Sept. 14, 2022

Proposed Rule – Nondiscrimination in Health Programs and Activities

CHA Summary

Internal

On Aug. 4, the HHS Office of Civil Rights (OCR) released the proposed rule, Nondiscrimination in Health Programs and Activities, which reinstates key provisions of the Affordable Care Act's (ACA) Section 1557 nondiscrimination requirements that were rolled back by the prior administration and adds a few new provisions responding to recent legal and policy developments. Section 1557 protects individuals from discrimination by health programs or activities, including those that are HHS-funded or HHS-administered, based on their race, color, national origin, sex, age or disability. **Please provide any comments or feedback on this rule to Jan Kaplan by COB Sept. 23. Comments are due to HHS on Oct. 3.**

This proposed rule reinstates, and in certain situations modifies, Section 1557 nondiscrimination protections that had been implemented in 2016 by the Obama administration but were then limited by the Trump administration. In particular, this rule reinstates:

- Requirements that the nondiscrimination protections apply to all health programs or activities, including the provision of health insurance or health-related coverage.[1]
- Requirements that covered entities provide non-discrimination notices and grievance procedures.
- The right of private individuals to challenge alleged violations of the law in court.
- Requirements for assistive devices and language and interpretation services for individuals with disabilities and limited English Proficiency (LEP), respectively.
- Nondiscrimination protections based on gender identity, sexual orientation and pregnancy-related conditions.

The rule also newly requires insurers, providers and others that use clinical decision-making algorithms to ensure that they are not inherently biased, and to provide nondiscriminatory access to telehealth services.

SUMMARY OF KEY PROVISIONS AFFECTING CHILDREN'S HOSPITALS

The following summary highlights those aspects of the final rule that are of most interest to children's hospitals.

Covered entities – Entities covered by the rule include:

- Any that receive Medicaid or Medicare payments or other federal funds to administer their health programs, such as hospitals,[2] laboratories, skilled nursing facilities, ambulatory surgical centers, federally qualified health centers, intermediate care facilities, comprehensive outpatient rehabilitation facilities, physical therapy/speech pathology programs and individual physicians.

[1] The Trump administration rule limited the applicability of Section 1557 to Medicare Advantage plans, Medicaid managed care organizations and the qualified health plans (QHPs) sold through the Exchanges, rather than to all types of commercial insurance and the broader Medicaid, CHIP and Medicare programs. This proposed rule, like the 2016 rule, does not apply to TRICARE or other Department of Defense programs, or the Federal Employees' Health Benefit Program administered by the Office of Personnel Management.
[2] Hospitals' employee health benefit programs are also subject to the proposed rule.

- State Medicaid and public health agencies.
- Health insurance Exchanges.
- Insurers in the individual (including QHPs sold through the Exchanges), small and large group markets, as well as plans providing third-party administration for self-insured plans and short-term limited duration plans.

Religious exemptions – The proposed rule does not establish a religious exemption to Section 1557, but notes that covered entities could seek an exemption under other federal laws[3] and existing conscience protections.

Employer liability related to employee health benefit programs – Unlike the 2016 rule, the proposed rule does not apply to covered entities' employment practices, including their employee health benefits programs.

Covered entities' assurance of compliance with Section 1557 – Each entity must submit an assurance that its health programs and activities will comply with Section 1557 when applying for federal financial assistance.

Remedial and voluntary action – A covered entity that has been found to have discriminated against an individual on any of the bases prohibited by Section 1557 will be required to take remedial action (as determined by the Director of OCR) to overcome the effects of the discrimination.

- Covered entities' remedial actions must address discrimination that may affect:
  - Individuals who no longer participate in the health program or activity but participated when the discrimination occurred.
  - Individuals who would have participated had the discrimination not occurred.
- Individuals may also sue a covered entity for Section 1557 violations in federal court, restoring a private right to action, which was eliminated by the prior administration.

