rule, we show that there is not a significant economic impact on these firms due to their large revenues.

E. Accounting Statement and Table

Consistent with OMB Circular A–4 (available at <https://www.whitehouse.gov/wp-content/uploads/2025/08/CircularA-4.pdf>), we have prepared an accounting statement in Table 13 showing the classification of the impact associated with the provisions of this final rule.

¹⁷⁴ “Accounting Methods under Executive Order 14192,” Office of Information and Regulatory Affairs, accessed July 10, 2026, https://www.reginfo.gov/public/pdf/eo14192/Accounting_Methods_under_EO_14192.pdf.

¹⁷⁵ Department of Health and Human Services, “Guidance on Proper Consideration of Small Entities in Rulemakings,” (May 2003): 9, <https://aspe.hhs.gov/sites/default/files/documents/dd6288d1b8db19ee8a1f37b3ce775003/guidance-proper-consideration-hhs-2003-rulemaking.pdf>.

¹⁷⁶ Department of Health and Human Services, “Guidance on Proper Consideration of Small Entities in Rulemakings,” (May 2003): 2–3, <https://aspe.hhs.gov/sites/default/files/documents/dd6288d1b8db19ee8a1f37b3ce775003/guidance-proper-consideration-hhs-2003-rulemaking.pdf>.

TABLE 13: Accounting Statement

Transfers	Estimate	Year Dollar	Discount Rate	Period Covered
Annualized Monetized (\$/year)	\$13.6 million	2027	7 percent	2027-2036
	\$13.7 million	2027	3 percent	2027-2036
Quantitative: Estimated reduction in transfers from Federal Government to healthcare providers (including hospitals, physicians, and pharmacies) and to beneficiaries due to no longer covering sex-rejecting procedures for individuals under 18.				
Annualized Monetized (\$/year)	\$9.5 million	2027	7 percent	2027-2036
	\$9.6 million	2027	3 percent	2027-2036
Quantitative: Estimated reduction in transfers from States to healthcare providers (including hospitals, physicians, and pharmacies) and to beneficiaries due to no longer covering sex-rejecting procedures for individuals under 18.				

Table 13 shows the annualized monetized transfer values required under OMB Circular A–4. At a discount rate of 7 percent, the annualized monetized transfers are \$13.6 million to the Federal government and \$9.5 million to the States, reflecting a reduction in payment for these services to healthcare providers. At a discount rate of 3 percent, the annualized monetized transfers are \$13.7 million to the Federal government and \$9.6 million to the States.

We received public comments on this RIA. The following is a summary of the comments we received and our responses.

Comment: Many commenters stated that the proposed rule's RIA failed to fully account for the range of costs associated with the rule, including costs to States, providers, managed care organizations, insurers, individuals, and drug manufacturers, as well as the long-term costs of individuals forgoing care or seeking procedures out of pocket. Commenters also stated that the RIA understated the potential harms of the rule, including the mental and physical health consequences for affected individuals and the professional impact on providers, while insufficiently quantifying the benefits of the procedures in question. Additionally, several commenters raised concerns about methodological flaws in the RIA, including unsupported assumptions about patient switching rates, inaccurate estimates of procedure volume, inconsistencies with the RIA of a companion rule, and a failure to account for the combined fiscal impact of both rules.

Response: We appreciate the detailed comments received regarding the RIA and have carefully considered the

concerns raised. We do not agree with the characterization that the RIA is materially deficient or methodologically unsound.

The RIA was prepared using the most recently available program data and reasonable assumptions consistent with standard Federal regulatory analysis practice. As we noted in the proposed rule, we projected spending forward from 2023 using established methodology, and we acknowledged the limitations of available data, including the absence of direct empirical studies on the effects of coverage restrictions of this type. Where data were unavailable to support precise estimates, we used reasonable assumptions and disclosed them transparently. We acknowledge that some individuals may transition to private coverage or State-only funded programs, and we noted in the RIA that we could not estimate with precision the full range of downstream effects, including potential changes in utilization of other health care services. Commenters did not provide data or studies that could be used to quantify the impacts of this rule. For commenters' concerns that the RIA failed to quantify the mental and physical health benefits of the procedures in question, we note that the scientific evidence regarding the long-term benefits of sex-rejecting procedures for children with gender dysphoria is, as discussed extensively in the proposed rule, of very low quality. The HHS Review and the systematic reviews underlying it found the evidence base to be insufficient to support conclusions about the effectiveness of these interventions in improving mental health outcomes or reducing symptoms of gender dysphoria over the long term. In the absence of reliable evidence of

