UNITED STATES OF AMERICA
BEFORE THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERVICES
OFFICE OF THE SECRETARY

NONDISCRIMINATION IN HEALTH PROGRAMS AND ACTIVITIES	))	Docket ID HHS–OS–2022–0012 RIN 0945-AA17

COMMENTS OF WHITMAN-WALKER HEALTH AND WHITMAN-WALKER INSTITUTE IN STRONG SUPPORT OF THE PROPOSED RULE, WITH REQUESTED MODIFICATIONS

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I. Introduction and Summary

Pursuant to HHS' Notice of Proposed Rulemaking, 87 FR 47,824 (Aug. 4, 2022) (hereafter, NPRM or Proposed Rule), Whitman-Walker Health and Whitman-Walker Institute (collectively Whitman-Walker) submit these comments on the proposed rule under Section 1557 of the Affordable Care Act, 42 U.S.C. § 18116, and related modifications to a number of nondiscrimination regulations applicable to critical programs administered by CMS.

Whitman-Walker strongly supports the Proposed Rule, and we submit these comments to document the need for the rule's far-reaching, well-founded provisions to address continuing discrimination in health care and health insurance, and to further HHS' mission of advancing health equity. We fully support the Proposed Rule's many far-reaching measures that will provide safeguards against racial and ethnic discrimination in health care and health insurance; protect the rights of patients with Limited English Proficiency; and ensure access to nondiscriminatory care for elders and persons living with disabilities. We focus these comments on issues pertaining to the sexual and gender diverse communities at the heart of our mission: lesbian, gay, bisexual, transgender, queer, and intersex (LGBTQI+) persons.

In addition to offering support for the Proposed Rule's many advances for protection of these communities, we offer suggested additions and modifications to several provisions in order to strengthen the Proposed Rule's impact. Specifically, we propose

- Modification of § 92.101(a)(1) to more clearly recognize intersectional discrimination (Part IV)
- Addition of "transgender status" to the enumerated categories of prohibited sex discrimination, and modification of the required Notice of Discrimination to mirror the more precise and inclusive language of § 92.101(a)(2) (Part V)
- Addition of language in § 92.206(c) to emphasize that the final rule, and Section 1557, preempt state and local laws that dictate or endorse discrimination against LGBTQI+

people; and addition of "transgender status" to the enumerated categories of prohibited sex discrimination in 206(b) (Part VI)

- Addition of language in § 92.207**,** or the preamble of the final rule, to provide additional safeguards against discriminatory insurance practices: the use of sex/gender edits to deny care needed by many transgender people, and provider networks that restrict access to competent health care for non-cisgender persons and persons living with disabilities. Also, addition of "transgender status" to the enumerated categories of prohibited sex discrimination in 207(b)(3) and clarification of the language in 207(b)(4) (Part VII)

- Elaboration of the provisions for addressing claims of covered persons and entities for religious- or conscience-based exemptions from nondiscrimination mandates, to increase transparency and ensure fair and full investigations (Part IX)

- Inclusion of data collection requirements in the final rule itself, including collection of data on sexual orientation, gender identity, and sex characteristics (Part XI)

- Further amendment of nondiscrimination regulations applicable to CMS-administered programs to expressly proscribe discrimination based on sex characteristics and sex stereotypes (Part XII)

- Addition of language, comparable to language in the 2016 rule and on HHS's website, clarifying the application of the final rule to research projects and activities (Part XIII)

II. Expertise and Interest of Whitman-Walker

Whitman-Walker Health is a Federally Qualified Health Center serving the greater Washington, DC metropolitan area with a wide range of health-related services, with special expertise in LGBTQ care and HIV treatment and prevention. We seek to empower all persons to live healthy, love openly, and achieve equality and inclusion. During the 12 months from July 2021 through June 2022, Whitman-Walker provided health care services to 16,668 unique individuals living in the District of Columbia, Maryland, Virginia, and neighboring states. Our patient population is very diverse racially, ethnically, and with regard to income. More than 65% of patients in the July 2021 – June 2022 period who identified their sexual orientation self-identified as lesbian, gay, bisexual, or otherwise non-heterosexual. With regard to gender identity, 16% of our patients self-identified as transgender, nonbinary, gender queer, or otherwise

non-cisgender. Twenty-two percent of our patients – more than 3,600 individuals – were living with HIV. Substantial numbers of our patients have Limited English Proficiency – during the recent 12-month period in question, 9.5% of them were primarily Spanish-speaking, and the primary language of a significant number was Amharic or American Sign Language.

Whitman-Walker's Legal Services Department is the nation's oldest medical-legal partnership, and over more than three decades we have become a national leader in HIV law; gender identity and sexual orientation law; medical privacy law; and Medicaid, Medicare, and other public benefits health law. Our Public Benefits and Insurance Navigation Team, under the direction of senior Legal Services managers, has played a key role in implementation of the Affordable Care Act in the District of Columbia. In the 12 months from September 1, 2021, through August 31, 2022, Whitman-Walker attorneys and Public Benefits and Insurance Navigators served 2,009 clients in new cases (not including continuing cases opened prior to September 1). Of the clients who identified a sexual orientation, 60% identified as lesbian, gay, same-gender-loving, bisexual, or otherwise non-heterosexual. Of the clients who identified their gender identity, 25% identified as transgender, nonbinary, genderqueer, or otherwise non-cisgender. Forty-eight percent were living with HIV, and 25% relied on a language other than English to communicate.

The Whitman-Walker Institute combines clinical and public health research, public policy advocacy, and professional and community education, with the goal of expanding the body of knowledge and science needed to advance health and wellness, particularly for sexual and gender diverse communities. Our Institute is particularly active in researching and promoting PrEP and other HIV prevention strategies; providing culturally competent training for

health care professionals; ensuring access to gender-affirming care; and identifying and addressing racial, sexual, and gender health disparities.

As health care providers, health researchers, public policy advocates, and health educators, Whitman-Walker Health and the Whitman-Walker Institute are strongly committed to the nondiscrimination and health equity goals of this Proposed Rule. Whitman-Walker's lawyers and Public Benefits and Insurance Navigators, medical and behavioral health providers, transgender care advocates and navigators, and executive leadership have been involved in Section 1557 rulemaking proceedings, directly or indirectly, since the first HHS Request for Information in 2013. Whitman-Walker Health and our Chief Health Officer and Senior Director of Behavioral Health joined as plaintiffs in litigation challenging the 2020 rule.[1]

III. There is a Compelling Need for This New Rule to Address Continuing Discrimination and Health Injustices Experienced by Sexual and Gender Diverse Communities

Whitman-Walker fully concurs with HHS' conclusion that the current Section 1557 rule, issued by the previous Administration in 2020 and subject to a number of pending lawsuits and several partial preliminary injunctions, is legally defective, provides inadequate guidance to the industry and health care and health insurance patients and customers, and is bad public policy. Moreover, as elaborated below, in specific respects the Proposed Rule improves upon the 2016 rule issued under Section 1557: the new Proposed Rule expressly recognizes that sex discrimination encompasses discrimination based on sexual orientation and sex characteristics including intersex traits; it recognizes that Medicare Part B is federal financial assistance for purposes of federal antidiscrimination law; it includes protections against discrimination based

[1] *Whitman-Walker Clinic, Inc., et al. v. United States Dept. of Health and Human Servs.,* 485 F.Supp.3d 1 (D.D.C. 2020).

on family status, discriminatory use of algorithms in clinical decision-making, and discrimination in telehealth services; and it proposes a procedure for investigating and determining the merits of claims by covered entities for exemptions under federal conscience or religious freedom laws.

