
November 9, 2015

*Submitted via email to Federal eRulemaking Portal: http://www.regulations.gov*

U.S. Department of Health and Human Services
Office of Civil Rights
Attention: 1557 NPRM (RIN 0945-AA02)
Hubert H. Humphrey Building
Room 509F
200 Independence Avenue, SW
Washington, DC 20201

**Re: NPRM – Section 1557 – Nondiscrimination in Health Programs and Activities**

Dear Sir or Madam:

We write on behalf of the American Benefits Council ("Council") to provide comment in connection with the Office for Civil Rights ("OCR"), U.S. Department of Health and Human Services ("HHS") notice of proposed rulemaking ("Proposed Rule") to implement Section 1557 of the Affordable Care Act ("ACA") regarding Nondiscrimination in Health Programs and Activities.

The Council is a public policy organization representing principally Fortune 500 companies and other organizations that assist employers of all sizes in providing benefits to employees. Collectively, the Council's members either sponsor directly or provide services to health and retirement plans that cover more than 100 million Americans.

## INTRODUCTORY COMMENTS

The OCR proposes to apply Section 1557 to all of an issuer's health-related products and services, including when an issuer is acting solely as a third-party administrator ("TPA") for a self-insured employer-sponsored group health plan. While the Council is

supportive of the public policy goals of Section 1557, as well as the underlying federal nondiscrimination statutes, we are concerned that this proposed interpretation represents a serious overreaching by OCR and is contrary to the statutory language of Section 1557, as well as sound public policy. Accordingly, the Council strongly urges OCR to implement Section 1557 in a manner that is consistent with statutory intent and least disruptive to employer-sponsored health coverage.

We also recommend that the final rule incorporate the following comments:

- In determining the scope of Section 1557, OCR should more closely hew any final rule to the statutory language of Section 1557, which expressly limits the application of Section 1557 to those "health programs or activities" with respect to which the covered entity receives federal financial assistance ("FFA"). To the extent that a covered entity is not directly receiving FFA in connection with its TPA services, Section 1557 should not apply.

- Employer group waiver plans ("EGWPs") should be excluded from the scope of Section 1557. These arrangements provide comprehensive and cost-effective prescription drug coverage to retirees and their spouses. To apply Section 1557 to these plans, and possibly to the other benefit plans of the employer sponsor, could create disincentives for establishing and maintaining EGWPs, with the downstream result that American retirees and their families could be left without coverage they have otherwise come to depend upon.

- Final regulations should further clarify requirements for coverage of transgender services. Although the Proposed Rule provides that it does not require any specific benefit coverage for transgender services, it prohibits the categorical exclusions of treatment for gender dysphoria. Further clarity is needed regarding how final rules will apply to coverage for transgender services.

- The Proposed Rule indicates that final rules will be effective 60 days after publication of the final rule. Sixty days provides insufficient time for covered entities – as well as downstream employer plan sponsor clients – to modify coverage terms as needed to comply with new requirements imposed under a final rule. This is, in part, because of the requirement that employers, with respect to their plans, prepare and provide various federally-mandated disclosures and summary documents to participants, such as Summary Plan Descriptions ("SPDs") and Summaries of Benefits and Coverage ("SBCs"). To ensure that employers have sufficient time to modify their plan designs, if needed by reason of Section 1557, the Council urges that the effective date of the final rule be delayed and made applicable no sooner than with respect to the first plan year that begins on or after 12 months following the issuance of the final rule.

- Final regulations should clarify remedies and the enforcement scheme under Section 1557 with respect to requirements for exhaustion of administrative remedies.

**Self-insured employer-sponsored plans that do not receive FFA should not be subject to Section 1557 based on the mere fact that its TPA is also an issuer receiving FFA with respect to other products and services.**

The Proposed Rule applies Section 1557 to "all health programs and activities, any part of which receives FFA administered by HHS; health programs and activities administered by the Department, including the Federally-facilitated Marketplaces; and health programs and activities administered by entities established under Title I of the ACA, including State-based Marketplaces." OCR broadly defines "health program or activity" to include *all of the operations* of an entity principally engaged in providing or administering health services or health insurance coverage.

The preamble to the Proposed Rule specifies OCR's intent that if an issuer is receiving FFA generally, Section 1557 would apply to its services as a TPA for self-insured employer-sponsored group health plans – even if the entity is not receiving FFA with respect to such TPA services. In a footnote to this preamble language,[1] OCR states that, where an entity that acts as a TPA for an employer's employee health benefit plan is legally separate from an issuer that receives FFA for its insurance plans, OCR will engage in a case-by-case inquiry to evaluate whether the entity is appropriately subject to Section 1557; thereby suggesting that in some instances a covered entity's TPA services may not be subject to Section 1557 where the covered entity otherwise receives FFA.

