EXHIBIT C1

HHS ISSUES PROPOSED RULE UNDER SECTION 1557 OF THE AFFORDABLE CARE ACT: NONDISCRIMINATION IN HEALTH PROGRAMS AND ACTIVITIES

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On August 4, 2022, the US Department of Health and Human Services (HHS) issued a Notice of Proposed Rulemaking (NPRM or proposed rule) to reinterpret section 1557 of the Affordable Care Act (ACA), which prohibits discrimination on the basis of race, color, national origin, sex, age or disability in a health program or activity, any part of which is receiving federal financial assistance. The proposed rule restores and strengthens certain civil right protections under federally funded health programs and HHS programs which were limited following the 2020 Trump-era version of the rule, specifically regarding discrimination on the basis of sex, including sexual orientation and gender identity, and returns certain protections for individuals with limited English proficiency (LEP). Additionally, the proposed rule bolsters protections against discrimination in healthcare by clarifying that funds received under several federal healthcare programs, including Medicare Part B, are included in the definition of federal financial assistance under the law. As such, under the proposed rule, the list of entities expected to comply with the nondiscrimination measures outlined in Section 1557 of the ACA is significantly expanded, in many ways aligning with the 2016 Obama-era version of the rule. The NPRM also proposes to expand the applicability of the post-*Bostock* interpretation of "on the basis of sex" to Medicaid, Children's Health Insurance Programs (CHIP) and Programs of All-Inclusive Care for the Elderly (PACE). For now, portions of the 2020 Final Rule not discordant with *Bostock* continue to apply.

IN DEPTH

Background

Section 1557 of the ACA prohibits any healthcare program or activity, any part of which is receiving federal financial assistance, from discrimination in specific health programs or activities based on race, color, national origin, sex, age and disability. On May 18, 2016, during the Obama administration, HHS originally sought to implement this prohibition in a Final Rule by announcing its interpretation that the statutory provision of discrimination "on the basis of sex" included, among other things, discrimination based on sex stereotyping, gender expression, gender identity and termination of pregnancy. The 2016 Final Rule also set forth obligations to provide certain language assistance to LEP individuals and auxiliary aids and services for individuals with disabilities.

In 2020, during the Trump administration, HHS revised the 2016 Final Rule, the result of which was the elimination of many protections outlined in 2016, particularly those protections related to gender identity, gender expression, sex stereotyping and termination of pregnancy. The 2020 Final Rule declined altogether to put forth a definition of "on the basis of sex" as used in the ACA. (See our more detailed *On the Subject* Here).

On August 4, 2022, HHS issued an NPRM which proposes to restore and strengthen civil right protections under federally funded health programs and HHS programs, which protections were limited following the 2020 version of the rule. The NPRM appears to be the culmination of an executive order issued by the Biden administration and an Equity Action Plan issued by HHS.

Scope of Section 1557 and Definition of "Covered Entity"

health program or activity receiving federal funds from HHS, any program or activity administered under Title I of the ACA, and health insurance marketplace participants.

Under the newly proposed rule, HHS clarifies that the scope of Section 1557 should apply broadly to health programs or activities, including providing, administering or assisting persons with health-related services or insurance; providing pharmaceutical, clinical or medical care; engaging in health research; or providing health education for healthcare professionals or others. HHS elucidates its intended breadth by listing certain entities that would be captured by the enlarged scope, including state and local health agencies, hospitals, health clinics, health insurance issuers, physician practices, community-based healthcare providers, nursing facilities, residential or community-based treatment facilities, or similar entities or combinations, though not intending this to be an exhaustive list. Noticeably missing from this list are employer-sponsored group health plans.