As noted in the preamble to the NPRM (87 FR at 47,833-35), LGBTQI+ people face both health disparities and barriers to health care. The National Academies of Sciences, Engineering, and Medicine[2] report that discrimination against sexual- and gender-diverse persons in obtaining health insurance, and in the terms of insurance coverage, has long been a barrier to accessing health care, which has contributed to significant health inequalities. LGBTQI+ people report poorer health overall and are at increased risk of numerous health conditions such as sexually transmitted infections, HIV, obesity, substance abuse, and mental health conditions including suicidality. LGBTQ people also are more likely than heterosexual and cisgender individuals to acquire a disability at a young age.

HHS's Healthy People 2020 initiative recognized that "LGBT individuals face health disparities linked to societal stigma, discrimination, and denial of their civil and human rights."[3] This surfaces in a wide variety of contexts, including physical and mental health care services. In a study published in *Health Affairs*, researchers examined the intersection of gender identity, sexual orientation, race, and economic factors in health care access. They concluded that discrimination, as well as insensitivity or disrespect on the part of health care providers, were

[2] Nat'l Acads. Of Sci., Eng'g, & Med., UNDERSTANDING THE WELLBEING OF LGBTQI+ POPULATIONS (2020), https://www.nap.edu/catalog/25877/understanding-the-well-being-of-lgbtqi-populations.

[3] U.S. Dept. of Health & Human Servs., Healthypeople.gov, *Lesbian, Gay, Bisexual, and Transgender Health,* https://wayback.archive-it.org/5774/20220413203148/https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health (last visited Oct. 1, 2022).

key barriers to health care access.[4] Moreover, a recent systematic literature review conducted by Cornell University "found robust evidence that discrimination on the basis of sexual orientation or gender identity is associated with harms to the health of LGBT people."[5]

These problems persist in 2022. Data in a new report from the Center for American Progress "reveal that LGBTQI+ communities encounter discrimination and other challenges when interacting with health care providers and health insurers, underscoring the importance of strengthening nondiscrimination protections through Section 1557 of the Affordable Care Act."[6] Key findings from the report include:

- 23 percent of LGBTQI+ respondents, including 27 percent of LGBTQI+ respondents of color, reported that, in the past year, they postponed or avoided getting needed medical care when sick or injured due to disrespect or discrimination from doctors or other health care providers;
- Overall, 15 percent of LGBQ respondents, including 23 percent of LGBQ respondents of color, reported experiencing some form of care refusal by a doctor or other health care provider in the year prior;
- Overall, 32 percent of transgender or nonbinary respondents, including 46 percent of transgender or nonbinary respondents of color, reported that they experienced at least one kind of care refusal by a health care provider in the past year;
- 55 percent of intersex respondents reported that, in the past year, a health care provider refused to see them because of their sex characteristics or intersex variation;

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[4] Ning Hsieh & Matt Ruther, *Despite Increased Insurance Coverage, Nonwhite Sexual Minorities Still Experience Disparities in Access to Care,* 36 Health Affairs No. 10 (Oct. 2017), https://doi.org/10.1377/hlthaff.2017.0455.

[5] Cornell University Public Policy Research Portal, *What Does the Scholarly Research Say About the Effects of Discrimination on the Health of LGBT People?* (2019), https://whatweknow.inequality.cornell.edu/topics/lgbt-equality/what-does-scholarly-research-say-about-the-effects-of-discrimination-on-the-health-of-lgbt-people/.

[6] Caroline Medina & Lindsay Mahowald, Center for Amer. Prog., *Advancing Health Care Nondiscrimination Protections for LGBTQI+ Communities* (Sept. 8, 2022), https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi-communities/.

- Overall, 30 percent of transgender or nonbinary respondents, including 47 percent of transgender or nonbinary respondents of color, reported experiencing one form of denial by a health insurance company in the past year;

- 28 percent of transgender or nonbinary respondents, including 29 percent of transgender or nonbinary respondents of color, reported that a health insurance company denied them coverage for gender-affirming hormone therapy in the year prior; and

- 22 percent of transgender or nonbinary respondents, including 30 percent of transgender or nonbinary respondents of color, reported that a health insurance company denied them coverage for a gender-affirming surgery in the year prior.

The recent experiences of Whitman-Walker's patients and legal clients underscore the persistence of discrimination and its health-harming effects. We offer examples below.

Discrimination in health care

- A transgender and non-binary patient of Whitman-Walker Health has had repeated problems at two local hospitals:

    - In 2022, they presented to the Breast Imaging Center for follow-up on a detected lump and recent breast cancer diagnosis. At that imaging visit, the patient checked in at the front desk and told staff what their name and pronouns are, announcing that they are transgender. The front desk person refused to use their name or pronouns and instead demanded to see their ID; upon looking on their ID, staff said, "see, that's not your name" and continued to refuse to use the patient's affirmed name or pronouns.

    - In 2021, the individual was attempting to schedule at the same hospital an MRI that accommodated their experiences with trauma, which required several phone conversations. They were mis-gendered by hospital staff in every phone call during the process, despite repeatedly informing the hospital of their gender identity, chosen name, and pronouns.

    - In 2021, the same individual had an outpatient endoscopy procedure at a different hospital. A staff person misgendered them in a face-to-face encounter, and when the patient corrected them, the staff person and others continued to misgender the patient, and talked derisively about the patient behind the curtain while the patient was waiting for, and experiencing, the procedure.

- A transgender woman patient of Whitman-Walker Health underwent a vaginoplasty at a local hospital. She had a good experience with the surgeon, but experienced problems with other staff. She was repeatedly misgendered by staff throughout her stay. Just

minutes before the surgery in the operating room, the head nurse on the surgical team misgendered her before she lost consciousness, which was quite distressing.

During her recovery after the surgery – she remained at the hospital for several days – she was neglected by meals and cleaning staff compared to other patients. (Whitman-Walker's legal staff were told by the hospital that the patient was kept on the Orthopedic Wing because of the availability of more private rooms there, but that the staff in that wing were not as well trained on "LGBTQ sensitivity" as other hospital staff.)

The patient was seen by a large number of rotating medical students and residents, and many of them seemed to view her as a curiosity rather than a "normal" person. In one experience when she was dilated, the dilation was initiated without warning and, she felt, somewhat aggressively. Her mother reported that she heard nurses gossiping about the patient being dilated.

After her discharge, she developed a fever, shortness of breath, and acute pain and swelling in her vaginal area. She returned to the hospital's ER, was not seen for 19 hours, and then was readmitted for observation. She was initially told that she had a bacterial infection that was not a major concern, but after vigorous advocacy on her own behalf, the doctors diagnosed an abscess that needed to be drained.

Shortly after this feedback was reported to hospital executives, the hospital announced that no additional gender-affirming genital surgeries would be performed there due to "staffing and operational challenges."

- A transgender woman patient of Whitman-Walker Health went to a different local hospital for a bilateral bunionectomy (a procedure to remove a bunion and move the toes back into the correct position). Despite conversations with hospital staff, including a one-on-one conversation with the surgeon, about her transgender identity, name, and correct pronouns, she was repeatedly misgendered during her stay and encountered hostility from staff. After the procedure, she received virtually no follow-up care. She was discharged with pain medication but no antibiotics. Her wounds were not stitched, merely bandaged, requiring her to care for her open wounds at home herself. She received no referral to physical therapy. It seemed to her that the surgeon had simply shaved down her bunions but not re-set her toes. When she called the hospital, attempting to reach the surgeon or someone else to get information about follow-up care and other support, she was told the doctor was busy, and she never received any follow-up calls. She did return for one follow-up appointment with the surgeon, but when she talked about her pain and expressed her concerns, the doctor became angry and abusive, shouting at her, "What do you want me to do about it?" She was traumatized by the experience and did not return. The patient's foot problems and mobility challenges have not been effectively treated.

- A gay man was hospitalized locally for a Monkeypox infection. During his week-long stay at the hospital, his room was never cleaned, and the bedsheets were never changed.

