**Regulatory Update June 2019**

**Final Rule Conscience Rule, NPRM - ACA Nondiscrimination in Health and Health Education Programs or Activities (including Taglines and LEP Section 1557 and BA Liability Fact Sheet**

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Final Rule - Protecting Statutory Conscience Rights in Health Care; Delegations of Authority – May 2019

Final Rule copy in PrivacyPro: <https://library.privacyprosolutions.com/doc/dyYtXTQneMHM>

Commentary from Fierce Healthcare

<https://www.fiercehealthcare.com/payer/trump-administration-proposes-rollback-transgender-healthcare-protections?mkt_tok=eyJpIjoiTmpFM016RXlPVFZtTTJRMiIsInQiOiJNZGVqUXBjK2JZZmVmNk5qcjArVzhVSTBcL3BIOVR0WVF4bmRwVEhLTE8reXVEWU5xUVdMMnFcL1N1eGNWS3dcL2tPbm9KMDkxQlloYzN0aDg4WjI0Y2VUdlhXWjg3SXo1RzQ5Nkd5eEhoTk10ZFB0d2dXUjNwNUlFdHhoUmM0Y0h1biJ9&mrkid=66948425>

This final rule revises existing regulations to ensure vigorous enforcement of Federal Conscience and Anti‐discrimination laws applicable to the Department, its programs, and recipients of HHS funds, and to delegate overall enforcement and compliance responsibility to the Department’s Office for Civil Rights (“OCR”)

In addition, this final rule clarifies OCR’s authority to initiate compliance reviews, conduct investigations, supervise and coordinate compliance by the Department and its components, and use enforcement tools otherwise available in existing regulations to address violations and resolve complaints

In order to ensure that recipients of Federal financial assistance and other Department funds comply with their legal obligations, this final rule requires certain recipients to maintain records; cooperate with OCR’s investigations, reviews, or other proceedings; and submit written assurances and certifications of compliance to the Department

The final rule also encourages the recipients of HHS funds to provide notice to individuals and entities about their right be free from coercion or discrimination on account of religious beliefs or moral convictions

This Final Rule has been enjoined by a lawsuit from several states

Kelly Commentary from Final Rule read through:

* 60 days from publication in Federal register implementation period for Conscious and Anti-Discrimination Laws
* Fact sheet exists
* 12 FTEs for OCR to enforce $3M per year
* Applies to recipients of federal funds only
* §88.1 Pg 395 list of definitions
* OCR has the right to investigate and enforce reviews and uses compliance as a factor
* Conscious Rule Update policy and procedure in accordance with §88.4
* No mention of HIPAA
* Modify antidiscrimination notice language and training - OCR will take this into account as it’s not mandatory
* Pg 210 - 223 – record keeping – 3 years
* Use current record keeping for federal funding requirements
* Pg 221 May be liable for subs behavior
* Compliance review based on compliance or other source leads where OCR suspects non-compliance
* Dept (OCR) will try for voluntary resolutions
* Pg 439 has model notice language
* Implementation costs based upon these steps in §88.5
  + Familiarization
  + Assurance and certification
  + Voluntary actions to provide
    - Notice of Rights
    - Post and Distribute Notice
    - Methods
      * Physical Locations
      * On Website
      * Publications: Personnel or other workforce manuals and student handbooks
      * Or Document member participation
      * Can be electronic notice only since it’s voluntary
* Reporting a notice of non-compliance only by OCR determining non-compliance
* 3-year period disclosed in finding application
* Voluntary remediation efforts – put grievance plan in place and OCR will look favorably
* Intimidation and retaliatory acts prohibited

NPRM - Proposed Rule – Nondiscrimination in Health and Health Education Programs or Activities

On May 25, 2019 OCR issued a Proposed Rule impacting: 42 CFR Parts 438, 440, and 460; 45 CFR Parts 86, 92, 147, 155, and 156 called:

“Section 1557 of the ACA…In 2016, HHS issued a new rule that redefined discrimination "on the basis of sex" to include termination of pregnancy and gender identity which it defined as one's internal sense of being "male, female, neither, or a combination of male and female."

“subsequent lawsuit by several states and healthcare entities…a federal court preliminarily enjoined the rule's gender identity and termination of pregnancy provisions on a nationwide basis, finding them contrary to the applicable civil rights law, the Religious Freedom Restoration Act, and the Administrative Procedure Act. A second federal court agreed.

