BECOMES EFFECTIVE], for any eligible investigational drugs supplied to any eligible patients under section 561B of the Federal Food, Drug, and Cosmetic Act.

(c) For each eligible investigational drug, the annual summary must include:

(1) The name of the eligible investigational drug and applicable IND number. The name and IND number of the eligible investigational drug supplied by the manufacturer or sponsor for use under section 561B of the Federal Food, Drug, and Cosmetic Act.

(2) Number of doses supplied. The total number of doses supplied by the manufacturer or sponsor to eligible patients for use under section 561B of the Federal Food, Drug, and Cosmetic Act. Each dose of an eligible investigational drug supplied for an eligible patient shall be counted as a dose supplied.

(3) Number of patients treated. The total number of eligible patients for whom the manufacturer or sponsor provided the eligible investigational drug for use under section 561B of the Federal Food, Drug, and Cosmetic Act. An eligible patient treated more than one time or with multiple doses of an eligible investigational drug shall be counted as a single patient.

(4) Use for which the eligible investigational drug was made available. A tabular summary identifying the disease or conditions for which the eligible investigational drug was made available for use under section 561B of the Federal Food, Drug, and Cosmetic Act.

(5) Any known serious adverse events and outcomes. A tabular summary of any known serious adverse events, including resulting outcomes, experienced by patients treated with the eligible investigational drug under section 561B of the Federal Food, Drug, and Cosmetic Act.

(d) Annual summaries submitted pursuant to this section shall be submitted in an electronic format that FDA can process, review, and archive, and shall be sent directly to a designated point of contact for submissions made under section 561B of the Federal Food, Drug, and Cosmetic Act. The annual summaries must be submitted to the designated point of contact and shall not be submitted to a particular IND. FDA will specify the designated point of contact for submission of the annual summary on FDA's website, located at https:// www.fda.gov.

Dated: July 10, 2020. **Stephen M. Hahn,** *Commissioner of Food and Drugs.* [FR Doc. 2020–16016 Filed 7–23–20; 8:45 am] **BILLING CODE 4164–01–P**

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 5 and 576

[Docket No. FR-6152-P-01] RIN 2506-AC53

Making Admission or Placement Determinations Based on Sex in Facilities Under Community Planning and Development Housing Programs

AGENCY: Office of the Secretary, HUD. **ACTION:** Proposed rule.

SUMMARY: This proposed rule would provide that grant recipients, subrecipients, owners, operators, managers, and providers under HUD programs that permit single-sex or sexspecific facilities (such as temporary, emergency shelters or other facilities with physical limitations or configurations that require and are permitted to have shared sleeping quarters or bathrooms) may establish a policy, consistent with federal, state, and local law, to accommodate persons based on sex. The proposed rule would maintain requirements from HUD's 2012 final rule entitled "Equal Access to Housing in HUD Programs Regardless of Sexual Orientation or Gender Identity" and would require shelters to uniformly and consistently apply any such policy the shelter develops. The proposed rule would require any determination of sex by the shelter provider to be based on a good faith belief, and require the shelter provider to provide transfer recommendations if a person is of the sex not accommodated by the shelter and in some other circumstances.

DATES: *Comment Due Date:* September 22, 2020.

ADDRESSES: Interested persons are invited to submit comments regarding this Proposed Rule to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410–0500. Room 10276, Washington, DC 20410–0500. Communications must refer to the above docket number and title. There are two methods for submitting public comments. All submissions must refer to the above docket number and title.

1. Submission of Comments by Mail. Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Room 10276, Washington, DC 20410–0500.

2. Electronic Submission of Comments. Interested persons may submit comments electronically through the Federal eRulemaking Portal at www.regulations.gov. HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the www.regulations.gov website can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

Note: To receive consideration as public comments, comments must be submitted through one of the two methods specified above. All submissions must refer to the docket number and title of the rule.

No Facsimile Comments. Facsimile (FAX) comments are not acceptable.

Public Inspection of Public Comments. All properly submitted comments and communications submitted to HUD will be available for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, an advance appointment to review the public comments must be scheduled by calling the Regulations Division at 202-708-3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number through TTY by calling the Federal Relay Service at 800-877-8339 (toll-free number). Copies of all comments submitted are available for inspection and downloading at www.regulations.gov.

FOR FURTHER INFORMATION CONTACT:

Andrew Hughes, Chief of Staff, U.S. Department of Housing and Urban Development, 451 7th Street, SW, Washington, DC 20410, telephone number 202–402–7204 (this is not a tollfree number). Persons with hearing or speech impairments may access this number via TTY by calling the Federal Relay Service at 800–877–8389 (toll-free number).

SUPPLEMENTARY INFORMATION:

I. History

HUD has always supported effective models at reducing homelessness and providing emergency shelter for those in need, including through supporting single-sex or sex-specific shelters.

In 2012, HUD published a final rule entitled "Equal Access to Housing in HUD Programs Regardless of Sexual Orientation or Gender Identity" (2012 Rule) to ensure that its core housing programs are open to all eligible families and individuals "without regard to actual or perceived sexual orientation, gender identity, or marital status."¹ The 2012 Rule defined 'gender identity'' as ''actual or perceived gender-related characteristics."² The 2012 Rule generally prohibited inquiries into gender identity in determining eligibility or making housing available, but permitted inquiries related to an applicant's or occupant's sex for the limited purpose of determining placement in temporary, emergency shelters with shared bedrooms or bathrooms, or for determining the number of bedrooms to which a household may be entitled.³ In promulgating the 2012 Rule, HUD relied on the Secretary's general rulemaking authority pursuant to section 7(d) of the Department of HUD Act,⁴ rather than the Fair Housing Act⁵, or other civil rights and nondiscrimination authorities.