He was neglected by staff and consistently treated in an unfriendly manner. He had prolonged high fever, and his throat and mouth were swollen and very painful. His pleas to the medical providers and staff that he could not eat, or even swallow, were openly not believed, until he demonstrated for them by unsuccessfully attempting to swallow and having food and liquid leak from his mouth in their presence, which was humiliating. When he was discharged, no one asked whether he had a ride or means of transportation, or offered to contact someone on his behalf; he was simply ignored and left to himself. He had to arrange his own transportation, still feeling weak, and finally took a rideshare service to his home. It would seem that the fact that the patient was a gay man with Monkeypox may have triggered responses at the hospital very similar to those experienced by AIDS patients in the very early days of that epidemic.

- Transgender patients are frequently misgendered and/or referred to by an incorrect name (an insult commonly known as "dead-naming"), which at a minimum is distressing to the patient and undermines trust and necessary communication. Our providers conclude that this is often intentional and likely due to factors such as provider bias or poorly trained/uncomfortable staff. Our providers also report that this inaccurate recognition of a patient's gender identity and/or sex assigned at birth can be dangerous: medical records with incorrect information in these critical areas can miss important alerts for screenings.

- Whitman-Walker Health has a number of transgender patients with Limited English Proficiency – mostly Spanish-speaking individuals. Many of them encounter repeated incidents of discrimination – because of their transgender status, their Spanish language, their ethnicity, their assumed immigration status, or for all of these reasons.

- Our LEP patients face many language-based barriers to receiving the care they need. One serious problem is faced by many LEP patients seeking to fill prescriptions at pharmacies. When patients cannot communicate in English, pharmacy staff often do not use the available language line even though they are required to do so. Patients are often told, or given to understand, that the medications they need are "not here" even though the prescriptions have been called in. As a result, these patients do not get the medications they need for diabetes, hypertension, and other conditions. If our providers learn of the problem, they can intervene promptly, but too often the patient may not tell the provider until the next regular appointment, which may be 3 months later – which means there may be a delay of 3 months or longer in the patient's medication.

- There is also a significant problem with language access when our LEP patients are referred to outside clinics and specialists. In particular, many low-income patients need financial assistance, which requires extensive paperwork, and hospitals and non-Whitman-Walker clinics often do not provide adequate assistance to LEP patients with this. As a consequence, patients do not get the access they need to critical care – for instance, uninsured patients with diabetes too often cannot get ophthalmology screenings or surgery. In addition, cisgender and transgender LEP patients too often miss appointments because they cannot get to the right building or office because of language barriers and lack of adequate assistance.

Discrimination in health insurance coverage for gender-affirming care

Whitman-Walker's lawyers, transgender care navigators, and providers spend substantial time and effort on appealing denials of gender-affirming care procedures by private and public health plans. These denials are due to facial exclusions of certain procedures in some plans; or, even in the absence of any such plan language, due to assertions that a specific procedure for a specific client is "cosmetic" or not medically necessary, despite ample evidence to the contrary. Several recent cases include:

- A transgender woman developed a two-part breast augmentation plan with a local surgeon. The first phase was completed and was covered by the patient's Medigap plan, but the second phase was denied as "cosmetic" the day before the surgery was scheduled, resulting in cancellation of the surgery.

- A transgender woman needing facial feminization surgery sought prior authorization, as required by her employer's health plan, but prior authorization was denied. Our attorneys believe, although the employer has not confirmed, that the plan excludes coverage of such procedures for transgender people.

- A transgender woman obtained coverage of her vaginoplasty by her private insurance plan, but the breast surgery she needs is on the plan's list of excluded procedures.

- Another transgender woman received a vaginoplasty that was covered by her private insurance plan. However, the plan has denied coverage of the facial surgery that she needs – even though the surgery is needed to correct for a "botched" facial operation that the patient received in India.

IV. The General Prohibition of Discrimination in § 92.101(a)(1) Should Be Modified to More Clearly Recognize Intersectional Discrimination

The NPRM recognizes the existence and harms of intersectional discrimination, meaning discrimination faced by persons with multiple stigmatized or marginalized identities, on the basis of those multiple identities (87 FR at 47, 831, 47,837 and 47,847). For instance, as noted in the previous section of these Comments, Whitman-Walker's LEP transgender patients have frequently experienced discrimination both because of their lack of English proficiency (and, too often, because of a health care provider's or staff person's hostility towards Spanish speakers)

and also their transgender status. It would strengthen the rule to include more explicit references to intersectional discrimination within the regulatory text. Therefore, we propose the following change to § 92.101(a)(1):

> Except as provided in Title I of the ACA, an individual must not, on the basis of race, color, national origin, sex, age, or disability, **or any combination; thereof,** be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any health program or activity operated by a covered entity.

This language should also be added to §§ 92.207(a), (b)(1), and (b)(2).

V. The Proposed Rule's Expansive Interpretation of Sex Discrimination in § 92.101(a)(2) is Legally Sound and Essential to Advance Health Equity, With One Addition to Strengthen Protections for Transgender People

The interpretation of sex discrimination in proposed § 92.101(a)(2),

> Discrimination on the basis of sex includes, but is not limited to, discrimination on the basis of sex stereotypes; sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; and gender identity[,]

is amply supported by Supreme Court and other judicial precedent, as the NPRM elaborates (87 FR at 47,829-30 and 47,858). We applaud HHS for articulating a clear and expansive explanation of discrimination on the basis of sex. Supreme Court case law, including *Price Waterhouse v. Hopkins* and *Bostock v. Clayton County*, makes clear that federal sex discrimination law includes sex stereotypes, sexual orientation, and gender identity, including transgender status. It is essential that this rule track those decisions to provide assurance to participants, beneficiaries, and enrollees and notice to covered entities that these bases are unequivocally included. Whitman-Walker also strongly supports the explicit inclusion of "sex characteristics, including intersex traits" as a protected category. As HHS recognizes, intersex discrimination as a form of sex discrimination follows from the logic of *Bostock,* because such discrimination is inherently sex-based (87 FR at 47,858), and persons with intersex traits

experience systemic, widespread stigma and discrimination with serious health consequences (87 FR at 47,834).

We suggest, however, that the language in section 92.101(a)(2) be amended to explicitly include transgender status. While the terms "gender identity" and "transgender status" are often used interchangeably, there have been instances in which those seeking to permit discrimination against transgender people have justified it by pressing distinctions between the two concepts.[7] It is therefore preferable to enumerate both in the regulatory text.

We suggest, therefore, that this provision be revised as follows:

> Discrimination on the basis of sex includes, but is not limited to, discrimination on the basis of sex stereotypes; sex characteristics, including intersex traits; pregnancy or related condition:**,** sexual orientation; **transgender status;** and gender identity.

In addition, we note that the description in § 92.101(a)(2) is somewhat different from the description in the Notice of Nondiscrimination in § 92.10, which requires notice that the covered entity "does not discriminate on the basis of … sex (including pregnancy, sexual orientation, gender identity, and sex characteristics)." To avoid any possible misunderstanding, the more expansive definition of sex discrimination in § 92.101(a)(2), amended to include transgender status as well as gender identity, should be used in § 92.10.

VI. The Proposed Rule's Elaboration of Sex Discrimination in the Provision of Health Care in § 92.206 is a Substantial Advance, With Modifications to Clarify the Rule's Reach

Whitman-Walker fully supports the antidiscrimination standards, and detailed elaboration of examples of sexual orientation, gender identity, and intersex discrimination in health care, in proposed § 92.206 and in the NPRM preamble (87 FR at 47,865-68). In light of the many

[7] *See, e.g., Making Admission or Placement Determinations Based on Sex in Facilities Under Community Planning and Development Housing Programs: Proposed Rule,* 85 FR 44,811 (2020), which notes that state and local laws and policies regarding access to homeless shelter facilities and services use different criteria and definitions for which non-cisgender people can be admitted or excluded.

different manifestations of discriminatory behavior that sexual and gender diverse patients have experienced, the examples in § 92.206, while not identifying every possible form of discrimination, provide helpful guidance to providers and health care administrators and managers as well as to patient advocates. However, "transgender status" should be added to 206(b)(1), (2) and (4), consistent with the addition of "transgender status" to the protected categories in § 92.101(a)(2).