Because the preliminary injunction continues to be in effect, HHS cannot, and has not since the date of the injunction, enforced the rule's provisions the court said are likely unlawful. The proposed rule would revise the provisions subject to those injunctions to conform with the plain understanding recognized by the court…”

"When Congress prohibited sex discrimination, it did so according to the plain meaning of the term, and we are making our regulations conform," said OCR Director Roger Severino…revising certain provisions of the current Section 1557 rule that a federal court has said is likely unlawful

“The proposal also would relieve the American people of approximately $3.6 billion in unnecessary regulatory costs over five years.”

Click to read the Proposed Regulation on Section 1557 – <https://library.privacyprosolutions.com/doc/Rf6YMd7MoKLk>

Click to read the proposed regulation Factsheet on Section 1557 - <https://library.privacyprosolutions.com/doc/ncBLMP5U26sM>

Commentary Per Lexology June, 01, 2019 - HHS Proposes Eliminating Mandatory Notices, Gender Identity Protections From Nondiscrimination Rules - [McGuireWoods LLP](https://www.lexology.com/contributors/mcguirewoods-llp) – May 30th, 2019

<https://www.lexology.com/library/detail.aspx?g=3019ee66-2f1d-4de7-93e1-1f0580d775c8&utm_source=lexology+daily+newsfeed&utm_medium=html+email+-+body+-+general+section&utm_campaign=lexology+subscriber+daily+feed&utm_content=lexology+daily+newsfeed+2019-06-03&utm_term=>

On May 24, the U.S. Department of Health and Human Services Office for Civil Rights issued a [proposed rule](https://www.hhs.gov/sites/default/files/1557-nprm-hhs.pdf) reversing certain provisions of its [2016 rule](https://www.govinfo.gov/content/pkg/FR-2016-05-18/pdf/2016-11458.pdf) prohibiting certain forms of discrimination under Section 1557 of the Affordable Care Act. Section 1557, incorporating other civil rights laws, “prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities.” The proposed rule would remove certain mandatory notice and tagline requirements for individuals with limited English proficiency (LEP), eliminate gender identity and termination of pregnancy from the definition of “sex discrimination,” clarify protections for certain conscience-based objections and revise OCR’s enforcement mechanisms.

HHS stated the proposed rule seeks to align its regulations with recent court rulings with respect to sex discrimination. Furthermore, as highlighted in the [factsheet accompanying the proposed rule](https://www.hhs.gov/sites/default/files/factsheet-section-1557.pdf), HHS sought to reduce approximately $3.6 billion in unnecessary regulatory costs over five years. The following outlines the major proposed changes to the ACA nondiscrimination regulations.

**1. Eliminate Mandatory Nondiscrimination Notices**

As discussed in a [prior McGuireWoods alert](https://www.mcguirewoods.com/client-resources/Alerts/2016/10/Healthcare-Providers-Must-Post-Nondiscrimination-Notice), beginning in 2016, most healthcare providers and other entities covered under the regulations must publish and disseminate nondiscrimination notices, including disclosures for language assistance services for LEP individuals. Entities covered under this rule include those operating a health program or activity receiving, even in part, federal financial assistance (including Medicaid, Medicare Part A but not Part B, Medicare Advantage and meaningful use payments) and entities established under Title I of the ACA administering a health program or activity. For such covered entities, the required notices must meet several criteria, and include a tagline in at least 15 non-English languages describing the entity’s ability to provide free language assistance services. Such nondiscrimination notices and taglines must be distributed in all “significant communications and significant publications” to patients and customers.

According to HHS, those required to provide notice have reported that this rule required such entities to send “billions” of notices in aggregate each year, and HHS estimates that the cost of this requirement is $3.2 billion over a five-year period. Furthermore, HHS reports that the rule has not had a meaningful impact on language access since 2016, specifically suggesting that many providers have not been providing this notice. Therefore, the proposed rule would eliminate the requirement for entities to send notice and tagline inserts in communications to patients and customers.

**2. Allow Providers to Balance Four Factors to Determine Whether Language Assistance Services Are Required for LEP Patients**

Under the 2016 rule, most healthcare providers and other covered entities are required to take reasonable steps to provide LEP individuals with meaningful access to services, including language assistance. OCR proposes revising this regulatory text to require providers to take reasonable steps to ensure meaningful access, and added a four-factor balancing test to determine whether the provider is meeting this requirement.