benefit, we cannot quantify such benefits in the RIA. We continue to believe that the prohibition on Federal financial participation for these procedures is consistent with States' statutory obligations to ensure that Medicaid- and CHIP-covered services be provided in a manner consistent with the best interests of beneficiaries and that payments be consistent with quality of care, and meet the effective and efficient standard.

We also do not agree with commenters who suggested that our cost estimates were inflated by failing to account for existing restrictions. To the contrary, as noted in the proposed rule, States that had not enacted bans on these procedures as of 2023 accounted for 76 percent of relevant Medicaid spending. Our analysis focused on the expected reduction in Federal expenditures attributable to the proposed rule and reflects the scope of coverage that would actually be affected. We issued a companion proposed rule addressing hospital conditions of participation contemporaneously with the proposed rule. The potential interactions between the two rules were acknowledged in the proposed rule, and we noted that the effects attributable to this rule may be lower in magnitude if the companion rule were to be finalized first.

We believe that the use of the diagnosis codes was correct and that the data likely does not include unrelated claims. In addition, the relatively small amount of expenditures identified in our analysis for inpatient and outpatient procedures (about \$2.4 million in 2023) suggests that there are not a large number of other claims included. We have clarified the approach that we used in our analysis.

We acknowledge that the impact analysis does not provide estimates of impacts on other programs. There are different ways that beneficiaries, providers, and States may react to this rule, including obtaining payment for these services from other programs or private payers, and States electing to pay for services without Federal contributions. We have added a description of these potential responses in the impact analysis.

Comment: Several commenters stated that the RIA failed to meaningfully consider reasonable alternatives to the proposed rule, such as informed consent requirements, utilization controls, centers of excellence pathways, coverage with evidence development, or approaches modeled on European regulatory frameworks. Commenters also indicated that the RIA did not fulfill certain analytical requirements, including a distributional analysis under OMB Circular A–4, an intersectional health equity analysis, and a Family Policymaking Assessment, with particular concern that the rule's costs would fall disproportionately on vulnerable populations such as rural beneficiaries, individuals with disabilities, tribal communities, and foster or justice-involved youth.

Response: We do not agree with commenters who stated that the RIA failed to meaningfully consider alternatives or to fulfill applicable analytical requirements.

For regulatory alternatives, as described in the proposed rule, we considered whether to take no action. In finalizing this rule, we concluded that permitting the use of Federal Medicaid and CHIP dollars to fund sex-rejecting procedures for children would be inconsistent with sections 1902(a)(19), 1902(a)(30)(A), and 2101(a) of the Act which require that services be provided in a manner consistent with the best interests of beneficiaries and that payments be consistent with quality of care and meet the effective and efficient standard. We acknowledge that alternative actions could have been taken such as issuing sub-regulatory guidance suggesting States refrain from offering these services based on the evidence described in the HHS Review, issuing a regulation to require utilization management in advance of the provision of these services to ensure appropriate State oversight of these services, or simply allowing continued Federal matching for these services. While these actions continue to be possible, they were not considered as alternatives as we concluded that a prohibition of Federal matching funds was warranted in the immediate term in

light of the current evidence described in the HHS Review identifying significant risks associated with sex-rejecting procedures, including potentially irreversible harms, and the growing international retreat from the use of puberty blockers, cross-sex hormones, and surgeries to treat gender dysphoria in children.

Procedures that carry risks of permanent infertility, sexual dysfunction, impaired bone density, and other serious long-term effects cannot be rendered appropriate for Federal funding through administrative safeguards alone when the evidence of benefit is, as the HHS Review found, of very low quality.

For commenters' suggestions that we model our approach on certain European regulatory frameworks, we note that the international developments discussed in the proposed rule—including the systematic reviews conducted by Sweden, Finland, and the United Kingdom—actually support the conclusion that a more restrictive approach to these procedures for children is warranted. Those countries undertook rigorous independent reviews and concluded that the risks of these interventions may outweigh their benefits at the population level. While the specific policy responses in those jurisdictions vary, the underlying scientific findings are consistent with the conclusions of the HHS Review on which this rule is based.