Section 92.206(c) importantly clarifies that, while providers may exercise clinical judgment when determining if a particular service is appropriate for an individual patient, they may not refuse gender-affirming care based on a personal belief that such care is never clinically appropriate. We suggest strengthening the language pertaining to providers complying with a state or local law as a justification for denying gender-affirming care to state unequivocally that Section 1557, as federal law, preempts any such state or local law restricting access to this care.

VII. The Proposed Rule's Elaboration of Sex Discrimination in Health Insurance in § 92.207 Also Constitutes a Major Advance; the Final Rule Should Add Additional Safeguards Against Health Insurance Plan Discrimination

Whitman-Walker fully supports the detailed elaboration of examples of gender identity discrimination in health insurance coverage in proposed Section 92.207 and in the NPRM preamble (87 FR at 47,868-72 and 47,873-74). As noted in the recent consensus report of the National Academies of Sciences, Engineering, and Medicine: [8]

> Gender-affirming care for transgender people, including non-binary and other gender diverse people, is an essential and medically necessary intervention to improve health and well-being. . . . Insurance coverage of gender-affirming services and procedures by public and private payers, according to the most updated expert standards in the field and without inappropriate age or other restrictions, is necessary to facilitate access to these services and to avoid discrimination on the basis of sex and gender identity.

[8] UNDERSTANDING THE WELLBEING OF LGBTQI+ POPULATIONS, *supra* note *2,* at 380.

Every major U.S medical and mental health organization, including the American Medical Association,[9] American Academy of Pediatrics,[10] Federation of Pediatric Organizations,[11] and American Psychological Association,[12] supports access to gender-affirming support and care for transgender adults and young people. Unfortunately, discrimination against sexual- and gender-diverse persons in obtaining health insurance, and in the terms of insurance coverage, is longstanding and has long been a barrier to accessing health care, which in turn has contributed to deep and broad health inequalities in sexual and gender diverse populations.[13] As noted above (Part II of these comments), discriminatory insurance policies and practices range from outright exclusions of any gender-transition-related treatment or procedure, to explicit limits on specific gender-affirming procedures, to unreasonable requirements for documentation, to practices that result in de facto denials of gender-affirming procedures. The detailed examples of types of discrimination set out in § 92.207(b)(3)-(5) are thus an important and necessary advance (with the addition of "transgender status" to 207(b)(3), noted below).

Notwithstanding assertions by politically motivated opponents of transgender people's existence and their need for access to appropriate health care services, there is powerful, solid

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[9] American Medical Association, AMA Reinforces Opposition to Restrictions on Transgender Medical Care (June 15, 2021), https://www.ama-assn.org/press-center/press-releases/ama-reinforces-opposition-restrictions-transgender-medical-care.

[10] American Academy of Pediatrics, Policy Statement: Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents, 142 Pediatrics e20182162 (2018), https://doi.org/10.1542/peds.2018-2162.

[11] Federation of Pediatric Organizations, Statement in Support of Transgender Children and Youth, their Families, and Health Care Providers (March 28, 2022), https://www.abp.org/sites/public/files/pdf/news-fopo-statement-transgender-care.pdf.

[12] American Psychological Association, Guidelines for Psychological Practice With Transgender and Gender Nonconforming People. 70 Amer. Psychologist 832 (2015), https://www.apa.org/practice/guidelines/transgender.pdf.

[13] UNDERSTANDING THE WELLBEING OF LGBTQI+ POPULATIONS, *supra* note 2, at 350-55.

scientific evidence of the physical and mental health benefits of gender-affirming care – including social transition, supportive counseling, hormone therapy (and puberty delay medications for young people), and surgeries. For example:

- A 2022 review of over 50 studies found reduced rates of suicide attempts, anxiety, depression, and symptoms of gender dysphoria along with higher levels of life satisfaction, happiness, and quality of life after gender-affirming surgery among transgender adults.[14]

- A 2018 review of over 50 research studies indicated that gender-affirming health care services are associated with better mental health for transgender people, including reduced suicide attempts, less depression, and higher life satisfaction.[15]

- A 2022 peer-reviewed study found that receipt of gender-affirming care among young people aged 13 to 20 was associated with 60% lower odds of depression and 73% lower odds of suicidality over a 12-month follow-up.[16]

- A 2021 peer-reviewed study found that transgender and nonbinary adolescents with access to gender-affirming hormone therapy treatments had nearly 40% lower odds of having had a suicide attempt in the past year, compared to peers who did not have access to affirming care.[17]

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[14] Jaime Swan et al., *Mental Health and Quality of Life Outcomes of Gender-affirming Surgery: A Systematic Literature Review,* J. Gay & Lesbian Mental Health (2022), https://doi.org/10.1080/19359705.2021.2016537.

[15] Cornell Public Policy Research Portal, *What Does the Scholarly Research Say About the Effects of Discrimination on the Health of LGBT People?*, *supra* note 5.

[16] Diana M. Tordoff et al., *Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-affirming Care,* JAMA Network Open 2022;5(2):e220978, doi:10.1001/jamanetworkopen.2022.0978, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2789423.

[17] Amy E. Green et al., *Association of Gender-affirming Hormone Therapy With Depression, Thoughts of Suicide, and Attempted Suicide Among Transgender and Nonbinary Youth*, 70 J. Adolescent Health 643 (2021), https://www.jahonline.org/article/S1054-139X(21)00568-1/fulltext.

Expert medical standards for gender-affirming care are well-established and supported by decades of solid scientific consensus. Just this past month, the World Professional Association for Transgender Health (WPATH) released its updated *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*. These standards, which reflect a global expert medical and scientific consensus around the medical necessity of gender-affirming care for the health and well-being of transgender and gender diverse people, have been continuously maintained since 1979. The most recent version of the standards is based on systematic evidence reviews conducted by an independent team of investigators at the Johns Hopkins Evidence-Based Practice Center and is the product of a decade of review and deliberation among leading experts across the globe.[18]

Moreover, as HHS correctly notes (87 FR at 47,902-03), studies that have looked closely at the costs of coverage of gender-affirming care, compared to coverage of other health conditions, have concluded that the former costs are relatively small, even insignificant. Therefore, there is no basis for concern that comprehensive coverage of gender-affirming care by health insurers, consistent with standard medical necessity standards applicable to coverage decisions generally, will impose undue, disproportionate, or substantial costs or burdens on insurers or on insured persons generally.

Whitman-Walker also supports the proposed provisions intended to protect persons living with disabilities against insurance discrimination, including but not limited to "adverse tiering" practices that target high-cost medications needed by persons living with HIV or other serious, disabling conditions.

[18] World Prof. Ass'n for Transgender Health, Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People (8th Version 2022), 23 Int'l J. Trans. Health Supp. 1, https://doi.org/10.1080/26895269.2022.2100644.

We have several specific suggestions to strengthen the safeguards against discriminatory health insurance plan practices.

Clarifying the reach of 207(b). "Transgender status" should be added to 207(b)(3), consistent with the addition of "transgender status" to the protected categories in § 92.101(a)(2). In addition, we recommend a slight modification to 207(b)(4), which bars categorical coverage exclusions of services related to gender transition or other gender-affirming care. As currently worded, this provision could be misconstrued to only apply if an insurer excludes "all" health services related to gender transition or other gender-affirming care, whereas we believe the true intent is to proscribe exclusions of "any" such services. Thus, we propose deleting the word "all" from this paragraph such that the final text reads:

> A covered entity must not, in providing or administering health insurance coverage or other health-related coverage: … (4) Have or implement a categorical coverage exclusion or limitation for ~~**all**~~ health services related to gender transition or other gender-affirming care.