After the promulgation of the 2012 Rule, HUD determined that the 2012 Rule did not comprehensively define how shelters must accommodate transgender individuals. On September 21, 2016, HUD expanded on its 2012 Rule and published a final rule entitled, "Equal Access in Accordance with an Individual's Gender Identity in Community Planning and Development Programs" (2016 Rule). HUD mandated that transgender persons and other persons "who do not identify with the sex they were assigned at birth" be given access to Community Planning and Development (CPD)-assisted programs, benefits, services, and accommodations, some of which are permitted to be operated on a single-sex or sex-specific basis (collectively, ''single-sex facilities''), in accordance with their gender identity. These programs include temporary and emergency shelter programs, such as the Emergency Solutions Grants ⁶ program and the Housing Opportunities for

Persons with AIDS (HOPWA) program.⁷ The 2016 Rule maintained the definition of "gender identity" included in the 2012 Rule to mean "the gender with which a person identifies, regardless of the sex assigned at birth[.]"8

The 2016 Rule removed paragraph 5.105(a)(2)(ii), the provision of the 2012 Rule that allowed for lawful inquiries into an occupant's sex in the case of temporary or emergency shelters with shared bathroom or bedroom facilities, or for the purpose of determining the number of bedrooms to which a household may be entitled. Instead, the 2016 Rule contained a provision that policies and procedures must ensure that individuals are not subject to intrusive questioning or asked to provide anatomical information or documentary, physical, or medical evidence of their gender identity.9

The 2016 Rule, § 5.106(c), requires that individuals seeking access to single-sex facilities be placed and accommodated in accordance with their self-identified gender identity, expressly declining to adopt a provision of the proposed rule that provided that in certain cases, an alternative accommodation for a transgender persons and other persons "who do not identify with the sex they were assigned at birth" would be appropriate to ensure health and safety. Section 5.106(c) requires recipients to take nondiscriminatory steps as necessary and appropriate to address the privacy concerns of all residents and occupants. No funding was specifically provided for this purpose.

Finally, the Housing Trust Fund and **Rural Housing Stability Assistance** programs were added explicitly to the non-exclusive list of programs covered, and language was added to indicate that the 2016 rule applies to both recipients of HUD CPD grants and subrecipients, as well as those who administer CPDfunded programs and services.

II. Proposed Rule

HUD has reconsidered its 2016 Rule and determined that providers should be allowed, as permitted by the Fair Housing Act, to consider biological sex in placement and accommodation decisions in single-sex facilities. HUD thus proposes to allow shelters that may already consider sex in admission and accommodation decisions (i.e., facilities that are not covered by the Fair Housing Act) to establish a policy that places and accommodates individuals on the basis

of their biological sex, without regard to their gender identity. This will allow single-sex facilities to regain the flexibility to serve their unique populations that they have following the 2012 Rule. Nothing in the proposed rule restricts shelters from maintaining a policy on placing and accommodating an individual based on gender identity.

The proposed rule leaves in place requirements from the 2012 Rule that shelters and all other participants in HUD programs ensure that their programs are open to all eligible individuals and families without regard to sexual orientation or gender identity. Thus, a shelter may place an individual based on his or her biological sex but may not discriminate against an individual because the person is or is perceived as transgender.

For example, under the proposed rule, if a single-sex facility permissibly provides accommodation for women, and its policy is to serve only biological women, without regard to gender identity, it may decline to accommodate a person who identifies as female but who is a biological male. Conversely, the same shelter may not, on the basis of sex, decline to accommodate a person who identifies as male but who is a biological female. A different shelter may choose not to make placement decisions or accommodations based on biological sex and there remains no mandate that shelters take biological sex into account.

III. Justification for the Rule Change

HUD believes this proposed rule better resolves the various equities involved within the shelter context than HUD's 2016 Rule. In particular, HUD believes that the 2016 Rule impermissibly restricted single-sex facilities in a way not supported by congressional enactment, minimized local control, burdened religious organizations, manifested privacy issues, and imposed regulatory burdens.

First, the 2016 Rule restricted singlesex facilities in a way not supported by Congressional enactment. Congress has prohibited discrimination on the basis of sex in "dwellings under the Fair Housing Act. But it has not acted to prohibit consideration of sex in temporary and emergency shelters, many of which do offer sex-specific housing or sex-specific areas of housing (such as facilities with physical limitations or configurations that have shared sleeping quarters or bathing areas). As the 2016 Rule recognizes, "[a]n emergency shelter and other building and facility that would not qualify as dwellings under the Fair Housing Act are not subject to the Act's

¹77 FR 5662, February 3, 2012.

² See § 5.100 at 77 FR 5674. This definition comes from 18 U.S.C. 249.

³ See § 5.105(a)(2)(ii) at 77 FR 5674. 4 42 U.S.C. 3535(d).

⁵⁴² U.S.C. 3601-3619 (prohibits discrimination in housing because of race, color, national origin, religion, sex, familiar status and disability).

⁶Codified in 24 CFR part 576.

⁷ Codified in 24 CFR part 574.

⁸⁸⁰ FR 72648.

⁹ Section 5.106(b)(3).

prohibition against sex discrimination and thus may be permitted by statute to be sex segregated."¹⁰ But HUD's 2016 Rule effectively restricts shelters from making this policy choice permitted by the Fair Housing Act, by—for example requiring shelters to allow biological males who self-identify as females to be admitted to female-only shelters. Thus, under HUD's 2016 Rule, the femalespecific shelters that are permitted under the Fair Housing Act can be effectively restricted from being femalespecific.