For the analytical requirements identified by commenters, we note that we conducted the analyses required under E.O. 12866, the Regulatory Flexibility Act, section 1102(b) of the Act, and section 202 of the Unfunded Mandates Reform Act of 1995, and we certified, consistent with our findings, that the proposed rule will not have a significant economic impact on a substantial number of small entities and will not mandate significant spending costs on State, local, or Tribal governments in excess of the applicable threshold. We acknowledge commenters' concerns that the rule's costs may fall disproportionately on certain populations, including rural beneficiaries, individuals with disabilities, tribal communities, and foster or justice-involved youth. We take these concerns seriously and note that the Federal Medicaid and CHIP programs will continue to cover a broad range of services for eligible individuals in all of these populations, including mental health counseling and psychotherapy, which we believe offer meaningful and evidence-supported interventions for children diagnosed

with gender dysphoria. We are committed to ensuring that these alternative services remain accessible to the children and families who rely on Medicaid and CHIP. Executive Order 14192, entitled “Unleashing Prosperity Through Deregulation” was issued on January 31, 2025, and requires that “any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.” This final rule is neither a regulatory nor a deregulatory action under E.O. 14192.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on August 10, 2026.

List of Subjects

42 CFR Part 441

Grant programs—health. Health professions, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 457

CHIP, Grant programs—health, Health professions, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

- 1. The authority citation for part 441 continues to read as follows:

Authority: 42 U.S.C. 1302.

- 2. Add subpart N to read as follows:

Subpart N—Prohibition on Federal Medicaid Funding for Sex-Rejecting Procedures Furnished to Children

Sec.

441.800 Basis and purpose.

441.801 Definitions.

441.802 General rules.

§ 441.800 Basis and purpose.

The purpose of this subpart is to implement sections 1902(a)(19) and 1902(a)(30)(A) of the Act to protect Medicaid beneficiaries and ensure Medicaid payment is consistent with quality of care by prohibiting Federal financial participation in payments by States for sex-rejecting procedures for a child under the age of 18.

(a) As relevant to this subpart, section 1902(a)(19) of the Act requires that States ensure that care and services will be provided in a manner consistent with the best interests of the recipients.

(b) As relevant to this subpart, section 1902(a)(30)(A) of the Act requires that

States' payment methods be consistent with quality of care.

§ 441.801 Definitions.

As used in this subpart—

Female means a person of the sex characterized by a reproductive system with the biological function of (at maturity, absent disruption or congenital anomaly) producing eggs (ova).

FFP means Federal financial participation.

Male means a person of the sex characterized by a reproductive system with the biological function of (at maturity, absent disruption or congenital anomaly) producing sperm.

Sex means a person's immutable biological classification as either male or female.

Sex-rejecting procedure means, except as specified in paragraph (3) of this definition, any pharmaceutical or surgical intervention that attempts to align an individual's physical appearance or body with an asserted identity that differs from the individual's sex by either of the following:

- (1) Intentionally disrupting or suppressing the normal development of natural biological functions, including primary or secondary sex-based traits; or
- (2) Intentionally altering an individual's physical appearance or body, including amputating, minimizing or destroying primary or secondary sex-based traits such as the sexual and reproductive organs.

(3) For purposes of this definition, the term *sex-rejecting procedure* does not include procedures undertaken—

(i) To treat an individual with a medically verifiable disorder of sexual development; or

(ii) For purposes other than attempting to align an individual's physical appearance or body with an asserted identity that differs from the individual's sex; or

(iii) To treat complications, including any infection, injury, disease, or disorder that has been caused by or exacerbated by the performance of sex-rejecting procedure(s).

§ 441.802 General rules.

(a) Except as provided in paragraph (c) of this section, a State plan must provide that the Medicaid agency will not make payment under the plan for sex-rejecting procedures for children under the age of 18.

(b) Except as provided in paragraph (c) of this section, FFP is not available in State expenditures for sex-rejecting procedures for children under the age of 18.

