

MEMORANDUM

To: CPR Coalition
From: Peter Thomas and Michael Barnett
Date: June 11, 2024
Subject: Summary of Final Rule of Section 1557 of the Affordable Care Act

On April 26, 2024, the U.S. Department of Health and Human Services (“HHS”) Office of Civil Rights (“OCR”) issued a long-awaited Final Rule that will substantially replace the current rules implementing Section 1557 of the Affordable Care Act (“ACA”), which prohibits discrimination on the basis of race, color, national origin, disability, age, and sex.¹ The final rule is long and detailed, and is consistent with the recent final rule on Section 504 of the Rehabilitation Act of 1973, as amended. These two major final rules, coupled with the Department of Justice’s recent regulation on website and information technology accessibility materially advance legal protections in health care for people with disabilities.

The ITEM Coalition submitted comments on the proposed rule in October 2022, and we are pleased that the Biden Administration has taken steps under this Final Rule to restore and strengthen civil rights protections for individuals consistent with the plain meaning of the statutory text of the Affordable Care Act. The previous version of this rule, issued in 2020, covers fewer programs and services and offers limited nondiscrimination protections for individuals. This Final Rule applies to health programs or activities that receive HHS funding, health programs or activities administered by HHS (such as the Medicare Part D program), and the health insurance Marketplace (and all plans offered by issuers that participate in those Marketplaces that receive Federal financial assistance).

This memorandum will focus on the finalized policies that impact the implementation and enforcement of Section 1557’s prohibition of discrimination on the basis of disability.

Background on Section 1557 of the ACA

Section 1557 applies to any health program or activity that receives Federal financial assistance, any program or activity that is administered by an executive agency under Title I of the ACA, and any entity established under Title I of the ACA.² This provision prohibits discrimination on

¹ Nondiscrimination in Health Programs and Activities (hereinafter the “Final Rule”), currently available at: <https://www.federalregister.gov/public-inspection/2024-08711/nondiscrimination-in-health-programs-and-activities>.

² Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1557, 124 Stat. 119, 260 (2010) (codified at 42 U.S.C. § 18116).

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any grounds prohibited by the following statutes, including:³

- Title VI of the Civil Rights Act of 1964 (race, color, and national origin);⁴
- Title IX of the Education Amendments of 1972 (sex);⁵
- The Age Discrimination Act of 1975 (age);⁶ and
- Section 504 of the Rehabilitation Act of 1973 (disability).⁷

On May 18, 2016, HHS finalized its first set of regulations implementing Section 1557 at 45 C.F.R. Part 92.⁸ Several states and religiously-affiliated health care organizations subsequently filed lawsuits challenging certain aspects of the regulations, particularly the prohibition of discrimination on the basis of gender identity and termination of pregnancy—this litigation is ongoing.⁹ In June 2020, the Trump Administration revised the Rule and posted it in the Federal Register “with preamble language that was inconsistent with the Supreme Court’s *Bostock* Opinion,” which held that discrimination based on sexual orientation and gender identity constitute discrimination under Title VII.¹⁰ Several litigants challenged aspects of the regulation, and those lawsuits are currently stayed pending the Department’s review of the 2020 Rule.¹¹ In 2022, HHS proposed to revise the 2020 Rule to reinstate regulatory protections consistent with the statutory text of Section 1557 and Congressional intent, although the proposed rule also addressed other aspects of the regulations.¹²

Change in Interpretation on Section 1557 Applicability to Medicare Part B

- **Proposed Rule:** HHS’s longstanding position has been that Medicare Part B funding does not meet the definition of “Federal financial assistance” for purposes of title VI, title IX, section 504, the Age Discrimination Act, and section 1557 of the ACA.¹³ In the 2022 Section 1557 proposed rule, HHS proposed to change that position after evaluating the Part B program and the definition of “Federal financial assistance,” such that Part B funds will be considered Federal financial assistance when received by providers and suppliers. HHS sought comment on the impact that this change in position may have on recipients that receive only by Part B funds but do not receive any other form of Federal financial assistance from HHS. HHS also invited comment on the amount of time that should be

³ *Id.*

⁴ 42 U.S.C. § 2000d *et seq.*

⁵ 20 U.S.C. § 1681 *et seq.*

⁶ 42 U.S.C. § 6101 *et seq.*

⁷ 29 U.S.C. § 794.