Moreover, HUD did not rely on explicit statutory authorization, like the prohibition against "sex" discrimination under the Fair Housing Act, when HUD implemented its 2016 Rule. Rather, HUD relied on the Secretary's plenary authority to issue regulations, indicating that "HUD's establishment of programmatic requirements for temporary, emergency shelters and other buildings and facilities funded through HUD programs is well within HUD's statutory authority and an important part of HUD's mission in ensuring access to housing for all Americans." But HUD should not reach beyond the authority granted to HUD by Congress. By acting under plenary authority instead of a more specific affirmative grant of authority from Congress, the 2016 Rule violated the basic principle of administrative law that an agency should not go beyond the scope of the power granted them by duly enacted legislation and imposed a regulatory burden. Agencies are to "implement the statute according to its text and to apply the law no further than the text would permit" because "any attempt to do so is a threat to individual freedom."¹¹

Second, the 2016 Rule minimized local control. The 2016 Rule also adopted a one-size-fits-all approach to admission and accommodation by gender identity in temporary shelters, despite significant variation in State and local law. In just one example, the Rule requires shelters to admit individuals based on self-identification as the only method of determining a person's sex. This approach elevates subjective assertions by persons seeking accommodation and disallows other factors that could be used to objectively verify sex. Recognizing concerns with this approach, many states and localities prohibiting transgender discrimination require a differing bar in enforcing a

nondiscrimination claim based on gender identity, as three examples demonstrate.

Anchorage, Alaska, for example, requires evidence that "the gender identity is sincerely held, core to a person's gender-related self-identity, and not being asserted for an improper purpose."¹² HUD's definition does not require such evidence. In a second example, New York City's code prohibits discrimination on the basis an individual's gender identity, including for housing accommodations. New York City's code defines gender to encompass perceived gender identity.¹³ In contrast, HUD's current regulations define gender identity to ignore an individual's perceived gender identity. More notably, directly contrary to HUD's regulations, New York City's code explicitly excludes "shelters for the homeless where such distinctions are intended to recognize generally accepted values of personal modesty and privacy or to protect the health, safety or welfare of families with children."¹⁴ In a third example, Massachusetts public accommodations must accommodate individuals based upon their gender identity. Unlike HUD's current regulations, Massachusetts law does not contain a reference to the gender with which an individual identifies. Instead, it defines

¹³ See N.Y.C. Admin. Code § 8–102 ("Gender"), available at: https://www1.nyc.gov/assets/cchr/ downloads/pdf/TITLE_8_ Human%20Rights%20Law_May%202019.pdf. (Gender "includes actual or perceived sex, gender identity and gender expression, including a person's actual or perceived gender-related selfimage, appearance, behavior, expression or other gender-related characteristic, regardless of the sex assigned to that person at birth.")

¹⁴N.Y.C. Admin. Code section 8–107(5)(k) ("Applicability"), available at: https:// www1.nyc.gov/assets/cchr/downloads/pdf/TITLE_ 8_Human%20Rights%20Law_May%202019.pdf. New York City's Department of Homeless Services has recently issued binding guidance to require placement of individuals based on their selfprofessed gender identity. See NYC Department of Homeless Services, Office of Policy, Procedures and Training, DHS-PB-2019-015 (July 15, 2019), available at: https://www1.nyc.gov/assets/dhs/ downloads/pdf/dhs_policy_on_serving_ transgender_non_binary_and_intersex_clients.pdf. However, this guidance only applies to locallyfunded shelters.

gender identity to mean "a person's gender-related identity, appearance or behavior, whether or not that genderrelated identity, appearance or behavior is different from that traditionally associated with the person's physiology or assigned sex at birth."¹⁵ Thus, this definition contains more objective factors than HUD's current, purely selfidentified regime. Further, unlike HUD's current regulations, Massachusetts law provides that "gender-related identity may be shown by providing evidence including, but not limited to, medical history, care or treatment of the genderrelated identity, consistent and uniform assertion of the gender-related identity or any other evidence that the genderrelated identity is sincerely held as part of a person's core identity. . ." Finally, in Massachusetts, "gender-related identity shall not be asserted for any improper purpose. . ." $^{\rm 16}$ while HUD's regulations contain no reference to improper purposes. Given this wide policy variation, HUD believes that shelters are best able to serve their beneficiaries when they can develop their own policies on accommodating those whose gender identity conflicts with their biological sex and that the issuance of the 2016 prescriptive rule was not appropriate.

By adopting a less prescriptive approach, HUD's new proposed rule better reflects constitutional principles of democracy and federalism. The current approach requires that shelters admit and accommodate individuals on the basis of their gender identity, even though more than 30 states do not have such a requirement. It also prescribed the means by which shelters had to determine an individual's gender identity (self-identification), even though states have differing approaches to this issue, not to mention localities. As this President's Executive Order 13132, "Federalism," explains, "issues that are not national in scope or significance are most appropriately addressed by the level of government closest to the people," and that the "national government should be deferential to the States when taking action that affects the policymaking of the States. . ."¹⁷ HUD believes the best way to fulfill this federalism mandateparticularly in a difficult issue like this with a lack of clear national

¹⁰ 80 FR 72644 (preamble) (emphasis added).
¹¹ White House memorandum "Legal Principles for All Administrative Action," by Donald F. McGahn II to General Counsels and Chief Legal Officers of All Executive Branch Agencies (May 10, 2018).

¹² Anchorage Municipal Code § 5.020.010, available at: https://library.municode.com/ak/ anchorage/codes/code_of_ ordinances?nodeId=TIT5EQRI_CH5.20UNDIPR_ 5.20.0 10DE; see also, Devin Kelly, Discrimination complaint against downtown Anchorage women's shelter opens up political front (March 14, 2018), available at: https://www.adn.com/alaska-news/ anchorage/2018/03/14/discrimination-complaintagainst-downtown-anchorage-womens-shelteropens-up-political-front/ ("The law requires the person to prove, through medical history and evidence of care or treatment of their gender identity, that their gender identity is "sincerely held, core to a person's gender-related self identity, and not being asserted for an improper purpose.").

¹⁵ See Mass. Gen. Laws ch. 22C, section 32, available at: https://malegislature.gov/laws/ generallaws/parti/titleii/chapter22c/section32.

¹⁶ See Mass. Gen. Laws ch. 4, section 7, available at: https://malegislature.gov/Laws/GeneralLaws/ Partl/Titlel/Chapter4/section7.

¹⁷ Executive Order 1313132, "Federalism," 64 FR 43255, August 10, 1999.

consensus—is to refrain from enforcing a national solution.