Covered entities' nondiscrimination policies and procedures – Covered entities with 15 or more employees must:

- Adopt and implement policies and procedures to support compliance with Section 1557 requirements and train staff on those requirements. Policies and procedures must address language access, the provision of auxiliary aids and services, and reasonable modifications for individuals with disabilities.
- Establish grievance procedures to resolve complaints of nondiscrimination violations, designate at least one employee to coordinate Section 1557 compliance efforts, and post a nondiscrimination notice.
  - OCR notes that an individual does not need to exhaust a covered entity's grievance procedure before filing a Section 1557 complaint directly with OCR.
  - Entities must retain records on grievances for three years.

HHS seeks comment on: Privacy concerns or concerns regarding unauthorized use of grievance records as well as best practices for ensuring patient privacy in record retention.

Nondiscrimination Notice Requirement – Covered entities must provide a notice of nondiscrimination to participants, beneficiaries, enrollees and applicants of their programs and to members of the public on an annual basis and upon request. The notice of nondiscrimination may be combined with the content of other notices required by civil rights laws as long as they meet the requirements of Section 1557. The rule specifies the content of the notice.

- The notice must be placed in:
  - A conspicuous location on the entity's or program's website.
  - Clear and prominent physical locations where individuals seeking services will see or hear it (for those who need an auxiliary aid or service).

[3] The rule cites the Religious Freedom Restoration Act, the Weldon Amendment, the Coats-Snowe Amendment, the Church Amendments, Section 1303 of the ACA and the Hyde Amendment.

HHS seeks comments on: The best ways to provide an accessible notice to individuals who may require aids and services for their disabilities and those with LEP.

Notice of availability of auxiliary aids/services and language assistance services – The proposed rule modifies the 2016 requirements related to taglines[4] and requires a covered entity to provide a notice on an annual basis that states, at a minimum, that it provides language assistance services and appropriate auxiliary aids and services free of charge.

- Notice can be provided through written translations, recorded audio or video clips, and must be provided in English and at least the 15 most common languages spoken by LEP individuals in the relevant state or states served.[5]
- The notice of availability must be provided with the following documents:
    - Section 1557 notices of nondiscrimination, HIPAA privacy notices, application, intake and consent forms, and instructions for medical procedures, medical powers of attorney or living wills.
    - Explanation of Benefits; notices of denial or termination of eligibility, benefits or services; notices of grievance and appeals rights.
    - Any communication on eligibility, benefits or services that requires a response from the individual.
    - Communications related to the public health emergency.
    - Discharge papers, complaint forms and patient/member handbooks.
- Covered entities may allow individuals to opt out but must provide communications to those individuals in their primary language in lieu of a notice.

HHS seeks comment on: Whether the notice of availability requirements are practical, as well as the anticipated costs to comply with the requirements.

Equal program access on the basis of sex –The proposed rule clarifies that "on the basis of sex" includes sex stereotypes; sex characteristics, including intersex traits; pregnancy or related conditions;[6] sexual orientation; and gender identity.[7]

- Covered entities cannot:
    - Deny or limit services, including providers' ability to provide services or health insurance coverage based on an individual's assigned sex at birth or gender identity. Payers cannot impose additional cost sharing, exclusions or other coverage restrictions.
    - Apply a policy or practice that treats individuals differently or separates them on the basis of sex.
    - Deny or limit access to gender transition or gender-affirming care or information about that care.
- The rule specifies that gender-affirming care, like all medical care, should follow clinical practice guidelines and professional standards of care, including standards for informed consent.
    - When providing gender-affirming care to minors, informed consent involves discussions among providers, minors and parents or guardians.

HHS seeks comments on:

- Whether it should add specific provisions on pregnancy-related prohibitions in light of the Dobbs Supreme Court decision.

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[4] The 2016 rule required covered entities to notify individuals of the availability of language assistance services in at least the top fifteen languages spoken by individuals with LEP in the state or states served.

[5] OCR plans to provide a sample notice as well as the 15 most common languages for each state.

[6] Includes, but is not limited to, discrimination on the basis of pregnancy, false pregnancy, termination of pregnancy or recovery therefrom, childbirth or related medical conditions. The rule does not include separate provisions on the prohibitions related to pregnancy, relying on Title IX prohibitions instead.