⁸ Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,376 (May 18, 2016).

⁹ See *Franciscan All., Inc. v. Becerra*, 553 F. Supp. 3d 361 (N.D. Tex. 2021), *amended*, No. 7:16-cv-00108-O, 2021 WL 6774686 (N.D. Tex. Oct. 1, 2021), *appeal pending*, No. 21-11174 (5th Cir. Nov. 21, 2021); *Religious Sisters of Mercy v. Azar*, 513 F. Supp. 3d 1113 (D.N.D. 2021), *judgment entered sub nom. Religious Sisters of Mercy v. Cochran*, No. 3:16-cv-00386, 2021 WL 1574628 (D.N.D. Feb. 19, 2021), *appeal pending*, No. 21-1890 (8th Cir. April 20, 2021) (oral argument held Dec. 15, 2021).

¹⁰ Proposed Rule at 47,827.

¹¹ *Id.*

¹² *Id.* at 47,828.

¹³ 81 FR 31375, 31383 (May 18, 2016)

allowed for recipients of Part B funds to come into compliance with the applicable statutes and their implementing regulations.

- **Rehabilitation Stakeholder Comment:** Stakeholder feedback on this proposal was mixed. Some commenters objected to the proposal, claiming that interpreting Part B as meeting the definition of “Federal financial assistance” would reduce access to care because forcing these providers to implement new requirements would discourage them from participating in federally funded health care programs. Other commenters were supportive of proposed change in interpretation. Supporting commenters noted that because funds received under Medicare Part A and Part B are fundamentally similar and Medicare Part A payments have long been considered Federal financial assistance, it is reasonable for HHS to similarly consider Part B payments as Federal financial assistance. Therefore, the commenters argued, considering Part B payments to be Federal financial assistance would allow individuals with disabilities additional options to bring discrimination claims against discriminatory conduct in all health care settings.
- **Final Rule:** HHS is finalizing this proposed change in interpretation without modification. HHS agreed with commenters that because Part B payments, like those of Medicare Part A, are Federal funds directly or indirectly received by providers, they squarely meet the definition of “Federal financial assistance.” HHS states that this position provides uniformity across the various Parts of the Medicare program, but also ensures that HHS is applying the definition of “Federal financial assistance” consistently across all federally funded programs. HHS believes that because many recipients of Part B funds are already recipients of some other form of Federal financial assistance, this change will not impose excessive burdens on those covered entities. HHS also acknowledges that recipients will require time to come into compliance as a result of this change in position. Therefore, while the revised interpretation is effective upon publication in the Federal register, the new regulatory interpretation will have a one-year delayed applicability date. As such, compliance by entities whose Federal program participation has been limited to Part B must be in compliance with title VI, title IX, section 504, the Age Act, and section 1557 no later than May 6, 2025.

Ensuring the Availability of Accessible Medical Diagnostic Equipment

- **Proposed Rule:** HHS solicited feedback regarding whether existing standards developed by the U.S. Access Board on accessible medical diagnostic equipment (“MDE”) should be incorporated as an enforceable standard for covered entities under Section 1557, and whether lack of access to accessible MDE constituted discriminatory benefit design or network inadequacy.
- **Rehabilitation Stakeholder Comment:** Stakeholders strongly encouraged OCR to incorporate the Access Board’s standards as a requirement for entities covered under Section 1557, and to standardize these requirements across other areas of the Department’s regulatory scope. Stakeholders also urged OCR to ensure that the Section 1557 regulations consider the full range of medical equipment that must be made accessible, including at-home diagnostic tools, telehealth equipment, and other equipment frequently used in the health care setting.