Third, the 2016 Rule burdened those shelters with deeply held religious convictions.¹⁸ Although not discussed in the 2016 Rule, the prescriptive approach to admission and accommodation on the basis of gender identity raises concerns about burdens on faith-based shelter providers. In some faith traditions, sex is viewed as an immutable characteristic determined at birth. Thus, legally compelled accommodation determined on a basis in conflict with the provider's beliefs could violate religious freedom precepts. For example, Hope Center in Alaska, a faith-based homeless shelter for women, sued in Federal District Court to prevent the application of a local law that would require them to serve biological males who identify as females.¹⁹ Hope Center believes that doing so would violate their sincerely held religious belief that the Bible teaches that God creates people male or female and "that it should care for women who lack shelter," thus excluding men.²⁰ Hope Center believes that the application of laws like HUD's 2016 Rule violate the First Amendment's Free Exercise Clause. HUD's 2016 Rule raises the same potential issue of coercing ministries like Hope to ''abandon [their] mission

¹⁹ See James Brooks, Municipality of Anchorage will pay \$100,001 to settle transgenderdiscrimination lawsuit involving homeless shelter (October 1, 2019), available at: https:// www.adn.com/alaska-news/anchorage/2019/10/01/ municipality-of-anchorage-will-pay-100001-tosettle-transgender-discrimination-lawsuit-involvinghomeless-shelter/.

²⁰ For a full discussion of their religious beliefs. see The Downtown Soup Kitchen v. Municipality of Anchorage, No. 3:18-cv-00190-SLG, Dkt. No. 1, "Verified Complaint", available at: https:// adflegal.blob.core.windows.net/mainsite-new/docs/ default-source/documents/legal-documents/thedowntown-soup-kitchen-dba-downtown-hopecenter-v.-municipality-of-anchorage/hope-center-v--complaint.pdf?sfvrsn=9536cb21_4 pp. anchorage-8-10; see also Alliance Defending Freedom For Faith and Justice, Downtown Hope Center v Municipality of Anchorage, et al., available at: https://adflegal.blob.core.windows.net/mainsitenew/docs/default-source/documents/resources/ media-resources/cases/the-downtown-soup-kitchend-b-a-downtown-hope-center-v.-municipality-ofanchorage/hope-center-v-anchorage--one-pagesummary.pdf?sfvrsn=fa9b07be_6.

and message. . ."²¹ in order to participate in government-funded programs.

The lack of attention in HUD's 2016 Rule to religious liberty is problematic because the Department of Justice has emphasized that "to the greatest extent practicable and permitted by law, religious observance and practice should be reasonably accommodated in all government activity."²² In some instances, accommodations of religious objections are necessitated by protections in the First Amendment's Free Exercise Clause.²³ In other instances, religious accommodations may be undertaken in furtherance of a secular governmental goal that is not designed to advance or further religion.²⁴ And yet, to protect their religious practice, shelters currently must seek individual, specific waivers under the Religious Freedom Restoration Act or potentially under the Secretary's general waiver authority,²⁵ which can be both time consuming and burdensome. Further, the 2016 Rule's approach discourages some religious providers from accepting HUD funding at all, to avoid being forced to either comply with the rule or the need to request a waiver. The large percentage of single-sex facilities sponsored by religious organizations that do not participate in HUD programs may reflect the burden or perceived burden of both current HUD requirements and the waiver process. Instead of continuing a piecemeal and ineffective way of accounting for religious beliefs, HUD proposes a policy that will respect the religious beliefs of shelters as they develop the admissions and

²² Federal Law Protections for Religious Liberty,82 FR 206 (October 6, 2017).

²³ The protection of the Free Exercise Clause extends to acts undertaken in accordance with sincerely held beliefs. The First Amendment guarantees the freedom to "*exercise*" religion, not just the freedom to "believe" in religion. Jurisprudence concerning this important area of law is complex and continues to develop. *See Fulton* v. *City of Phila.*, 922 F.3d 140 (3rd Cir.), *cert. granted*, 2020 U.S. LEXIS 961 (U.S. Feb. 24, 2020) (No. 19– 123). HUD believes it is appropriate to take steps to ensure that rights under the Free Exercise Clause are not infringed.

²⁴ The Supreme Court has said that "'there is room for play in the joints' between the Clauses, some space for legislative action neither compelled by the Free Exercise Clause nor prohibited by the Establishment Clause." *Cutter* v. *Wilkinson*, 544 U.S. 709, 719 (2005) (internal quotation and citation omitted).

25 42 U.S.C. 3535(q).

accommodations policy, provided that each policy is consistent with state and local law. By respecting the religious beliefs of shelters, HUD, can better provide wide availability of shelters to participate in the program.

Fourth, the 2016 Rule has manifested *privacy issues.* The current rule gives little consideration to the shelter's need to take care of the mental health and privacy concerns of at-risk clients, particularly "the special needs of program residents that are victims of domestic violence" along with "dating violence, sexual assault, and stalking."²⁶ A shelter may want to reduce unwelcome or accidental exposure to, or by, persons of the opposite biological sex where either party may be in a state of undress—such as in changing rooms, shared living quarters, showers, or other shared intimate facilities—to address privacy concerns which must be considered and respected.27 Such a desire, which is critical in providing care for vulnerable populations, currently requires shelters to forego HUD assistance.