[7] "Gender identity" means an individual's internal sense of gender, which may be male, female, neither or a combination of male and female, and which may be different from an individual's sex assigned at birth. A transgender individual is an individual whose gender identity is different from the sex assigned to that person at birth.

- Whether the rule adequately addresses the forms of discrimination faced by individuals on the basis of sex (including pregnancy, sexual orientation and gender identity).

Meaningful access for individuals with limited English proficiency (LEP) – Covered entities must take reasonable steps to assess and provide meaningful and timely access to programs or activities by individuals with LEP who are eligible to be served, including a parent seeking health services for a child.

- The proposed rule encourages but does not require a language access plan, which was required under the 2016 rule.
- Language assistance services must be provided free of charge, be accurate and timely, and protect the privacy and independent decision-making ability of an LEP individual.
- Services include qualified interpreters and translators, if needed. Machine translation may be used in certain circumstances but must be reviewed by a qualified translator when the information provided is highly complex.
- States may claim Medicaid reimbursement for the cost of interpretation services, either as medical assistance or administration-related expenditures.
- Covered entities cannot:
    - Require an individual to provide their own interpreter.
    - Rely on an accompanying adult or a minor child to interpret or facilitate communication, except temporarily in emergency situations (such as a natural disaster) when the individual requests that the accompanying adult or minor child interpret or facilitate communication.
    - Rely on staff other than qualified bilingual/multilingual staff to communicate with individuals with LEP.
- Covered entities may provide video and audio remote interpreting services using a qualified interpreter if certain standards are met.
- When evaluating compliance with this section, OCR will consider:
    - The nature and importance of the health care activity and communication to the LEP individual.
    - Other relative factors, such as the effectiveness of the covered entity's written language access procedures.

Discrimination against people with disabilities – Covered entities must provide appropriate services to individuals with impaired sensory, manual or speaking skills, including auxiliary aids and service, interpreters and remote interpreting services, telecommunications and telephone emergency services, etc.

- Effective communication – Covered entities must ensure that communications with individuals with disabilities and companions with disabilities are as effective as communications with other individuals in the health programs and activities, as required by the ADA Title II implementing regulations.
- Accessibility standards for buildings and facilities – Buildings and facilities in which health programs and activities are conducted must comply with the 2010 ADA Standards for Accessible Design if construction began on or after July 18, 2016, or if they were not previously covered by the 2010 Standards and construction began after Jan. 18, 2018.
- Accessibility of electronic and information technology – Covered entities must ensure that their health programs and activities provided through electronic and information technology—including through websites, portals and mobile applications—are accessible to individuals with disabilities.
    - When this would create undue financial, administrative or programmatic burden, the entity must provide the information in an alternative format that ensures that individuals with disabilities can receive the benefits and services of the program or activity.
- Reasonable modifications – Covered entities must make reasonable modifications, as required under the ADA, to policies, practices or procedures when necessary to avoid discrimination on the basis of disability, unless they can demonstrate that the modification would fundamentally alter the nature of the health program or activity.

Nondiscrimination in health insurance and other health coverage – The rule prohibits discrimination in the administration or provision of health-related insurance or coverage, including coverage offered in the individual (including short-term limited duration plans), small and large group markets, as well as through Medicaid and CHIP.