- **Final Rule:** On September 14, 2023, OCR issued a proposed rule to update HHS’s section 504 regulations.¹⁴ In that proposed rule, OCR proposed specific accessibility standards, scoping requirements, and time periods for compliance for MDE used by recipients of Federal financial assistance. Accordingly, while OCR recognizes the importance of ensuring that all people, regardless of disability status, receive effective preventative care, OCR has decided to not address the MDE Standards in regulatory text of this Section 1557 Final Rule. OCR will continue to enforce existing nondiscrimination obligations and will adopt enforceable standards for accessible MDE under Section 504.

Accessibility of Information and Communication Technology for Individuals with Disabilities

- **Proposed Rule:** In the proposed rule, OCR sought comment on several proposals relating to accessibility of information and communication technology (“ICT”) for people with disabilities. ICT is defined as information technology and other equipment, systems, technologies, or processes, for which the principal function is the creation, manipulation, storage, display, receipt, or transmission of electronic data and information, as well as any associated content. Examples of ICT include, but are not limited to: computers and peripheral equipment; information kiosks and transaction machines; telecommunications equipment; telehealth interfaces or applications; customer premises equipment; multifunction office machines; software; mobile applications; websites; videos; and electronic documents.

The current iteration of the Section 1557 regulations require covered entities to ensure that “their health programs and activities provided through ICT are accessible to individuals with disabilities,” a requirement that OCR proposed to maintain with redesignation. Covered entities under Section 1557 are thus already required to provide accessible ICT unless such provision would result in undue burden or a fundamental alteration of their programs (in such cases, covered entities must then provide reasonable accommodations to ensure that individuals with disabilities can receive the benefits of the program or activity to the maximum extent possible). OCR also proposed to apply these existing requirements applicable to websites to mobile applications as well.

- **Rehabilitation Stakeholder Comment:** Stakeholders urged OCR to include specific, clear, and enforceable ICT accessibility and usability standards in the Section 1557 regulations that align with widely accepted standards that already exist for other entities, such as the Access Board’s Section 508 standards and the international Web Content Accessibility Guidelines (“WCAG”) 2.1 Levels A and AA. Stakeholders referenced that these standards, developed by the international standards body of the Worldwide Web Consortium (“W3C”), are regularly evolving through an expert stakeholder development and consensus process. Stakeholders encouraged OCR to develop regulatory language clarifying that compliance should relate to the currently accepted version of WCAG as well as successor standards as they are finalized and published. Further, stakeholders encouraged OCR to ensure that the regulations continue to make clear that ICT encompasses not only websites, but mobile applications, online systems, and other forms

¹⁴ 88 FR 63392 (September 14, 2023)

of ICT – all of which should be made accessible to individuals with disabilities. Lastly, stakeholders urged OCR to establish and communicate to covered entities clear consequences for failure to comply with and implement these accessibility requirements.

- **Final Rule:** Under the Final Rule, OCR has decided not to adopt specific accessibility standards or a safe harbor at this time. This is in part due to OCR and the Department of Justice recently publishing separate final rules addressing section 504 and title II of the ADA, respectively. These final rules require that recipients of Federal financial assistance and public entities must ensure that their web content and mobile applications comply with set accessibility standards. In this Final Rule, OCR continues to require covered entities to ensure that health programs and activities provided through ICT are accessible to individuals with disabilities sufficient to provide equal access to the health program or activity, unless doing so would impose undue financial and administrative burdens or would result in a fundamental alteration in the nature of the entity’s health program or activity. OCR strongly encourages covered entities that offer health programs and activities through ICT to incorporate current WCAG standards as they take steps to ensure that those programs and activities comply with requirements of this regulation and other Federal civil rights laws.