This need for privacy is especially strong among women who have "deeper psychological issues that prevent them from cohabitating with those of the opposite sex."²⁸ Homeless women have all too often been the subject of sexual abuse and assault. One study found that "92% of a racially diverse sample of homeless mothers had experienced severe physical and/or sexual violence at some point in their lives . . ." and another found that "13% of homeless women reported having been raped in the past 12 months and half of these were raped at least twice. . ."29 Further, between 22% and 55% of women are homeless because of intimate partner violence.³⁰ Given these

²⁷ United States v. Virginia, 518 U.S. 515, 550 n.19 (1996) ("Admitting women to [an all-male school] would undoubtedly require alterations necessary to afford members of each sex privacy from the other sex in living arrangements"); Fortner v. Thomas, 983 F.2d 1024, 1030 (11th Cir. 1993) ("[M]ost people have a special sense of privacy in their genitals, and involuntary exposure of them in the presence of people of the other sex may be especially demeaning or humiliating."); Fair Housing Council v. Roommate. Com, LLC, 666 F.3d 1216, 1221 (9th Cir. 2012) ("As roommates often share bathrooms and common areas, a girl may not want to walk around in her towel in front of a boy.").

²⁸NAHRO Comment Letter, available at: https:// www.regulations.gov/document?D=HUD-2015-0104-0083.

²⁹ https://vawnet.org/sites/default/files/materials/ files/2016-09/AR_SAHomelessness.pdf.

³⁰ U.S. Department of Health & Human Services, Administration for Children & Families, Family & Youth Services Bureau. "Domestic Violence and

¹⁸ See, e.g., Masterpiece Cakeshop, Ltd. v. Colo. Civil Rights Comm'n, 138 S. Ct. 1719, 1723 (2018) ("The case presents difficult questions as to the proper reconciliation of at least two principles. The first is the authority of a State and its governmental entities to protect the rights and dignity of gay persons who are, or wish to be, married but who face discrimination when they seek goods or services. The second is the right of all persons to exercise fundamental freedoms under the First Amendment, as applied to the States through the Fourteenth Amendment. The freedoms asserted here are both the freedom of speech and the free exercise of religion.").

²¹ The Downtown Soup Kitchen v. Municipality of Anchorage, No. 3:18-cv-00190-SLG, Dkt. No. 1, "Verified Complaint", available at: https:// adflegal.blob.core.windows.net/mainsite-new/docs/ default-source/documents/legal-documents/thedowntown-soup-kitchen-dba-downtown-hopecenter-v.-municipality-of-anchorage/hope-center-vanchorage-complaint.pdf?sfvrsn=9536cb21 4.

²⁶ NAHRO Comment Letter, available at:*https://www.regulations.gov/document?D=HUD-2015-0104-0083.*

jarring statistics, some homeless women would be expected to distrust and feel unsafe around biological men, even though they self-identify as women.

HUD does not believe it is beneficial to institute a national policy that may force homeless women to sleep alongside and interact with men in intimate settings—even though those women may have just been beaten, raped, and sexually assaulted by a man the day before. The 2016 Rule minimized the shelter's ability to protect the privacy interest of shelter seekers, not so that the shelter can better serve transgender individuals, but so that the shelter is forced to admit any individual who claims to be the gender the shelter serves.

While HUD is not aware of data suggesting that transgender individuals pose an inherent risk to biological women, there is anecdotal evidence that some women may fear that nontransgender, biological men may exploit the process of self-identification under the current rule in order to gain access to women's shelters. This could harm individuals in need of shelter by chilling their participation in HUD programs. For example, in Alaska, "women have told shelter officials that if biological men are allowed to spend the night alongside them, 'they would rather sleep in the woods,' even in extreme cold. . .with temperatures hovering around zero."³¹ HUD is also aware of a pending civil complaint in Fresno, California from nine homeless women against Naomi's House, a homeless shelter that receives HUD funding. These women allege that the shelter enabled sexual harassment because a biological male who selfidentified as a female entered a homeless shelter and showered with females. This individual would "repeatedly make lewd and sexually inappropriate comments to some of the Plaintiffs," "stare and leer at Plaintiffs while naked and make sexually harassing comments about their bodies," and show "sexual pictures and/or videos of [the individual] and mak[e] sexual advances on some of the pictures and/or videos of [the

individual] and mak[e] sexual advances on some of the Plaintiffs." ³²

The 2016 Rule attempted to address privacy and security through postadmission accommodations and procedures, but this has proven unworkable for too many shelters without alternative options to address practical and privacy concerns. Shelters operate in difficult conditions, often with troubled clientele, through overburdened and sometimes volunteer staff, and the current rule makes it impracticable for some shelters to, after admitting a biological male, adequately protect the privacy interests of their biological female clientele who do not want to shower, undress, and sleep in the same facilities as biological men. While HUD argued in 2016 that shelters could address privacy concerns through "schedules that provide equal access to bathing facilities, and modifications to facilities, such as the use of privacy screens and, where feasible, the installation of single occupant restrooms and bathing facilities," ³³ HUD believes that this is not an option for many shelters, whose budgets, staff, and space are already limited.

HUD recognizes that shelters must also take special care to address the mental health and safety needs of transgender individuals. HUD is aware that transgender individuals experience poverty, housing instability, mental health issues, domestic violence, and homelessness at high rates. Given the rates of violence and mistreatment that homeless transgender persons experience, HUD recognizes that shelter access for transgender persons is critical. Thus, the proposed rule requires that if a shelter denies access to a person based on a determination of sex, the shelter must utilize the CoC's centralized or coordinated assessment system to provide a transfer recommendation to an alternative shelter or accommodation.

Shelters may also choose to admit individuals on criteria other than biological sex. For example, under the proposed rule, a single-sex facility could continue to operate under the policy set forth in the 2016 Rule. Under that policy, an intake worker at a single-sex homelessness facility would ask an individual their gender identity, and if the person identified themselves with the gender served by the facility, they would be admitted. Under the proposed rule, a single-sex facility for women could have a policy that only admits biological women. A shelter would have the flexibility to implement this policy as they feel appropriate, provided that they only deny an individual seeking accommodation or access to the temporary, emergency shelters when they have a good faith belief that individual is not of the sex which the shelter's policy accommodates and they provide a transfer recommendation as required under the regulation. Denial of accommodation solely because of a person's gender identity that differs from biological sex is not permitted.