Addressing discriminatory reliance on sex/gender edits in insurance claims review and billing. Too many transgender and nonbinary individuals encounter significant barriers to obtaining medically indicated screenings and procedures because of sex or gender edits in insurance billing.[19] Specifically, automatic sex/gender edits in insurance submission and processing systems mean that transgender men are often denied screenings for breast or cervical cancer, or care related to pregnancy, and transgender women are often denied screenings for prostate cancer. We therefore urge that the final rule include language in the preamble to § 92.207 indicating that automatic sex/gender edits in insurance billing systems constitute an

[19] Insurance plans use "edits" to automatically flag certain procedure codes, or combinations of codes, as medically unlikely or otherwise improper, to prevent improper payments. *See, e.g.,* Debra Lansey, *Claims Coding Edits Target Improper Payments, Errors*, ACP Internist (Sept. 2010), https://acpinternist.org/archives/2010/09/coding.htm (visited Sept. 30, 2022).

impermissible form of sex-based discrimination, and must be eliminated or modified to allow for submission and processing of claims without automatic denials created by a difference between the "sex"/"gender" of the procedure and an individual's sex or gender as indicated in the medical record or the insurance beneficiary file.

Addressing discriminatorily narrow or otherwise restrictive health insurance networks. The NPRM notes that, although "it is outside the scope of Section 1557 to establish uniform or minimum network adequacy standards" (87 FR at 47,877), "to ensure compliance with Section 1557, payers must develop their networks in a manner that does not discriminate against enrollees on the basis of race, color, national origin, sex, age, or disability" (*id.* at 47,878). The NPRM recognizes that provider networks can have discriminatory impacts on people living with disabilities, transgender individuals, and other groups, by limiting the availability of providers competent to treat those populations (*id.* at 47,877). Whitman-Walker agrees; this problem for sexual and gender minority persons was highlighted in the comments submitted by the LGBTQI Health Policy Roundtable and LGBTQIA+ Primary Care Alliance in the ACA 2023 Benefit and Payment Parameters proceeding earlier in 2022.[20] We suggest that OCR include scrutiny of provider networks in regular compliance reviews, as well as investigate complaints of network discriminatory impacts when submitted by plan members or other interested parties.

[20] U.S. Dept. of Health & Human Servs., Ctr. For Medicare & Medicaid Servs., *Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023*, Docket No. CMS-9911-P, RIN 0938-AU65, Comments of the LGBTQI Health Policy Roundtable and the LGBTQIA+ Primary Care Alliance, submitted Jan. 27, 2022, at 28-31.

VIII. The Proposed Rule's Expansive Interpretation of Section 1557 to Reach All Health Programs and Activities Receiving HHS Funding is Legally Sound and Essential to Advance Health Equity

Whitman-Walker fully supports the NPRM's understanding of the expansive reach of Section 1557. HHS is completely correct to reject the 2020 rule's erroneous position that health insurance is not a "health program or activity" within the meaning of the statute (87 FR at 47,829). As the NPRM notes, health insurance is obviously a "*health* program or activity" and, therefore, covered by the statute's express language. As the Department also notes, the primary goal of the ACA was to expand affordable, accessible, and adequate health insurance; excluding health insurance from the ACA's key nondiscrimination provision would make no sense. Moreover, numerous court decisions have held that state Medicaid plans, state employee health plans, and private health plans are subject to Section 1557's sex discrimination mandate and violate the statute when they exclude coverage of medical procedures for transgender persons.[21]

In addition, we applaud HHS' conclusion that participation in Medicare Part B constitutes receipt of federal financial assistance for purposes of Section 1557 and other nondiscrimination requirements in federal programs (87 FR at 47.887-90). This well-founded conclusion promises to extend additional nondiscrimination protections to tens of millions of elderly or disabled persons in many new health care settings.[22] The relationship between Part B

[21] *Kadel v. Folwell*, 446 F. Supp. 3d 1 (M.D.N.C. 2020), *aff'd, Kadel v. N.C. State Health Plan Teachers & State Emples.,* 12 F.4th 422 (4th Cir. 2021), *cert den.,* 142 S. Ct. 861 (2022) (state employee health plan); *Boyden v. Conlin,* 341 F. Supp. 3d 979 (W.D. Wis. 2018) (state employee health plan); *Tovar v. Essentia Health*, 342 F.Supp.3d 947 (D. Minn. September 20, 2018) (employer-based health insurance plan); *Flack v. Wis. Dep't of Health Servs.*, 328 F.Supp.3d 931 (W.D. Wis. 2018), *subsequent decision,* 395 F.Supp.3d 1001 (W.D. Wis. 2019) (state Medicaid program); *Cruz v. Zucker*, 195 F.Supp.3d 554, *decision on reconsideration,* 218 F. Supp. 3d 246 (S.D.N.Y. 2016) (state Medicaid program).

[22] Medicare Part B enrollment in calendar year 2022 is estimated to be approximately 65 million individuals. Congressional Research Service, Medicare Part B: Enrollment and Premiums (Updated May 19, 2022), page 1, https://sgp.fas.org/crs/misc/R40082.pdf.

providers and HHS is not distinguishable from that of other providers who are already treated as recipients of federal financial assistance. It is time for the poorly reasoned, discriminatory carve-out of Medicare Part B from federal nondiscrimination obligations to end.

Limitations to scope of the Proposed Rule. The NPRM limits the Proposed Rule to health programs and activities operated, facilitated, or funded at least in part by HHS, as distinct from other federal agencies (87 FR at 47,838 and 47,842). Whitman-Walker urges HHS to work with the Department of Justice and other federal agencies to develop a common rule, applicable to all federal agencies that operate, facilitate, or fund health programs and activities, in order to fully implement the intent of Section 1557. In particular, agencies including the Department of Veterans Affairs, the Office of Personnel Management, the Department of Defense, the Department of Labor, the Department of State, USAID, USDA, and the Department of Education oversee substantial programs that provide health care to millions of Americans.[23] These programs are subject to Section 1557's nondiscrimination mandate, and regulatory standards and procedures to ensure consistent enforcement are greatly needed.

The NPRM asks for comments as to whether the rule should address HHS human services programs (87 FR at 47,838). We believe that nondiscrimination in human services programs operated, facilitated, or funded by HHS is essential but may be beyond the scope of Section 1557, and best addressed in a separate rulemaking proceeding. We urge the Department to ensure, through other timely rulemaking, that nondiscrimination safeguards for human

[23] As just one example of the many issues that call for a Section 1557 common rule, federal employee health plans, regulated by OPM, contain a number of discriminatory, medically unsupportable exclusions of gender-affirming procedures. Even in the absence of express exclusions, many transgender employees and their dependents are denied coverage of specific gender-affirming procedures, despite ample medical documentation, and the existing appeals process is quite lengthy and results in haphazard, often poorly reasoned dispositions.

services programs operated, facilitated, or funded by the Department are as robust as the protections in this Proposed Rule.

IX. The Proposed Procedures for Addressing Claims of Religious or Conscience Exemptions Under Other Federal Laws Need Significant Elaboration

We fully agree with HHS that the specific exemptions, religious and otherwise, provided in Title IX for educational institutions are not appropriate in health care contexts and should not be imported into Section 1557 (87 FR at 47,839-41). Most of the Title IX exemptions make no sense at all in the health care context. That is particularly true of Title IX's extremely broad religious exemption, which would wreak havoc if applied to the ACA by allowing health care providers to deny essential health care services based on disapproval of a particular group or for other non-medical reasons, thereby putting the health and wellbeing of already vulnerable individuals at risk. There are a number of other federal statutes that allow health care providers to invoke a conscience or religious objection to providing certain kinds of care, making an additional religious exemption in Section 1557 unnecessary.