Under the revised definition of "covered entity," those that would be subject to the scope of Section 1557 under the NPRM include: (1) recipients of federal assistance, (2) HHS and (3) entities established under Title I of the ACA. "Federal financial assistance" will include any grant, loan, credit, subsidy, contract or other arrangement by which the federal government provides assistance. The proposed definition of covered entities is intended to be expansive in order to capture "all of the operations of any entity principally engaged in the provision or administration of health projects, enterprises, ventures, or undertakings." This would include, for example, group health insurance issuers and a third-party administrator's services provided to a self-insured group health plan. The NPRM further explains that the more expansive definition more accurately reflects Congress's intent that Section 1557 should apply broadly to programs of health insurance, because it was passed as part of the ACA—a law predominantly intended to regulate health insurance.

Change in Interpretation—Medicare Part B Meets the Definition of Federal Financial Assistance

The NPRM announces HHS's position that funds received under Medicare Part B are included within the definition of federal financial assistance for the purpose of coverage under the federal civil rights statutes enforced by HHS, specifically Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, Title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975 and Section 1557 of the ACA. This is because Part B funds are intended to subsidize healthcare providers and suppliers for the health services and supplies rendered to program beneficiaries. In making this proclamation, HHS reverses the position it has held for nearly 40 years, but it explains its reasoning through a detailed discussion of the evolution of Medicare Part B. HHS also notes that funds received under Medicare Part A have long been considered federal financial assistance, and because Medicare Part A and Medicare Part B are fundamentally similar (*e.g.*, both are federal programs under which providers agree to conditions of participation or coverage in exchange for receiving federal payments for their services to eligible enrolled individuals), the rationale for excluding Medicare Part B funds from the definition of federal financial assistance is not consistent with the purpose and operation of the program.

Revisions to Prohibition on Discrimination Against Limited English Proficient (LEP) Individuals

The NPRM proposes language relating to Section 1557's prohibition on national origin discrimination as applied to LEP individuals in covered health programs and activities. In the NPRM, HHS recognizes that covered entities may violate this prohibition by failing to take reasonable steps to provide meaningful access to LEP individuals, such as providing free and effective language assistance services. To encourage providing such services, covered entities will be required to take reasonable steps toward providing meaningful access to language assistance services (*e.g.*, interpreter and translation services) to LEP individuals "eligible to be served or likely to be directly affected" by its health programs and activities. This is a slight revision to the language in the 2016 Final Rule, which required a covered entity to provide meaning access to LEP individuals "eligible to be served or likely to ***be encountered***." HHS believes the adjustment to the language will provide greater clarity to covered entities seeking to abide by the requirement and empower covered entities to be cognizant of treating LEP individuals on a case-by-case basis to better serve their needs.

The proposed rule also proposes to reinstate a requirement from the 2016 Final Rule that obligated covered entities to provide a notice of availability of language assistance services to better serve LEP individuals. The 2016 Final Rule had required these notices to be in "all significant publications," which was declared to be burdensome and rescinded as part of the 2020 Final Rule. To that end, under the NPRM, the notice must be provided on an annual basis to participants, beneficiaries, enrollees and applicants, and upon request at any time. Additionally, the notice must be provided in a conspicuous manner on the covered entity's health program or activity website (if one exists) as well as in other clear and prominent physical locations reasonably expected to be read or heard by individuals seeking services from the covered entities' health programs or activities. By returning the requirement, HHS seeks to balance the importance of the notice with the burden on covered entities.

rates of outpatient follow up, poor medication, adherence, and difficulty understanding diagnosis and discharge instructions.

Adherence to these requirements is particularly important in the telehealth context in light of the COVID-19 pandemic, and the proposed rule specifically addresses nondiscrimination in the delivery of telehealth services to LEP individuals.

Revisions to Prohibition Against Disability Discrimination

The 2016 Final Rule included definitions for a range of terms related to disability discrimination, including auxiliary aids and services; disability; qualified individual with a disability; and qualified interpreter for an individual with a disability. In the NPRM, HHS keeps the substantive definitions for these terms and adds a definition for "qualified reader" consistent with Title II of the American with Disabilities Act (ADA) to provide clarity to covered entities as well as protected individuals regarding the necessary qualifications of a reader, as required under the regulation.