The Council urges OCR to not extend the requirements of Section 1557 to a TPA's administration of a self-insured plan. Applying Section 1557 to such TPA services would be a broad regulatory overreach that is not supported by the statute. The statutory language of Section 1557 clearly limits its application to "any health program or activity, any part of which is receiving Federal financial assistance." The rule should be read to apply to the health program or activity that is receiving the FFA, rather than other health programs or activities of the covered entity for which it is not receiving FFA. Even in light of the longstanding civil rights principles as reiterated by Congress in the Civil Rights Restoration Act of 1987, OCR's proposed interpretation goes too far because it would not only directly regulate the covered entity, but would have the effect of regulating self-insured employer-sponsored plans –plans which are not themselves the recipients of FFA. By extending this rule to self-insured plans through its TPA, OCR has gone beyond the statutory authority provided by Congress.

[1] 80 Fed. Reg. 54172, 54189 (Footnote 73) (September 8, 2015).

The Council has become increasingly concerned about efforts by HHS and other federal agencies to regulate self-insured employer-sponsored plans where Congressional intent evidences otherwise. One earlier example pertains to the ACA maximum out-of-pocket ("MOOP") rules. In connection with certain rulemaking regarding individual and small group insured plans, HHS stated in preamble language that plans would be required to apply an "embedded" individual MOOP to individuals enrolled in a family plan. While existing federal statutes clearly provide the Department of Labor and the Department of the Treasury with the authority to interpret the maximum out-of-pocket requirement as it applies to self-insured plans, not HHS, HHS nonetheless issued this guidance stating that the embedded MOOP requirement applies broadly to all plans, including self-insured plans.[2]

The proposed interpretation by OCR is also contrary to sound public policy. The proposed interpretation creates an incentive for self-insured benefit plans to contract with entities whose TPA services are not subject to Section 1557. This is because, while the employer community supports offering nondiscriminatory benefit designs to employees, the specter of increased litigation risk may cause some employers to use TPAs where there is no risk that Section 1557 could have application (albeit indirectly) to their plans. We are concerned that this potential risk of Section 1557 liability could cause plans to change TPA services, where the employer plan sponsor is otherwise satisfied with the quality and cost of the TPA services it currently engages. Such changes would result in unnecessary administrative cost and burden to the employer plan.

Additionally, as noted above, OCR indicates in a footnote that it will use a case-by-case inquiry to evaluate whether a TPA is subject to Section 1557. We are concerned that this case-by-case inquiry may provide little practical relief for employer plan sponsors. This is because employers need to know with greater certainty when they are contracting with an entity for TPA services whether their plan design could be subject to indirect regulation as a result of the entity's receipt of FFA. Moreover, the proposed framework set forth by OCR would not require a complainant to exhaust administrative remedies prior to bringing a claim in federal court.

As noted below, we strongly urge the establishment of an administrative process that would require a claimant to exhaust administrative remedies prior to bringing a claim to federal court. We believe that such an administrative process is supported by public policy. In the absence of such a process, the use of a case-by-case determination regarding TPA services, such as that set forth in Footnote 73, is unworkable since this could leave the federal judiciary in the role of engaging in the case-by-case determination. As such, the Proposed Rule does not provide TPAs or employers with

[2] OCR establishes this broad policy of extending Section 1557 to a TPA's administration of a self-insured plan in Preamble language, rather than in the proposed regulation. By only making this reference to TPA services in the Preamble, OCR is regulating by preamble and regulating in a manner that is not transparent and clear to the regulated community.

sufficient information or certainty for them to understand when and how Section 1557 will apply to the TPA services.

**Employer group waiver plans ("EGWPs") should be excluded from the scope of Section 1557.**

Many employers currently sponsor employer group waiver plans ("EGWPs") for the benefit of their retirees and spouses. Generally, an EGWP is a Medicare Part D prescription drug plan. There are most commonly two types of EGWPs. The first type is often referred to as a "direct-contract" EGWP. The employer or plan contracts directly with Center for Medicare and Medicaid Services ("CMS") to provide the drug benefits and it receives payments directly from the government. The employer very often partners with a TPA or pharmacy benefit manager to help administer the benefits. The second type of EGWP is commonly referred to as a "Series 800" EGWP. Under this latter type, the drug benefit is insured by a third-party carrier and the insurer is liable for providing the benefits under a contract with CMS. The insurer receives payments directly from the federal government.

The Council is concerned about the potential application of Section 1557 to employers that sponsor EGWP plans. EGWPs are an important means by which employers provide drug coverage to their retirees and spouses. And the resulting coverage is typically offered at reduced costs to retirees. To the extent Section 1557 were made applicable to EGWPs and/or their plan sponsors, it could result in disincentives for employers to offer such plans. This is not because employers seek to offer discriminatory Part D coverage, but rather, because of the potential for increased litigation risk. Accordingly, we urge that all EGWPs be excepted from the scope of Section 1557. In support, we note that Congress could not have intended that employers would become subject to Section 1557 merely for sponsoring a retiree drug benefit for their retirees and spouses. Rather, we believe Congress was singularly concerned with applying Section 1557 to those entities that receive material FFA as a result of the enactment of the ACA, specifically with respect to "on-exchange" individual insurance. To construe Section 1557 to now apply to EGWPs – whether a direct contract or Series 800 EGWP – betrays common sense and for the reasons noted above, is contrary to public policy.