The NPRM's proposed procedure for considering claims of religious or conscience-based exemptions to Section 1557's nondiscrimination mandates (§ 92.302, 87 FR at 47,885-86) is a significant advance in the endeavor to appropriately balance nondiscrimination mandates – and, in particular, the central importance of health care, particularly for marginalized persons suffering from health disparities and a history of discrimination, and the fundamental obligations of those working in health care – with respect for religious beliefs and individual conscience. However, we respectfully submit that the proposed procedure needs significant elaboration in order to be effective.

Any investigation conducted by OCR into a claim for religious or conscience exemption by a covered entity must be fully transparent, resolved within a reasonable time, and conducted

in a balanced manner with appropriate weight to all relevant considerations. Therefore, § 92.302(a)-(c) should be modified to provide the following additional terms:

First, interested parties – primarily patients, insured companies and individuals, and potentially interested members of the public – should have reasonable notice that an exemption has been requested and an investigation initiated. If a covered entity claims such an exemption as a defense to a complaint, the complainant should be promptly notified. If the covered entity requests an exemption in any other context, notice to potentially interested parties and the public should be provided as follows: (1) the covered entity requesting an exemption should provide notice to its customers (as part of, and if necessary by amending, the notice of nondiscrimination required in § 92.10); and (2) OCR should provide public notice through the Federal Register.

Second, affected parties should have an opportunity to submit relevant evidence, including evidence of the health services provided by the entity requesting the exemption and the potential effects of granting the exemption on patients, customers, and on the general public. The NPRM correctly notes that consideration of claims under conscience and religious freedom laws – in particular, the Religious Freedom Restoration Act (RFRA) – should consider potential harms to third parties (87 FR at 47,842 and 47,886). Particularly for urgent or emergent health issues, a patient often has no ability to choose a particular provider in order to avoid a provider or institution that withholds care based on conscience or religious reasons, even if the patient is aware of such restrictions (which is not typically the case). Moreover, in many geographic areas and health care markets, there is a shortage of needed medical providers, particularly specialists. Thus, many individuals and families have few options for obtaining the care they need and have very limited ability to "shop around" – particularly lower-income individuals and families and persons who face serious challenges in traveling substantial distances for care. In order to give

substance to such considerations, interested third parties must be provided notice and reasonable opportunity to offer evidence of potential harms, the value of the health services provided by the entity claiming an exemption, and the availability of alternatives.

Third, rather than state that OCR "may determine at any time" whether an exemption applies, the regulation should provide a specific, reasonable timetable for providing notice of a request, entertaining relevant evidence and legal arguments, and issuing a determination.

Fourth, OCR should provide public notice of its decision, and publish its written disposition, with a statement of reasons for its decision, including a finding of facts and legal analysis, in a publicly available database or library that is publicly accessible and readily searchable. This will provide valuable guidance to the industry, the public, and OCR itself in future cases.

Fifth, any covered entity that receives an exemption must be required to provide written notice to its patients/customers, employees, and the general public through the notice of nondiscrimination required in § 92.10.

X. Other Provisions in the Proposed Rule are Important Advances

Whitman-Walker supports the prohibition of discrimination based on marital, parental, or family status in § 92.208. Such discrimination is clearly sex-based and harmful. In addition, we support the following additional provisions:

Prohibition of discrimination based on association (with someone in a protected category) - § 92.209. This protection is well-founded in case law, as the NPRM notes (87 FR at 47,879-80), and can be important for parents, other family members, and caregivers encountering discrimination based on a child or other family member or friend with a disability or of a different race, ethnicity, or gender; a child of same-sex parents; or any individual denied care

because of a partner of a different race, ethnicity, or gender. As noted in the NPRM preamble, certain protected populations, including LGBTQI+ people, are particularly susceptible to discrimination based on association. An individual in a same-sex relationship or marriage could be subjected to discrimination based on their own and their spouse or partner's sex, whereas that same individual might not be similarly mistreated were they not in a same-sex relationship. It is important that the final rule make clear that this kind of associational discrimination is within the ambit of the rule's protections.

Discriminatory reliance on algorithms in clinical decision-making - § 92.210. As noted in the NPRM (87 FR at 47,880-84), attention to discriminatory crisis decision-making protocols surfaced during the early stages of the COVID-19 pandemic. More generally, there is growing concern about discriminatory impacts of clinical algorithms increasingly in use.[24] There is a danger that algorithms based on unexamined cisgender norms, could result in discrimination against transgender and other gender diverse patients. For instance, reliance on algorithms for periodic screenings for cancer and other conditions, which rely on patient sex/gender, could miss important screenings for transgender patients if applied uncritically. We urge HHS to include mention of potential bias related to sex, with particular application to transgender and other gender diverse patients, in the discussion of the rule's prohibition on the use of discriminatory clinical algorithms.

Prohibition of discrimination in telehealth services – § 92.211. Whitman-Walker also supports the new, specific prohibition of discrimination in telehealth services. The COVID-19 pandemic stimulated a tremendous increase in telehealth services. Even with the waning of the

[24] *See, e.g.,* State of California Dept. of Justice, *Attorney General Bonta Launches Inquiry Into Racial and Ethnic Bias in Healthcare Algorithms* (Aug. 31, 2022), https://oag.ca.gov/news/press-releases/attorney-general-bonta-launches-inquiry-racial-and-ethnic-bias-healthcare.

pandemic, telehealth remains a substantial part of Whitman-Walker's services to our patients. As the NPRM notes, telehealth has benefitted many LGBTQ+ individuals, particularly transgender and non-binary individuals who live at significant distances from competent, welcoming health care providers. Telehealth is also proving to be of great benefit to many patients who face transportation, childcare, or work-related barriers to traveling to health care appointments, and elders and persons with disabilities who face significant challenges leaving their homes. However, significant barriers remain to full realization of telehealth's promise, particularly for low-income persons and others lacking the necessary technology, LEP patients, and many persons living with disabilities. While Section 1557 applies to all health care services, including telehealth, we agree that it is important to highlight telehealth in a separate regulatory provision.

XI. HHS Should Include Data Collection Requirements in the Final Section 1557 Rule, Including Collection of Data on Sexual Orientation, Gender Identity, and Sex Characteristics

The NPRM invites comments on the proposal to delegate to OCR the responsibility for data collection by covered entities, relying on OCR's authority and procedures in 45 C.F.R. 80.6 for enforcement of Title VI requirements and referring to the Department of Education's biennial data collection procedures for covered educational institutions (87 FR at 47,856-57). Whitman-Walker submits that a better approach is to include a basic demographic data collection requirement in the final rule, including a requirement to collect data on the sexual orientation, gender identity, and sex characteristics (intersex status) of patients, customers, and beneficiaries of HHS programs and of covered entities and their programs. We refer to and support the detailed explanation in the comments submitted by the National Health Law Program (NHeLP), and we highlight our fundamental points here.

Without demographic information on individuals served through its programs and activities, HHS often fails to effectively understand diversity in program populations and to ensure equity. Currently, collection of demographic data within HHS programs is less than systematic and thorough. A clear requirement in the final rule itself would further demographic data collection across the agency, improve civil rights enforcement, and reach toward the goal of health equity.

HHS must invest in demographic data collection in any program or activity that serves the public. Only by understanding who uses each program can HHS ensure that groups of people with different experiences – and particularly members of historically underserved populations – are served equitably. Having data on hand is also the most essential and straightforward way to ensure and demonstrate compliance with § 1557's civil rights requirements. Establishing a requirement within the final rule would bring weight and clarity to demographic data collection as a key component of civil rights enforcement.