HHS also proposes to require covered entities to make reasonable modifications to policies, practices or procedures as necessary to avoid discrimination on the basis of disability, unless the covered entity can demonstrate that implementing the modifications would significantly change the nature of the health program or activity. HHS clarifies that the term "reasonable modifications" should be interpreted in a manner consistent with the term as set forth in the regulation implementing Title II of the Americans with Disabilities Act.

Furthermore, as with the requirements specific to LEP individuals, the proposed rule specifically addresses nondiscrimination in the delivery of telehealth services to individuals with disabilities and requires a notice of the availability of auxiliary aids and services for individuals with disabilities.

Revisions to Prohibition Against Sex Discrimination

In a shift from the 2020 Rule, which declined to adopt a definition of "on the basis of sex," HHS aligns regulatory requirements with federal court opinions to prohibit discrimination on the basis of sex, including sexual orientation and gender identity. Consistent with the US Supreme Court's holdings in *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020), the proposed rule codifies protections against discrimination on the basis of sex as including discrimination on the basis of sexual orientation and gender identity (see Federal Register Notice 86 Fed. Reg. 27984), stating that Section 1557 would be enforced consistent with *Bostock*.

Additionally, the proposed rule includes other categories of sex discrimination, such as discrimination on the basis of sex characteristics, including intersex traits, and pregnancy or related conditions, including pregnancy termination. HHS proposes the inclusion of "sex characteristics" on grounds that discrimination based on anatomical or physiological sex characteristics is inherently sex-based.

HHS also recognizes in the proposed rule that including "pregnancy or related conditions" is consistent with the longstanding interpretation of sex discrimination under Title IX, including HHS's Title IX implementing regulation (45 CFR § 86.21(c)(2), (3); § 86.40(b)(1), (4), (5); § 86.51(b)(6); § 86.57(b)(d) (Title IX regulation)).

Finally, HHS stated its belief that it could be beneficial to include a provision specifically prohibiting discrimination on the basis of pregnancy-related conditions as a form of sex-based discrimination. HHS is requesting comments on how it should do so and any impact that the Supreme Court decision in *Dobbs v. Jackson Women's Health Organization* (see our *On the Subject* here and here) has on the implementation of Section 1557 and how it should be reflected in the Final Rule.

New Requirements for Operationalizing Compliance with Section 1557

The proposed rule requires covered entities to develop and implement written policies and procedures to facilitate the implementation of Section 1557. HHS states that written policies and procedures will better equip covered entities to provide services in a nondiscriminatory manner, consistent with the goals of Section 1557.

The proposed language requires covered entities, in their health programs and activities, to adopt and implement a nondiscrimination policy, grievance procedures (for covered entities employing 15 or more persons), language access procedures, auxiliary aids and services procedures, and procedures for reasonable modifications for individuals with disabilities.

programs and activities.

Although this was similarly required under the 2016 Final Rule, HHS now expands on the obligation by acknowledging that some covered entities might prefer to spread out the responsibilities of a Section 1557 coordinator. In recognition of those covered entities, HHS proposes to permit covered entities to assign one or more designees to carry out the duties of a Section 1557 coordinator. These duties include: (1) receiving, reviewing and processing grievances filed under the grievance procedures; (2) coordinating the covered entity's recordkeeping requirements; (3) coordinating effective implementation of the covered entity's language access procedures; (4) coordinating effective implementation of the covered entity's communication procedures; (5) coordinating the covered entity's procedures for providing reasonable modifications for individuals with disabilities; and (6) coordinating training for employees.