The four factors are: (1) the number or proportion of LEP individuals the provider is likely to encounter; (2) the frequency with which LEP individuals receive services; (3) the nature and importance of the entity’s health program, activity or service; and (4) the resources available to the entity and costs of the services. Once a provider determines that language assistance services are required under this four-factor test, OCR would maintain the requirements surrounding the language assistance services that must be offered free of charge, required qualifications for bilingual or multilingual staff, translators and interpreters to assist and the limitations on requiring a patient’s family to assist. OCR also clarified that remote audio interpretation will be acceptable for LEP individuals, whereas video connection may be more appropriate for deaf individuals.

**3. Eliminate Gender Identity and Termination of Pregnancy From the Definition of “Sex Discrimination”**

As discussed above, Section 1557 directs HHS to apply existing civil rights laws and regulations to healthcare providers and ACA exchanges, including Title IX prohibitions on discrimination on the basis of sex. The 2016 rule defines discrimination “on the basis of sex” to include gender identity, or an individual’s “internal sense of gender, which may be different from an individual’s sex assigned at birth” that “may be male, female, neither, or a combination of male and female.” *See*45 C.F.R. 92.4. The 2016 rule also includes “termination of pregnancy” and “sex stereotyping” under the definition of discrimination “on the basis of sex.”

The proposed rule would eliminate gender identity, sex stereotyping and termination of pregnancy from the definition of sex discrimination, stating that such definitions are inconsistent with various federal rulings imposing an injunction on the 2016 rule, the Religious Freedom Restoration Act (RFRA) and the Administrative Procedure Act (APA).

**4. Implement Protections for Conscience-Based Objections**

HHS acknowledges that protections already exist in federal law with respect to religious beliefs (i.e., RFRA and ACA provisions related to abortion services), but that such references were not included in the 2016 rule prohibiting discrimination in federal healthcare programs.

OCR proposes to incorporate such protections in its updated regulation by reference to the statutes concerning religious and abortion exemptions. The purpose of explicitly incorporating such federal laws is to bring greater clarity to the law, similar to the references to race, color, national origin, sex, age or disability discrimination prohibitions. This provision explicitly references Section 1553 of the ACA (prohibiting discrimination for those that do not provide assisted suicides), RFRA, the Weldon and Coats-Snowe Amendment prohibiting government entities from discrimination against healthcare providers who do not perform abortions, the Church Amendments (conscience protections for providers), and related conscience provisions in appropriations law (e.g., Consolidated Appropriations Act of 2019).

**5. Revise OCR’s Enforcement Mechanisms**

The proposed rule attempts to simplify OCR’s enforcement structure to avoid legal confusion and challenge. As discussed, Section 1557 applies multiple civil rights statutes to the healthcare setting. In the 2016 rule, OCR included a single enforcement structure for every type of discrimination claim. HHS proposes to return to the enforcement structure for each underlying civil rights statute instead of using the single structure, since courts have split on whether the new mechanism is appropriate or whether it deviated inappropriately from longstanding civil rights regulations.

Furthermore, for non-healthcare providers, such as insurance companies, HHS would revise the rules to apply Section 1557 nondiscrimination standards only to programs funded by HHS. For instance, HHS provides the example of short-term limited duration insurance, which would not have to comply with the rule because such insurers are not principally engaged in the business of healthcare, and those specific plans do not receive federal financial assistance, even if the insurer sells other HHS-funded insurance programs.

Kelly Commentary:

* ACA 1557 Programs and Entities based 200+ pages
* Non-discrimination entities that provide healthcare coverage or health insurance
* Pending appeal per District Court challenges on use of the word ‘sex’ in nondiscrimination – 2016 District Court issued injunction
* The NPRM Giveth and Taketh away from patient and provider rights and responsibilities:
  + Taketh Away: Eliminate Mandatory Nondiscrimination Notice
  + Taketh Away: New test to determine whether Language Assistance Services are required for LEP Patients
    - Once a provider determines that language assistance services are required under this four-factor test, OCR would maintain the requirements surrounding the language assistance services that must be offered free of charge, required qualifications for bilingual or multilingual staff, translators and interpreters to assist and the limitations on requiring a patient’s family to assist. OCR also clarified that remote audio interpretation will be acceptable for LEP individuals, whereas video connection may be more appropriate for deaf individuals.
    - 4 factor Test:
      * (1) the number or proportion of LEP individuals the provider is likely to encounter;
      * (2) the frequency with which LEP individuals receive services;
      * (3) the nature and importance of the entity’s health program, activity or service; and
      * (4) the resources available to the entity and costs of the services.
  + Taketh Away: Eliminate Gender Identity and Termination of Pregnancy from Definition of Sex Discrimination
  + Giveth: Implement Protections for Conscious Based Objections
* Pg 59 when can be replaced
* Retains obligation to submit compliance on LEP (Limited English Proficiency)
* Pg 14 repeals provision related to mandatory notices of non-discrimination and availability of language assistance in 15 languages (Taglines)for every significant publication or communication larger than a postcard or brochure
* Prohibits discrimination based on sex but not gender identity or natural sense of identity rather than as born male or female
* Pg 62 descriptions
* Pg 80 4 factor LEP service determination
* Pg 116 Does not bar covered entities from choosing to grant protections for sexual orientation or gender identity that are not in conflict with any Federal law
* LEP (translators) can be audio only except as required by ADA for disabled where video is required
* Proposed rule Pg 179 Nondiscrimination and Taglines
* Pg 187 Must take reasonable steps for LEP 4 factor, section on disabilities, standards for buildings, eliminates tagline requirements