In the alternative, the Council requests that clarification be provided as part of any final rulemaking that employers that sponsor a Series 800 EGWP will not be subject to Section 1557. This should be without controversy given that the payments from the federal government are received by the insurer of the drug benefit directly and not the plan itself or the employer plan sponsor. Such treatment should be permitted regardless of any contractual arrangement that the insurer may have with the downstream employer plan or plan sponsor.

**Clarity is needed regarding the scope of the rule regarding transgender services.**

The Proposed Rule prohibits certain practices relating to transgender coverage. Specifically, the Proposed Rule would bar a covered entity from denying or limiting coverage, or denying a claim for coverage, for specific health services related to gender transition where such a denial or limitation results in discrimination against a transgender individual. In addition, under the Proposed Rule, an explicit, categorical (or automatic) exclusion of coverage for *all health services related to gender transition* is prohibited.

The Proposed Rule also states that Section 1557 does not, however, affirmatively require covered entities to cover any particular procedure or treatment for gender transition-related care; nor does it preclude a covered entity from applying neutral standards that govern the circumstances in which it will offer coverage to all its enrollees in a nondiscriminatory manner. In evaluating whether it is discriminatory to deny or limit a request for coverage of a particular service for an individual seeking the service as part of gender transition-related care, OCR noted that it will start by inquiring whether and to what extent coverage is available when the same service is not related to gender transition. Finally, the Proposed Rule clarifies that it is not intended to determine, or restrict a covered entity from determining, whether a particular health care service is medically necessary or otherwise meets applicable coverage requirements in any individual case.

Although the Proposed Rule clearly prohibits a complete exclusion of transgender services, there is uncertainty as to what limits, if any, may be applied to such coverage. In fact, the statement that "the rule does not require any particular benefit or service" is confusing in light of the prohibition of an explicit exclusion of coverage for all health services related to gender transition. Final regulations should further clarify and provide examples of what would be considered discriminatory practices so that covered entities, including issuers that provide TPA services to an employer-sponsored self-insured plan, have direction as to how to comply with these new requirements.

**The effective date of any final rule should apply no sooner than plan years beginning on or after 12 months following issuance.**

The Proposed Rule indicates that final rules will be effective 60 days after the publication of the final rule. OCR should adjust the effective date to allow additional time for covered entities, or entities indirectly impacted by the rule, to comply with the rule. In rulemaking relating to the ACA, the various agencies responsible for implementation have recognized the practical considerations involved in complying with new requirements, and have issued delayed effective dates to provide the regulated community sufficient time to come into compliance. Moreover, 60 days is not nearly enough time for covered entities – as well as for any affected downstream

employer plan sponsor clients – to modify coverages to comply with these new requirements. To ensure that employers have sufficient time to modify their plan designs, if needed by reason of Section 1557, we recommend that the effective date of the final rule apply no sooner than the first plan year that begins on or after 12 months following the issuance of the final rule.

**Clarity is needed regarding the remedies and enforcement scheme that applies for purposes of Section 1557.**

Under the Proposed Rule, the enforcement mechanisms under Title VI, Title IX, Section 504 or the Age Discrimination Act apply for violations of Section 1557. The enforcement mechanisms provided for and available under the civil rights laws in the event of noncompliance includes suspension of, termination of, or refusal to grant or continue FFA; referral to the Department of Justice with a recommendation to bring proceedings to enforce any rights of the United States; and any other means authorized by law. There is a private right of action, and damages for violations of Section 1557 are available to the same extent that such enforcement mechanisms are provided for and available under Title VI, Title IX, Section 504 or the Age Discrimination Act with respect to recipients of FFA.

The Proposed Rule is unclear with respect to administrative exhaustion for claims other than age discrimination. The enforcement mechanisms in place for race, sex and disability claims do not explicitly reference administrative exhaustion. Final regulations should clarify the enforcement scheme available under Section 1557 and adopt exhaustion requirements for all claims brought under Section 1557, similar to the exhaustion for age discrimination claims. Administrative exhaustion is critical given the several facts and circumstances and case-by-case analyses referenced in the Proposed Rule, which by their nature do not provide certainty for the regulated community. These types of facts and circumstances tests are reasonable in an enforcement scheme that includes administrative exhaustion, but to the extent OCR does not require administrative exhaustion, these case-by-case inquiries create significant liability for plans. Requiring administrative exhaustion is an efficient approach to enforcement for all parties.

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Thank you for considering these comments submitted in response to the Proposed Rule. If you have any questions or would like to discuss these comments further, please contact me at (202) 289-6700.

Sincerely,

Kathryn Wilber
Senior Counsel
Health Policy