HHS also proposes to require the Section 1557 coordinator, along with other relevant employees, to undergo training on the covered entity's written policies and procedures established pursuant to the rule. These trainings include instructing staff on the provision of language assistance services to LEP individuals and effective communication and reasonable modifications to policies and procedures for individuals with disabilities. HHS defines "relevant employees" in this context as those who "directly encounter or interact with individuals such as patients, clients, and members of the public." Additionally, "employees are also considered relevant when they make decisions regarding the services individuals seek from a covered entity's health programs and services." The NPRM recognizes that many covered entities already have existing civil rights trainings for their employees and that those can be modified to comply with this proposed provision.

Benefits Plan Design/Coverage

When and how employee benefit group health plans may be subject to Section 1557 continues to evolve. Under the 2016 Final Rule, employer-sponsored group health plans were directly subject to Section 1557. Under the 2020 Final Rule, employer-sponsored group health plans that do not receive federal financial assistance and are not principally engaged in the business of providing healthcare were no longer considered covered entities subject to Section 1557. The expansive definition of covered entity in the NPRM, while similar in many ways to the 2016 Final Rule, does not explicitly include employee benefit group health plans as covered entities subject to Section 1557. In reaching this conclusion, HHS provides the following:

"Although we still consider group health plans to be principally engaged in providing or administering health programs or activities [...], many group health plans themselves are not recipients of federal financial assistance (as opposed to the employer or plan sponsor offering the group health plan or the third party administrator administering the group health plan), so inclusion of group health plans on the list may be confusing. That said, if [HHS] receives a complaint against a group health plan, we will evaluate the facts on a case-by-case basis to determine whether the group health plan is a covered entity subject to this part."

As a result, the NPRM would not directly apply to many employee benefit plans. However, HHS leaves the issue open, providing that it may determine on a case-by-case basis whether a group health plan might be treated as a covered entity subject to Section 1557 and requesting further comments on the topic. Further, the NPRM would apply to many benefit plan vendors, which would include, for example, insurers and third-party administrators. As a result, the NPRM will indirectly apply to virtually all employee benefit plans.

Enforcement

The NPRM proposes to add a provision affirming that enforcement of Section 1557 will be consistent with mechanisms provided under Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, Section 504 of the Rehabilitation Act of 1973 and the Age Discrimination Act of 1975, and that private individuals may sue to enforce their rights under Section 1557. Through this lens, HHS clarifies that a covered entity can raise its belief that a provision of Section 1557, as applied to it, would violate federal conscience and religious freedom laws. Should a covered entity provide such a notification, HHS Office of Inspector General (OIG) will consider the facts and circumstances involved before determining whether to proceed with an investigation or enforcement activity or granting an exemption or modification to that covered entity. The NPRM further clarifies that an exemption or modification for one circumstance does not necessarily extend that exemption or modification for other circumstances. Previously, neither the 2016 Final Rule nor the 2020 Final Rule addressed the applicability of federal conscience or religious freedom laws to Section 1557 enforcement.

Amendments to the Nondiscrimination Regulatory Provisions in Other CMS Programs

basis of sexual orientation and gender identity as prohibited forms of discrimination based on sex. HHS believes these proposals would promote consistency across all programs of policies and requirements prohibiting discrimination on the basis of sexual orientation or gender identity.

Conclusion

HHS believes that its proposed rule will reinstate protections from discrimination on the basis of race, color, national origin, sex, age or disability in covered health programs and activities in a manner consistent with the statutory text of Section 1557 and congressional intent and in line with the 2016 Final Rule. To broadly achieve these goals, the proposed rule also requires covered entities to provide a notice of nondiscrimination, relating to their health programs and activities, to participants, beneficiaries, enrollees and applicants of its health programs and activities, and members of the public.

Given the copious detail that HHS put into the NPRM, including citations to peer-reviewed articles, case law, federal guidance documents and other materials, we anticipate that the NPRM will be finalized in materially the same format as proposed. However, we will monitor comments closely and will report any material developments. Public comments on the NPRM are due on or around October 4, 2022, or 60 days after publication of the NPRM in the Federal Register.

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