Shelters could also have policies that follow state or local law, such as perceived gender identity, that varies from the HUD definition of selfidentified gender identity. Other possible policies could be based on medical transition status, active hormone therapy or state recognized gender status. The key test for such policies is whether if another shelter adopted a "mirror" policy (that is, the same policy but directed at the other sex), any person not accommodated at one shelter would be accommodated at the other shelter.

In practice, where people seeking shelter are asked their sex at intake into the facility, and if they identify themselves as the sex that is served by the shelter, they are admitted unless the shelter has a good faith basis to doubt the consistency of the sex asserted with the sex served by the shelter, determined in accordance with its own policy. Where such doubt exists, the shelter could also have a list of possible sources of evidence the shelter seeker could provide such as a birth certificate, other identification, or medical records. This could occur at intake or subsequently, if the shelter resident is unable to verify their sex, the shelter would work through the centralized or coordinated assessment system to provide a transfer recommendation for another shelter.

This approach would better protect shelter clients as well. Under HUD's 2016 Rule, while privacy accommodations may sometimes be available for individuals who need additional privacy, "alternative accommodations can only be offered when an individual requests it, and under these proposed regulations, housing providers are likely only left with the option of moving the domestic violence victim resident. But some individuals may hesitate to raise their concerns, for fear of retaliation by the service provider or because they do not know whether privacy accommodation is an available option. HUD believes the easier approach would be to let shelters accommodate privacy concerns in a

Homelessness: Statistics (2016)." Published, June 24, 2016, accessed March 21, 2017. Available at: https://www.acf.hhs.gov/fysb/resource/ dvhomelessnessstats2016 (cited by http:// womensliberationfront.org/wp-content/uploads/ 2019/04/MAILED-Copy-of-Hands-Across-the-Aisle-Letter-to-HUD_dated-5-1-17.pdf).

³¹Rachel D'Oro, Faith-based shelter fights to keep out transgender women (January 11, 2019), available at:https://www.apnews.com/85494d367c2 d4a38b1749f76a89f49c3.

³² McGee v. Poverello House, No. 1:18–cv–00768– LJO–SAB, 2018 U.S. Dist. LEXIS 189174, at *3 (E.D. Cal. Nov. 5, 2018).

³³ 81 FR 64763, September 21, 2016.

manner that causes the least overall disruption to residents.

Finally, the 2016 Rule imposed regulatory burdens. The rule imposes several different types of regulatory burdens. It imposes a special document retention requirement applicable to determinations of "sex" that is burdensome and not supported either by statute or practice. This burden is inconsistent with Executive Orders directing agencies to "alleviate unnecessary regulatory burdens placed on the American people," ³⁴ and "manage the costs associated with the governmental imposition of private expenditures required to comply with Federal regulations."³⁵ Additionally, as discussed above in the fourth point, shelters may not have the resources to build individual privacy screens or single occupant restrooms and bathing facilities to address any privacy concerns that may arise.

These regulatory burdens could have a material impact on the availability of homelessness services. HUD's **Emergency Solutions Grants program** and other CPD programs provide a small share of the funding that is used for emergency shelters. For example, in fiscal year 2019, HUD's Emergency Solutions Grants program provided \$290 million in funding. In contrast, with nearly 300,000 emergency shelter beds and costs ranging from \$14 to \$61 per bed-night for individuals and more for families, overall spending for emergency shelter is several billion dollars per vear.

The lack of shelter capacity in many communities contributes to high numbers of people who experience unsheltered homelessness. Local governments and nonprofit organizations utilize any potential space to use as shelter, and many times, these shelters operate under severe financial constraints. Providing additional options for operating single-sex facilities as proposed by this rule may encourage more emergency shelters to participate in HUD's programs and prevent the loss of emergency shelter capacity. The additional funding could be used to upgrade facilities and services, improving the quality of assistance for people experiencing homelessness.

IV. Summary of Proposed Rule

This proposed rule would revise § 5.106(c)(1) to expressly allow a recipient, subrecipient, owner, operator,

manager, or provider to establish its own policies for determining whether to restrict access based on an individual's sex for the purposes of determining admissions and accommodation within a single-sex facility. Such a policy could align with, or borrow from, a state or local government's policy for determining an individual's sex,³⁶ but is not required to do so. The rule also provides in paragraph (c)(1) that such policies must be consistent with federal, state, and local law. Under paragraph (c)(2) a recipient, subrecipient, owner, operator, manager, or provider is permitted to take into account a wide variety of factors in issuing a policy, including privacy, safety, and similar concerns.

Proposed paragraph (c)(3) would restrict how a single-sex facility would apply the policy drafted under paragraph (c)(1) and require the singlesex facility to apply its policy uniformly and consistently. It would also provide that a recipient, subrecipient, owner, operator, manager, or provider may determine an individual's sex based on a good faith belief that an individual seeking access to the temporary, emergency shelters is not of the sex, as defined in the single-sex facility's policy, which the facility accommodates. HUD would consider this good faith beliefs sufficient to show that a decision maker was not discriminating for purposes of determining compliance based on an individual's actual or perceived gender identity in § 5.105(a)(2). HUD believes that reasonable considerations may include, but are not limited to a combination of factors such as height, the presence (but not the absence) of facial hair, the presence of an Adam's apple, and other physical characteristics which, when considered together, are indicative of a person's biological sex. A good faith determination could also be made if a person voluntarily selfidentifies as the biological sex that is opposite that served by the single sex facility if that is a part of its policy. In cases where a recipient, subrecipient, owner, operator, manager, or provider has a good faith belief that the individual is not of the biological sex served by the single-sex facility, the recipient, subrecipient, owner, operator, manager, or provider may request evidence of the individual's biological sex. Evidence requested must not be unduly intrusive of privacy, such as private physical anatomical evidence. Evidence requested could include government identification, but lack of

government identification alone cannot be the sole basis for denying admittance on the basis of sex.

