HHS Finalizes Section 1557 Nondiscrimination Regulations under the Affordable Care Act

May 9, 2024

The Office of Civil Rights (OCR) at the U.S. Department of Health and Human Services (HHS) together with the Centers for Medicare and Medicaid Services (CMS) released regulations under Section 1557 of the Affordable Care Act (the "Final Rule") on April 26, 2024. These final regulations follow almost two years after the publication of the earlier proposed rule. Updated Frequently Asked Questions were also published by the HHS to provide additional summaries and information on implementing the Final Rule. The regulations are expected to become effective July 5, 2024, 60 days after publication in the Federal Register; however, certain provisions are expected later to account for implementation time.

Background

Section 1557 rules regarding nondiscrimination were originally enacted in 2010 as part of the Affordable Care Act (ACA) to ensure individuals do not face discrimination in terms of participation in or receiving the benefits of any health program or activity that receives federal financial assistance. To this end, Section 1557 incorporated familiar civil rights laws such as Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, and Section 504 of the Rehabilitation Act of 1973.

Interpretations of the scope and reach of the Section 1557 rules have been in flux since 2016, with differing sets of regulations published at different times. The first set of regulations was published in May 2016 (the "2016 Rules") and a number of provisions included in that original publication were later overturned in the additional regulations published in June 2020 (the "2020 Rules").

The Final Rule restores some of the provisions from the 2016 Rules and provides additional clarifications and provisions.

Entities Subject to Section 1557 Final Rule

In general, Section 1557 applies to any health program or activity any part of which receives federal financial assistance. This "financial assistance" includes credits, subsidies, or contracts of insurance from HHS. The precise scope of entities subject to Section 1557 as a result of financial assistance has varied between the different regulations, particularly in terms of applicability to health insurance issuers receiving federal financial assistance.

The 2016 Rules applied Section 1557 to all operations of *any* covered entity that received federal financial assistance if the entity was "principally engaged in health services, health insurance coverage, or other health coverage, even if only part of the health program or activity receives such assistance." The 2020 Rule explicitly carved out health insurers. This was a significant limitation on the applicability of Section 1557 to health insurers only to the extent that the entity's products received federal funding (for example, health exchange products, Medicare, and Medicaid).

The Final Rule reinstates the broader applicability of the 2016 Rules, removing the limiting language in the 2020 Rules that health insurers are not considered to be "principally engaged in the business of providing health care." Therefore, the Section 1557 regulations will generally cover all products a health insurance issuer offered if any products received federal financial assistance.

The scope of Section 1557 applicability was further expanded in the Final Rule in two significant ways:

- The Final Rule includes a notice of interpretation that Medicaid Part B payments will be considered a form of federal financial assistance sufficient to cause an entity to become subject to the Section 1557 regulations.
- Explicitly expanding the scope of the Section 1557 regulations to apply to all health programs and activities of HHS.

Potential Impact of Expanded Scope of Entities Subject to Section 1557

As a result of its expanded scope, the Final Rule poses the potential to expand coverage of Section 1557 to a significant number of entities not previously considered a covered entity. This may impact:

- Insurers offering qualified health plans through the health exchange marketplace, large group market plans, excepted benefit plans, or self-insured group health plans
- Lines of business of third-party administrators (TPAs) if any portion of their business is operated by an insurer subject to Section 1557
- Lines of business of pharmacy benefit managers (PBMs) if any portion of their business is operated by an insurer subject to Section 1557
- Lines of business of TPAs and PBMs that are subrecipients of federal financial assistance
- Insurance agents or brokers if paid by a covered entity (such as an exchange marketplace) with federal financial assistance

An open question remains regarding whether and under what circumstances certain corporate structures (such as being part of an insurance holding company system) or status as an affiliate of a Section 1557 covered entity may render TPAs or PBMs subject to Section 1557. If an entity is not sufficiently independent, its status or affiliation may cover the entity under Section 1557 Final Rules.

Potential Allocation of Liability Between Insurers and TPAs or PBMs

TPAs and PBMs may also find themselves being indirectly subject to Section 1557 via contractual obligations. For example, insurers may be liable for the actions of TPAs and PBMs as the insurer's subcontractor. The insurers, as a result, may seek to have contractual obligations for their subcontractors to comply with Section 1557 requirements.

Since TPAs and PBMs may cause insurers to incur liabilities for violations of Section 1557, and insurers may also cause TPAs and PBMs to incur liability, the OCR has expressed an intent to make assessments of liability on a case-by-case basis in the event of noncompliant activities.

Other Provisions

In addition to the generally expanded scope of Section 1557, the Final Rules address several other issues. These include, but are not limited to:

- Prohibits covered entities from, in delivery of their health programs and activities through telehealth services, discriminating based on race, color, national origin, sex, age, or disability. To comply with the Final Rule, telehealth platforms must be accessible to individuals with disabilities and limited English proficiency. This includes communications before, during, and after the telehealth appointment. There are some limited exceptions to this general requirement.
- Requires nondiscrimination in the use of patient care decision support tools. These patient care decision support tools are any "automated or non-automated tool, mechanism, method, technology, or combination thereof used by a Covered Entity to support clinical decision-making in its health programs or activities." Tools may be used for activities such as screening, diagnosis, treatment planning, risk predictions, and health care operations. Covered entities must make "reasonable efforts" to identify the uses of patient care decision support tools to mitigate risk of discrimination.
- Reinstates protections for pregnant individuals and LGBTQIA+ individuals that have been subject to challenge since the 2016 Rule was published. The Final Rule restores language stating that "sex discrimination" includes discrimination relating to pregnancy, pregnancy-related conditions, and gender identity. There are some limited exceptions and the opportunity for covered entities to seek religious exemptions with the OCR.
- Requires covered entities to take certain actions to build up their Section 1557 compliance program, including:
    - Updating policies
    - Scheduling staff training

- Designating a Section 1557 coordinator
- Posting notices of nondiscrimination
- Posting notices of nondiscrimination availability of language assistance services, auxiliary aids, and other services

Conclusion

The Final Rule results in a significant expansion of what entity may be considered a covered entity under Section 1557, as well as providing for additional expansions of the rule when compared to the reach of the 2020 Rule. As a result, insurers, TPAs, PBMs, insurance brokers, and other entities should review their business models in light of the Final Rule in order to assess whether they will now be covered by Section 1557 and, if so, whether their practices, policies, and products are compliant.