The sub regulatory approach adopted by the Department of Education, referred to in the NPRM, may not be the most effective approach. A sub regulatory approach has thus far not yielded sufficient progress toward standardized demographic data collection within HHS.[25] Moreover, the Education Department collects data from school districts and juvenile facilities, whereas to ensure compliance with Section 1557, HHS must collect data from state exchanges, state Medicaid programs, hospitals, health centers, health clinics, clinicians' offices, insurance carriers, and more. We concur with the suggestion of NHeLP to set the baseline requirement in

[25] *See* Charly Gilfoil, Nat'l Health L. Prog., *Demographic Data Collection in Medicaid & CHIP: CMS Authority to Collect Race & Ethnicity Data* (Sept. 7, 2022), https://healthlaw.org/resource/demographic-data-collection-in-medicaid-chip-cms-authority-to-collect-race-ethnicity-data/.

the Section 1557 Final Rule, and then to direct each subagency or program to set its own requirements and methods for data collection with a specific timeline for implementation.

In order to realize the intent of Section 1557, of course, it is necessary that the final rule state that the demographic data to be collected on patients and insurance customers include sexual orientation, gender identity, and differences in sex characteristics (SOGISC) data. Just as the Proposed Rule updated protections against sex discrimination to include LGBTQI+ people, in recognition of developments in the law and the pressing need to address health disparities in those populations, HHS must ensure that its data collection requirements regarding sex – both in a clear requirement in Section 1557 and in a revision to the Department's 2011 standards promulgated under ACA Section 4302 – include SOGISC data. As noted in NHeLP's comments, HHS should adopt the recommendations of the National Academies of Science, Engineering and Medicine (NASEM) in its 2022 report, *Measuring Sex, Gender Identity, and Sexual Orientation* as the standard for how these data should be collected.[26]

Although the NPRM expresses concern regarding the sensitivity and privacy of information on gender identity, sexual orientation, and intersex traits (87 FR at 47,857), these concerns provide no basis for failing to collect this essential data. In particular, we note that the

[26] Nat'l Acads. Of Sci., Eng'g, & Med., MEASURING SEX, GENDER IDENTITY, AND SEXUAL ORIENTATION (2022), https://nap.nationalacademies.org/catalog/26424/measuring-sex-gender-identity-and-sexual-orientation. With regard to gender identity, the NASEM report recommends collecting two data points – the sex classification on an individual's original birth certificate and the individual's current gender identity – to identify both the individual's gender and whether or not the individual is transgender. With regard to intersex traits, few surveys collect information on individuals with differences in sex characteristics or intersex traits. Yet, the occurrence of individuals who have non-normative sex traits, such as differences in hormones or anatomy, is significant considering the number of individuals who may be intersex, who have had gender-affirming treatment, or who may have other medical conditions (such as a mastectomy for the purpose of treating breast cancer). An anatomical or organ inventory provides greater utility both medically and demographically when it comes to identifying sex traits. HHS should test methods of collecting demographic information about sex characteristics that can be used widely.

single citation provided in relation to these concerns reflects putative concerns from *providers*, not patients. As NHeLP observes, data collection requirements should include clear privacy and nondiscrimination safeguards, and patients and customers should always be informed that providing requested information is voluntary. Studies have shown high acceptability among patients and enrollees in self-reporting sexual orientation and gender identity,[27] given that appropriate steps are taken to support these data collection activities.[28] In the experience of Whitman-Walker and other health centers with substantial LGBTQ patient populations, most patients readily provide "highly personal" and "sensitive" information when the reasons for seeking the information, the voluntary nature of the ask, and assurance of privacy are explained. In our experience, reluctance to collect SOGISC information on patients tends to be based more on discomforts and unexamined biases of providers and administrators than on concerns of patients.[29]

Therefore, Whitman-Walker supports the specific recommendation of NHeLP to add the following to § 92.5, Assurances, as a new section (d):

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[27] Sean Cahill et al., *Do Ask Do Tell: High Levels of Acceptability by Patients of Routine Collection of Sexual Orientation and Gender Identity Data in Four Diverse American Community Health Centers*, 9 PLOS ONE e107104 (2014), https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0107104: Adil H. Haider et al., *Emergency Department Query for Patient-Centered Approaches to Sexual Orientation and Gender Identity: The EQUALITY Study*, 177 JAMA Intern. Med. 819 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5818827/.

[28] *See, e.g.*, Chris Grasso et al., *Planning and Implementing Sexual Orientation and Gender Identity Data Collection in Electronic Health Records*, 26 J. Am. Med. Inform. Assoc. 66 (2019), https://pubmed.ncbi.nlm.nih.gov/30445621/.

[29] *See Emergency Department Query for Patient-Centered Approaches to Sexual Orientation and Gender Identity: The EQUALITY Study*, *supra* note 27 ("Few patients will refuse to provide sexual orientation information in the emergency department setting in contrast to what most emergency department health care professionals think").

(d) Data Collection.

(i) Applicability. A covered entity shall, as a condition of receipt of such funds, collect demographic data of all the individuals served.

(ii) Standards. An entity described in paragraph (i) must:

A. Collect this data in a form and manner determined by the Secretary, but which at minimum shall include demographic categories for race, ethnicity, spoken and written language, disability status, age, sex and gender identity, sex characteristics, and sexual orientation, and comply with requirements in 42 U.S.C. § 300kk;

B. Provide this data to HHS at intervals determined by the Secretary and in a manner determined by the Secretary, to document compliance with this Part; and

C. Comply with relevant privacy protections in federal and state law, including HIPAA, when collecting, storing, sharing, and otherwise using this data.

XII. The Nondiscrimination Regulations Applicable to CMS-Administered Programs Should Be Amended to Expressly Proscribe Discrimination Based on Sex Characteristics and Sex Stereotypes

HHS appropriately proposes to amend a number of CMS regulations – applicable to Medicaid; CHIP; PACE; issuers of Essential Health Benefits and Qualified Health Plans and their agents and representatives; and the Health Insurance Marketplaces, their regulators, agents, brokers – to include provisions removed by the previous Administration prohibiting sexual orientation and gender identity discrimination.[30] We fully support HHS' conclusion that including sexual orientation and gender identity in these nondiscrimination regulations has ample statutory support in Section 1557, other provisions of the ACA, and the Social Security Act; is supported by the Supreme Court's interpretation of sex discrimination in *Bostock;* and is critical to advance health equity. We submit, however, that the proposed amendments need to be expanded to expressly recognize and be fully consistent with HHS' correct understanding of the scope of sex discrimination.

[30] And to correct previous oversights by amending certain other regulations to apply these nondiscrimination provisions to CHIP fee-for-service and CHIP managed care entities.

In particular, the regulations should add "sex stereotypes" and "sex characteristics, including intersex traits," to sexual orientation and gender identity as prohibited categories of discrimination. We respectfully submit that CMS' proposal to "limit[] the explicit mention [in these regulations] to gender identity and sexual orientation, while understanding that discrimination on the basis of sex stereotypes, sex characteristics, and pregnancy or related conditions is prohibited sex discrimination" (87 FR at 47,891) is insufficient, because it may engender confusion and fail to provide adequate notice to insurance personnel, agents, brokers, and others that sex stereotype and intersex discrimination is unlawful. As noted in the NPRM (87 FR at 47,858), discrimination based on sex stereotypes and discrimination against persons with intersex traits is widespread, and federal nondiscrimination regulations should put insurers, brokers, agents, Medicaid and PACE administrators, and other relevant personnel on clear notice.