ACA 1557 calls for entities to have “significant documents” translated in at least 15 languages

"We are committed to full enforcement of civil rights laws before, during, and after any rulemaking," said Severino. "We are also committed to the elimination of regulations that contradict law or raise the costs of healthcare without achieving intended results

Removing Costly and Unnecessary Regulatory Burdens The proposed revisions would eliminate $3.2 billion in unneeded paperwork burdens imposed by the 2016 rule. Covered entities report that the 2016 rule requires them to send billions of "tagline" notices each year informing patients and customers of their ability to have "significant documents" translated in at least 15 languages.

When HHS adopted the 2016 rule, it projected notice and taglines costs of about $7.2 million in the first five years. Because the 2016 rule did not fully account for printing and mailing costs associated with these notices and taglines, it underestimated the burden of these requirements by over three billion dollars over five years

Instead of requiring regulated health companies to mail billions of paper taglines to mostly English speakers, the money saved could be used to more effectively address individual needs of non-English speakers such as by providing increased access for translators and interpreters

The proposed Section 1557 rule estimates an additional savings of approximately $400 million over five years by eliminating duplicative requirements and reverting to well-established language access guidance, resulting in a total savings of approximately $3.6 billion in the first five years after finalization

New Business Associate (BA) Liabilities Explained in FAQ Sheet

New HHS Fact Sheet on Direct Liability of Business Associates under HIPAA

On May 24, issued May 25, 2019, see the link below for the Fact Sheet

<https://library.privacyprosolutions.com/doc/Rf6YMd7MoKLk>

“…OCR has issued a new fact sheet that provides a clear compilation of all provisions through which a business associate can be held directly liable for compliance with certain requirements of the HIPAA Privacy, Security, Breach Notification, and Enforcement Rules…under (HITECH) Act of 2009”. And the 2013 Omnibus Rules…

"As part of the Department's effort to fully protect patients' health information and their rights under HIPAA, OCR has issued this important new fact sheet clearly explaining a business associate's liability," said OCR Director Roger Severino. "We want to make it as easy as possible for regulated entities to understand, and comply with, their obligations under the law."

OCR has authority to take enforcement action against business associates only for those requirements and prohibitions of the HIPAA Rules that appear on the following list

1. Failure to provide the Secretary with records and compliance reports; cooperate with complaint investigations and compliance reviews; and permit access by the Secretary to information, including protected health information (PHI), pertinent to determining compliance

2. Taking any retaliatory action against any individual or other person for filing a HIPAA complaint, participating in an investigation or other enforcement process, or opposing an act or practice that is unlawful under the HIPAA Rules

3. Failure to comply with the requirements of the Security Rule

4. Failure to provide breach notification to a covered entity or another business associate

5. Impermissible uses and disclosures of PHI

6. Failure to disclose a copy of electronic PHI to either the covered entity, the individual, or the individual's designee (whichever is specified in the business associate agreement) to satisfy a covered entity's obligations regarding the form and format, and the time and manner of access under 45 C.F.R. §§ 164.524(c)(2)(ii) and 3(ii), respectively” … Will there be ROI company impact due to Patient Access mess?

7. Failure to make reasonable efforts to limit PHI to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request

8. Failure, in certain circumstances, to provide an accounting of disclosures

9. Failure to enter into business associate agreements with subcontractors that create or receive PHI on their behalf, and failure to comply with the implementation specifications for such agreements

10. Failure to take reasonable steps to address a material breach or violation of the subcontractor's business associate agreement

Kelly commentary:

* BAs better watch out! OCR means business
* Also there is language at the bottom of the list that may or may not indicate enforcement clarification for patient access request complaint enforcement, I’m unsure as I’m not an attorney.