Continuum of Care (CoC) is a regional or local planning group that coordinates homelessness services and is generally composed of representatives from governments and organizations that focus on fighting homelessness. CoCs are responsible for ensuring that people experiencing homelessness receive assistance in a coordinated and timely fashion. Specifically, CoCs are required to create and implement a plan that coordinates implementation of housing and service system that meets the needs of people experiencing homelessness (§ 578.7(c)(1)), and the requirement for CoCs, in consultation with a local recipient of Emergency Solutions Grants funds to operate a coordinated entry system that provides an initial, comprehensive assessment of needs for housing and services (§ 578.7(a)(8)). To help promote these objectives, HUD provides in paragraph (d)(4) of this proposed rule that if a single-sex facility denies access to a person under this rule based on a good faith belief that a person seeking access to the single-sex facility is not of the biological sex which the shelter accommodates, a shelter must use the coordinated entry system to provide a transfer recommendation to an alternative facility. In addition, the rule more broadly provides that if a person objects to the provider's policy for determining sex because of the person's sincerely held beliefs, then the shelter must also provide a transfer recommendation to an alternative shelter.

Finally, HUD proposes to remove paragraphs (b)(1) through (4), inclusively, which currently enumerates the applications of the antidiscrimination provision, in favor of a streamlined reference to § 5.105(a)(2). Section 105(a)(2) entitles equal access to HUD-assisted housing by prohibiting determinations for housing eligibility from being based on actual or perceived sexual orientation, gender identity, or marital status.

The proposed rule would also eliminate the previously discussed burdensome special document retention requirement in the current rule applicable to determinations of "sex." This proposed rule does not prohibit any individual from voluntarily selfidentifying sexual orientation or gender identity, as it does not prohibit a shelter, under its own policy, from recognizing such self-identification.

Other than these specified changes, the current regulations would remain in effect. HUD believes that a combination of strong anti-discrimination protections

³⁴ Executive Order 13777, "Enforcing the Regulatory Reform Agenda," 82 FR 12285, March 1, 2017.

³⁵ Executive Order 13771, "Reducing Regulation and Controlling Regulatory Costs," 82 FR 9339, Feb. 3, 2017.

³⁶ See, *e.g.*, Iowa state law for determining sex designation change. Iowa Code Ann. 144.23.

and affording grantees a large measure of discretion in an area with divergent, deeply held and substantially supported views offers the broadest workable protection for individuals, including transgender individuals.

This proposed rule would also amend § 576.400(e)(3)(iii) to add language allowing for exceptions as authorized under § 5.106 to written standards for HUD's Emergency Solutions Grant Program.

Request for Comments

1. HUD is maintaining the nondiscrimination protections from its 2012 rule, even though they lack an explicit statutory authorization, because HUD is not aware of any relevant party that has raised any material concerns about the 2012 rule. HUD believes all federally supported housing opportunities should be provided to all in a nondiscriminatory manner, including for sexual orientation and gender identity. HUD specifically seeks comments on whether HUD should maintain the anti-discrimination protections?

2. HUD requests comments on what are good faith considerations that are indicative of a person's biological sex. Should HUD define what constitutes a good faith belief for determining biological sex and what type of evidence would be helpful for determining an individual's biological sex? How, if at all, should government IDs be considered?

3. CoCs are responsible for creating and implementing a plan that coordinates the housing and service system that meets the needs of people experiencing homelessness (including unaccompanied youth) and families and includes, shelter, housing, and supportive services (§ 578.7(c)(1)). HUD is proposing that for people who are denied access to shelter because of a policy regarding admission or placement in single-sex facilities, the shelter must provide a transfer recommendation for individuals to the Coordinated Entry provider for the Continuum of Care. HUD is also seeking comment on what requirements, if any, HUD should include in the final rule to ensure that shelter policies are coordinated and implemented in a way that allows all persons experiencing homelessness in the geographic area (including persons with disabilities) to be served timely and in a nondiscriminatory manner? Is the requirement of providing a transfer recommendation unduly burdensome or does it otherwise pose operational challenges?

V. Findings and Certifications

Regulatory Review—Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Under Executive Order 12866 (Regulatory Planning and Review), a determination must be made whether a regulatory action is significant and, therefore, subject to review by the Office of Management and Budget (OMB) in accordance with the requirements of the order.

The proposed rule has been determined to be a "significant regulatory action," as defined in section 3(f) of the Order, but not economically significant under section 3(f)(1) of the Order. The docket file is available for public inspection in the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Room 10276, Washington, DC 20410-0500. Due to security measures at the HUD Headquarters building, please schedule an appointment to review the docket file by calling the Regulations Division at 202-402-3055 (this is not a toll-free number). Individuals who are deaf or hard of hearing and individuals with speech impairments may access this number via TTY by calling the Federal Relay Service at 800-877-8339 (this is a toll-free number).

Executive Order 13771

Executive Order 13771, entitled "Reducing Regulation and Controlling Regulatory Costs," was issued on January 30, 2017. Section 2(a) of Executive Order 13771 requires an Agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the Agency publicly proposes for notice and comment or otherwise promulgates a new regulation. In furtherance of this requirement, section 2(c) of Executive Order 13771 requires that the 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 two prior regulations. This proposed rule is expected to be a deregulatory

action under Executive Order 13771 by providing flexibility for grantees in determining their policies.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4; approved March 22, 1995) (UMRA) establishes requirements for Federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments, and on the private sector. This proposed rule does not impose any Federal mandates on any state, local, or tribal government, or on the private sector, within the meaning of the UMRA.

Environmental Review

This proposed rule sets forth nondiscrimination standards. Accordingly, under 24 CFR 50.19(c)(3), this proposed rule is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The number of entities that would be affected by this rule is limited to entities who can legally operate single-sex facilities and would change or establish policy as a result of the accommodation needs addressed by this rule. HUD does not have the exact number of entities that would be affected. However, as an example, approximately out of the 1,900 emergency shelters are funded by HUD programs. Out of this 1,900, HUD does not know how many of those would issue a new policy. Nor does HUD know how many of those are small entities. HUD specifically requests from the public any information about the number of small entities that might be impacted.