A. Nondiscrimination in Insurance Exchanges and Group and Individual Health Insurance Markets
45 CFR §§ 147.104, 155.120, 155.220, 156.200, and 156.1230

Whitman-Walker joined in comments submitted in the ACA 2023 Benefit and Payment Parameters proceeding earlier in 2022 in which these amendments were proposed, and as requested in the NPRM (87 FR at 47,891 and 47,895), will not repeat those arguments here.[31] However, we add here that, in view of the Proposed Rule's clear statement that sex discrimination includes discrimination based on sex stereotypes, this should be added to the regulations applicable to health insurance exchanges and group and individual health insurance

[31] CMS, *Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023*, Comments of the LGBTQI Health Policy Roundtable and the LGBTQIA+ Primary Care Alliance, *supra* note 20, at 4-17.

markets – an issue that was not addressed in our comments in the 2023 Benefit and Payment Parameters proceeding.

B. Nondiscrimination in Medicaid and CHIP
42 FR §§ 438.3(d)(4), 438.206(c)(2), 440.262, 457.495(e)
Nondiscrimination in PACE
42 CFR §§ 460.98(b)(3), 460.112(a)

We concur with HHS that amending these regulations to prohibit discrimination in Medicaid, CHIP, and PACE programs and services on the basis of sexual orientation and gender identity, are supported – indeed, compelled – not only by the reasoning of the Supreme Court's interpretation of sex discrimination in *Bostock,* and the case law and Administration issuances under Title IX and Section 1557 following *Bostock*, but also by:

- Section 1902(a)(19) of the Social Security Act, 42 USC 1396a(a)(19), which provides that state medical assistance plans must have safeguards to ensure that eligibility will be determined, and care and services provided, in the best interests in the recipients.
- Section 1902(a)(4)(A) of the Social Security Act, 42 USC 1396a(a)(4)(A), which authorizes HHS to provide methods of administration necessary for the proper and efficient operation of state medical assistance plans.
- Section 2101(a) of the Social Security Act, 42 U.S.C. 1397aa(a), which declares the purpose of the CHIP program is to provide funds to states for health assistance to low-income, uninsured children in an effective and efficient manner.
- Sections 1894(f)(4) and 1934(f)(4) of the Social Security Act, 42 U.S.C. 1395eee(f)(4) and 42 U.S.C. 1396u–4(f)(4), which authorize HHS to issue regulations "to ensure the health and safety of individuals enrolled in a PACE program."

These statutes provide ample support for express regulatory prohibitions of sexual orientation and gender identity discrimination in Medicaid, CHIP, and PACE programs. As noted in the

Proposed Rule (87 FR at 47,891, 47,892 and 47,894; *see also id.* at 47,833-35), and as further documented in Whitman-Walker's comments and in the submissions of numerous other health care providers, researchers, and advocacy organizations in this proceeding, discrimination against LGBTQ+ individuals and families by health care providers, insurers and insurance agents and brokers, and state Medicaid and other medical assistance programs is widespread, and it contributes directly and indirectly to substantial, systemic health disparities between LGBTQ+ non-LGBTQ populations. And, as HHS correctly notes (87 FR at 47,893-94), PACE participants, who are older and generally in fragile health, are particularly susceptible to discrimination and its ill effects.

These same considerations support expanding the regulations at issue to prohibit discrimination on the basis of sex characteristics, including intersex traits, and discrimination on the basis of sex stereotypes, as well as sexual orientation and gender identity. Anti-LGBTQI+ stigma and prejudice frequently manifest as adverse actions based on sex stereotypes: individuals or families are denied treatment, told that services are not available, offered inferior facilities or services, or treated with hostility, because they violate someone's view of sex stereotypes. As noted above, persons with intersex traits also encounter systemic discrimination in all aspects of the health care system. Amending the regulations in question to explicitly highlight these prohibited forms of discrimination is necessary to provide adequate notice to the many actors in health care systems. This is particularly important with regard to intersex discrimination because persons with intersex traits are widely misunderstood if not completely invisible to many in the health care system.

XIII. The Final Rule Should Clarify Its Application to Research Projects and Activities

The NPRM states that "health programs and activities" covered by Section 1557 include health-related research, when federally funded in whole or in part, or when part of the activities of an entity primarily engaged in health care or other health programs and activities, at least some of which are federally funded (§ 92.4; 87 FR at 47,844). However, the NPRM says nothing about how the provisions of the proposed rule apply to research programs and projects. Research is in many ways very different from the provision of health care to individual patients and families. Research aims to produce scientifically supportable and generalizable knowledge, through the application of rigorous protocols, including careful selection of study subjects. The Whitman-Walker Institute's research activities are strictly overseen by the funding agencies – primarily the National Institutes of Health, also the Centers for Disease Control and the Patient-Centered Outcomes Research Institute – and all protocols for treatment of individuals participating in research studies undergo rigorous Institutional Review Board review and approval.

The preamble to the 2016 rule appropriately contained the following language:

> We proposed to interpret "health programs and activities" to include programs such as health education and health research programs. Because Federal civil rights laws already prohibit discrimination on the basis of race, color, national origin, disability, or age in all health research programs and activities that receive Federal financial assistance and prohibit discrimination on the basis of sex in all health research programs conducted by colleges and universities, we determined that the application of Section 1557 to health research should impose limited additional burden on covered entities.
>
> However, OCR recognized that health research is conducted to answer scientific questions and improve health through the advancement of knowledge; it is not designed to result in direct health benefits to participants. We also recognized that research projects are often limited in scope for many reasons, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other nondiscriminatory considerations. Thus, we noted that criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that

such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research. OCR noted that we do not intend for inclusion of health research within the definition of health program or activity to alter the fundamental manner in which research projects are designed, conducted, or funded; nor did OCR propose to systematically review health research protocols.

Nondiscrimination in Health Programs and Activities; Final Rule, 81 FR 31,376, 31,385 (2016).

Moreover, HHS provides additional helpful guidance on Section 1557 and research activities on its website:

43. Does Section 1557 permit covered entities to limit some health research to only males or females?

Sex-specific programs or activities (those in which participation is limited to one sex only), including health research, are allowed only where a covered entity can show an exceedingly persuasive justification for the limitation to one sex. To establish an exceedingly persuasive justification, a covered entity must show that the sex-based classification is substantially related to the achievement of an important health-related or scientific objective. A covered entity must supply objective evidence, and empirical data if available, to justify the need to restrict participation in a health program to only one sex. Justifications that rely on overly broad generalizations about the sexes are not acceptable.

Health researchers will typically be able to show an exceedingly persuasive justification for a sex-specific clinical trial based on research protocols. These include protocols that target or exclude certain populations in order to account for the health or safety of the subjects, the study design, or the purpose of the research. For example, certain psychotropic drugs are known to affect women and men differently; men's kidneys tend to filter certain antianxiety medication more rapidly than women. Based on this scientific knowledge, a medical research institution that is a covered entity and that runs a clinical trial to test a modified release mechanism to slow the drug filtration and excretion in men's kidneys may permissibly exclude women from the trial under the standards set forth above.

* * *

55. May covered entities use health research protocols that target or exclude individuals with disabilities?

A covered entity conducting health research may design research protocols that target or exclude certain populations when necessary to protect the health or safety of the subjects or serve the purpose of the research. For example, a medical research institution that is a covered entity may exclude individuals who are deaf from a clinical trial designed to investigate a new brain imaging technology for assessing cognitive

> functioning where that trial relies on auditory stimulation as the test stimulus. This research design would not be discriminatory on the basis of disability because there is a nondiscriminatory justification for excluding individuals who are deaf. On the other hand, if an individual's disability does not interfere with the purpose of the study or the health or safety of the participants, an individual with a disability may not be excluded on the basis of his or her disability.

Section 1557: Frequently Asked Questions, https://www.hhs.gov/civil-rights/for-individuals/section-1557/1557faqs/index.html#General%20Questions (visited Sept. 19, 2022).

We request HHS to provide similar guidance in the final rule in this proceeding.

XIV. Conclusion

Thank you for this opportunity to offer our perspectives on this ground-breaking Proposed Rule. Please let us know if we can provide additional information or be of any other assistance.

Respectfully submitted,

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