(c) FFP will remain available for cross-sex hormone therapy for a tapering period of up to 6 months from October 13, 2026, for beneficiaries who were receiving such therapy as of October 13, 2026.

PART 457—ALLOTMENTS AND GRANTS TO STATES

■ 3. The authority citation for part 457 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 4. Add § 457.476 to read as follows:

§ 457.476 Limitations on coverage: Sex-rejecting procedures.

(a) The purpose of this section is to ensure that CHIP is operated in an effective and efficient manner that is coordinated with other sources of health benefits coverage, including Medicaid, for children consistent with 2101(a) of the Act by prohibiting Federal financial participation in payments by States for sex-rejecting procedures for a child under the age of 19.

(b) The prohibition on Federal financial participation for payments by States for sex-rejecting procedures for children applies in the same manner described in Medicaid at § 441.802 of this chapter to a State administering a separate CHIP except that it applies to children under the age of 19 in accordance with the definition of a targeted low-income child at § 457.310. This prohibition applies to CHIP regardless of the type of health benefit coverage option described at § 457.410. For purposes of this section, the definitions applied under Medicaid at § 441.801 of this chapter apply equally to a separate CHIP.

Robert F. Kennedy, Jr.,
Secretary, Department of Health and Human Services.

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EXHIBIT D

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MONTANA FOURTH JUDICIAL DISTRICT COURT
MISSOULA COUNTY

MOLLY CROSS, et al.,
Plaintiffs,

v.

STATE OF MONTANA, et al.,
Defendants.

Dept. No. 4
DV-32-2023-541
Hon. Jason Marks

**DECLARATION OF MICHAEL D.
RUSSELL IN SUPPORT OF MOTION
TO DISSOLVE INJUNCTION**

I, Michael D. Russell, upon oath, do hereby state and declare as follows:

1. I am a citizen of the United States and a resident of the State of Montana, Lewis & Clark County, and I am among several counsel of record in the above-captioned matter. I make this Declaration based upon

my own personal knowledge and upon review of materials relevant to Defendants' Motion to Dissolve Injunction in this matter.

2. This Declaration is Exhibit D to Defendants' Combined Brief in Support of Rule 60(b)(2) Motion for Relief from Judgment or Order and Motion to Dissolve Injunction ("Combined BIS").

3. Exhibit A to Defendants' Combined BIS is a true and correct copy of the World Professional Association for Transgender Health, Inc.'s ("WPATH") Memorandum in Support of Its Motion to Dismiss filed in *Federal Trade Commission, et al. v. World Professional Association for Transgender Health, Inc., et al.* No. 4:26-cv-00748-O (N.D. Tex.) on July 28, 2026.

4. Exhibit B to Defendants' Combined BIS is a true and correct copy of the Position Statement on Gender Surgery of Children and Adolescents issued by the American Society of Plastic Surgeons ("ASPS") on February 3, 2026.

5. Exhibit C to Defendants' Combined BIS is a true and correct copy of the Department of Health and Human Services final rule, Medicaid Program; Prohibition on Federal Medicaid and Children's Health Insurance Program Funding for Sex-Rejecting Procedures

Furnished to Children, 91 Fed. Reg. 52406 (Aug. 13, 2026) (to be codified at 42 C.F.R. pts. 441, 457).

6. Exhibits A, B, and C are newly discovered evidence that directly contradict this Court’s conclusion that the “evidence that major medical organizations acknowledge the gender-affirming medical care banned by SB 99 is generally appropriate for treating adolescents with gender dysphoria” is “undisputed.” (Doc. 279 at 20). Because this evidence severely undermines the central premises of this Court’s summary judgment analysis and resulting injunction of SB 99 as explained in greater detail in Defendants’ Combined BIS, there is not sufficient ground for that injunction to continue.

I declare under penalty of perjury that the foregoing is true and correct.

DATED this 4th day of September, 2026, in Helena, Montana.

/s/ Michael D. Russell

Michael D. Russell

CERTIFICATE OF SERVICE

I, Michael D. Russell, hereby certify that I have served true and accurate copies of the foregoing Answer/Brief - Brief In Support of Motion to the following on 09-04-2026:

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Electronically signed by Elena Hagen on behalf of Michael D. Russell
Dated: 09-04-2026