Furthermore, HUD anticipates that entities who develop a policy as a result of this rule will generally face only a small burden in determining and establishing an organizational policy. Accordingly, for the foregoing reasons, the undersigned certifies that this rule will not have a significant economic impact on a substantial number of small entities. Notwithstanding HUD's determination that this proposed rule would not have a significant effect on a substantial number of small entities, HUD specifically invites comments on whether it will not have a significant effect and regarding any less burdensome alternatives to this rule that will meet HUD's objectives.

Executive Order 13132, Federalism

Executive Order 13132 (entitled "Federalism") prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial direct compliance costs on state and local governments or is not required by statute, or the rule preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. This rule would not have federalism implications and would not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the Executive Order.

List of Subjects

24 CFR Part 5

Administrative practice and procedure, Aged, Claims, Drug abuse, Drug traffic control, Grant programshousing and community development, Grant programs—Indians, Individuals with disabilities, Loan programshousing and community development, Low and moderate income housing, Mortgage insurance, Pets, Public housing, Rent subsidies, Reporting and recordkeeping requirements.

24 CFR Part 576

Community facilities, Grant programshousing and community development, Grant programs-social programs, Homeless, Reporting and recordkeeping requirements.

Accordingly, for the reasons stated above, HUD proposes to amend 24 CFR parts 5 and 576 as follows:

PART 5—GENERAL HUD PROGRAM **REQUIREMENTS: WAIVERS**

■ 1. The authority citation for part 5 continues to read as follows:

Authority: 12 U.S.C. 1701x; 42 U.S.C. 1437a, 1437c, 1437d, 1437f, 1437n, 3535(d); Sec. 327, Pub. L. 109-115, 119 Stat. 2936; Sec. 607, Pub. L. 109-162, 119 Stat. 3051 (42 U.S.C. 14043e et seq.); E.O. 13279, 67 FR 77141, 3 CFR, 2002 Comp., p. 258; and E.O. 13559, 75 FR 71319, 3 CFR, 2010 Comp., p. 273.

■ 2. In § 5.100, revise the first sentence of the definition of "Gender identity" to read as follows:

§5.100 Definitions.

* * * *

Gender identity means actual or perceived gender-related characteristics.

* * * ■ 3. In § 5.106, revise the section heading and paragraphs (b) and (c), and remove paragraph (d) to read as follows:

§5.106 Access in community planning and development programs. *

*

*

(b) Access. The admissions, occupancy, and operating policies and procedures of recipients, subrecipients, owners, operators, managers, and providers identified in paragraph (a) of this section shall be established or amended, as necessary, and administered in a nondiscriminatory manner to ensure that eligibility determinations are made, and assisted housing is made available in CPD programs as required by § 5.105(a)(2).

(č) Admission and accommodation in temporary, emergency shelters and other buildings and facilities with shared sleeping quarters or shared bathing facilities—(1) Admission and accommodation policies. Recipients, subrecipients, owners, operators, managers, or providers of temporary, emergency shelters or other buildings and facilities with physical limitations or configurations may make admission and accommodation decisions based on its own policy for determining sex if the policy is consistent with paragraphs (c)(2) through (4) of this section. Any such policy must be consistent with federal, state, and local law.

(2) Privacy and safety considerations. The policy of a recipient, subrecipient, owner, operator, manager, or provider established pursuant to paragraph (c)(1)of this section may consider privacy, safety, and any other relevant factors.

(3) Application of the policy. A recipient, subrecipient, owner, operator, manager, or provider must apply any policy established pursuant to paragraph (c)(1) of this section in a uniform and consistent manner. A recipient, subrecipient, owner, operator, manager, or provider may deny admission or accommodation in temporary, emergency shelters and other buildings and facilities with physical limitations or configurations that require and are permitted to have shared sleeping quarters or shared bathing facilities based on a good faith belief that an individual seeking accommodation or access to the temporary, emergency shelters is not of the sex which the shelter's policy accommodates. If a temporary emergency shelter has a good faith belief that a person seeking access to the shelter is not of the sex which the

shelter accommodates, the shelter may request information or documentary evidence of the person's sex, except that the shelter may not request evidence which is unduly intrusive of privacy.

(4) Transfer recommendation. If a temporary, emergency shelter denies admission or accommodations based on a good faith belief that a person seeking access to the shelter is not of the sex which the shelter accommodates as determined under its policy, the shelter must use the centralized or coordinated assessment system, as defined in § 578.3 of this title, to provide a transfer recommendation to an alternative shelter. If a person states to the temporary, emergency shelter that the provider's policy for determining sex is inconsistent with the person's sincerely held beliefs, including privacy or safety concerns, then the shelter must use the centralized or coordinated assessment system, as defined in § 578.3 of this title, to provide a transfer recommendation to an alternative shelter.

PART 576—EMERGENCY SOLUTIONS **GRANTS PROGRAM**

■ 4. The authority for 24 CFR part 576 continues to read as follows:

Authority: 12 U.S.C. 1701x, 1701 x-1; 42 U.S.C. 11371 et seq., 42 U.S.C. 3535(d).

§576.400 [Amended]

■ 5. In § 576.400, add the parenthetical "(these policies must allow for the exceptions as authorized under the Equal Access Rule, 24 CFR 5.106)" at the end of paragraph (e)(3)(iii).

Dated: July 2, 2020.

Benjamin S. Carson, Sr.,

Secretary.

[FR Doc. 2020-14718 Filed 7-23-20; 8:45 am] BILLING CODE 4210-67-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 2 and 25

[IB Docket Nos. 17–95 and 18–315; FCC 20-66; FRS 16884]

Earth Stations in Motion

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Commission seeks to further develop the record regarding potential interference from out-of-band emissions of ESIMs in the 28.35-28.6 GHz band into the adjacent 27.5-28.35 GHz band used by Upper Microwave Flexible Use