- Examples of prohibited discriminatory actions include:
    - Denial, cancellation or refusal to issue or renew a health insurance plan or cover a claim on the basis of an enrollee's race, color, national origin, sex, age or disability.
    - The imposition of additional cost-sharing or other restrictions or exclusions on the basis of an enrollee's race, color, national origin, sex, age or disability, including health services related to gender transition.
    - Discriminatory benefit designs or marketing practices[8] on the basis of an enrollee's race, color, national origin, sex, age or disability.
        - This includes medical management techniques that exclude services related to gender-affirming care on the basis that those services are "experimental."
    - Benefit designs that do not cover care in the most integrated setting appropriate to the needs of an individual with a disability as required under Section 504 and the Olmstead Act.
- Network adequacy – Payers must develop provider networks in a manner that does not discriminate. OCR notes that narrow networks that limit or deny access to care by excluding certain providers that treat high-cost enrollees or require enrollees to go to less experienced providers to receive services would be considered discriminatory. However, OCR notes that network adequacy is regulated by other HHS regulations, in the case of QHPs, and by states. Therefore, OCR asserts that it is outside the scope of Section 1557 for the department to establish uniform or minimum network adequacy standards.
- OCR will evaluate on a case-by-case basis whether a particular design feature or coverage requirement is discriminatory. Where appropriate, OCR will determine if there is a legitimate, nondiscriminatory justification for the particular feature or requirement, but that justification cannot be pretext for discrimination.
- OCR does not propose to restrict payers from applying evidence-based criteria to determine whether health services are medically necessary or using reasonable medical management techniques or applying neutral, nondiscriminatory standards in evaluating coverage for all enrollees.

HHS seeks comments on:

- How Section 1557 might apply to provider networks and how they are developed, including how to ensure that an adequate number of providers and facilities that treat a variety of health conditions are included in the networks; and the way networks limit or deny access.
- How value-based purchasing arrangements might discriminate through utilization management, alternative payment models, formulary design, price negotiation, etc.

Nondiscrimination on the basis of association – The rule prohibits discrimination of someone on the basis of the race, color, national origin, sex, age or disability of an individual with whom that individual has a relationship or association. Examples include:

- A primary care physician cannot refuse to accept a new patient because of the race, color, national origin, age, sex or disability status of one or more of the patient's family members.
- A physician cannot deny a medical appointment to a patient who is an individual without a disability on the basis that they will be accompanied by a family member who is deaf and will require a sign language interpreter.
- A health insurance issuer may not exclude an eligible provider from their network because the provider's clientele is primarily composed of individuals with LEP.

[8] Includes limits and exclusions, drug formularies, cost-sharing policies, utilization management and medical management techniques, provider network design, reimbursement rates to providers, as well as activities that seek to influence individuals' decisions to enroll in a plan or steer individuals to certain types of plans.

Use of clinical algorithms in decision-making – The rule prohibits discrimination through the use of clinical algorithms that are used to guide healthcare decision-making in screenings, risk prediction, diagnoses and prognoses, treatment planning, health care operations and allocation of resources.

- Under the rule, an overreliance on an algorithm violates Section 1557 if a clinical decision stemming from that algorithm is based on, or results in, discrimination.
- Examples of clinical algorithms include flowcharts, complex computer algorithms, decision-support interventions and other models.
- Covered entities are not liable for algorithms they did not create, but must make reasonable changes to a biased algorithm, unless it fundamentally changes the nature of the health program or activity.
- OCR investigations of potentially discriminatory algorithms will consider, among other things:
    - What decisions and actions that were based on an algorithm were taken by the covered entity.
    - What measures the covered entity took to ensure that its decisions and actions based on a clinical algorithm are not discriminatory.

HHS seeks comments on:

- The types of clinical algorithms covered entities use and how they are being used, and whether algorithms are more prevalent in certain health settings.
- The relevant factors that OCR should consider when determining whether a covered entity is in violation of this provision.
- What possible defenses a covered entity may have when using a clinical algorithm that results in discrimination.

Nondiscrimination in the use of telehealth services – The rule prohibits covered entities from discriminating in their delivery of services through telehealth.[9] The rule also requires entities to ensure that telehealth services and platforms are accessible to individuals with disabilities and provide meaningful telehealth access to LEP individuals.

- These requirements apply to all aspects of the provision of telehealth services, including communications about the availability of the services, the process for scheduling appointments, and the telehealth appointment itself.

HHS seeks comments on: Whether more specific regulatory requirements are needed to address accessibility in telehealth services for individuals with disabilities and LEP.

[9] OCR defines telehealth consistent with how it is defined by HRSA: the use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health and health administration. Technologies include videoconferencing, the internet, store-and-forward imaging, streaming media and terrestrial and wireless communications.