Meaningful Access for Individuals with Limited English Proficiency (LEP)

- **Proposed Rule:** OCR proposed provisions to effectuate section 1557’s prohibition on national origin discrimination as it is applied to individuals with Limited English Proficiency (LEP) in covered health programs and activities. OCR proposed that covered entities “must take reasonable steps to provide meaningful access to each limited English proficient individual eligible to be served or likely to be directly affected by its health programs and activities.” OCR also proposed that language assistance services must be provided free of charge, be accurate and timely, and protect the privacy and independent decision-making ability of the individual with LEP. Additionally, OCR also proposed specific requirements for qualified interpreter and translation services. Moreover, OCR also proposed regulatory language requiring a covered entity that uses machine translation to have translated materials reviewed by a qualified human translator when the underlying text is critical to the rights, benefits, or meaningful access of an individual with LEP; when accuracy is essential; or when the source documents or materials contain complex, non-literal, or technical language.
- **Stakeholder Comment:** Commenters were generally supportive of these proposed policies, including the requirement that covered entities take reasonable steps to provide meaningful access to “each” individual with LEP eligible to be served or likely to be directly affected by its health programs and activities. Most commenters were supportive of the proposal to require language assistance services free of charge, be accurate and timely, and protect the privacy and independent decision-making ability of the individual with LEP. Many commenters supported the novel proposal to address machine translation in this regulation, with some requesting that machine translation always be checked by a qualified human translator and that patients be advised when a translation has been completed by machine translation due to high error rates.

- **Final Rule:** The Final Rule requires covered entities to take reasonable steps to identify those who are eligible for services or likely to be affected by the entity's health programs and activities, ensuring effective communication with individuals with LEP and disabilities.

Regarding individuals with LEP and their companions, the Final Rule mandates that covered entities provide "meaningful access." While the rule does not explicitly define this term, it allows for flexibility in determining appropriate language assistance services based on individual circumstances. OCR may consider issuing further guidance to supplement existing resources, such as the HHS LEP Guidance and the Language Access Annual Progress Report.

One essential aspect of "meaningful access" is the requirement for covered entities to provide language assistance services that are free, accurate, timely, and respect the privacy of individuals with LEP. This includes using qualified interpreters and translators, providing language assistance without causing undue burden or delay, and ensuring services are available in emergency situations. If an individual with LEP requests that a companion serve as an interpreter, the covered entity should ensure the request is made without the companion present, except in urgent situations. In cases where machine-translation is used, OCR mandates that a qualified human translator checks the translation promptly as soon as practicable or warns the patient in advance that the translation may contain errors.

Audio/video interpreting must be real-time, high-quality video/audio on dedicated high-speed, wide-bandwidth video/wireless connections without lags, blurry or grainy images, or irregular pauses in communication. Covered entities using audio/video interpreting must also include sharply delineated images large enough to display the interpreter's face and participation person's face regardless of the person's body position. Covered entities must also provide adequate training to users of the technology and others involved to quickly and efficiently set up and operate the system.

Notice of availability of language assistance services and auxiliary aides and services must be provided in English and the top 15 languages in the state. These notices must accompany "Notice of Nondiscrimination," which must be provided annually and on request, in addition to being published on websites and in prominent physical locations in no smaller than 20-point font.

Enforcement of Section 1557

OCR follows established procedures for handling complaints, which may include requiring public entities to make corrective changes such as updating policies and procedures, providing training, and implementing monitoring programs. If an entity refuses to comply, OCR may take further action, such as suspending or terminating federal financial assistance from the Department of Health and Human Services. A private right of action is available under the Final Rule, and non-compliant entities may also be liable to pay compensatory damages. In short, there are real "teeth" to these nondiscrimination regulations.

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The ITEM Coalition submitted comments on the proposed rule in October 2022, and we are pleased that the Biden Administration has taken steps under this Final Rule to restore and strengthen civil rights protections for individuals consistent with the plain meaning of the statutory text of the Affordable Care Act. The previous version of this rule, issued in 2020, covers fewer programs and services and offers limited nondiscrimination protections for individuals. This Final Rule applies to health programs or activities that receive HHS funding, health programs or activities administered by HHS (such as the Medicare Part D program), and the health insurance Marketplace (and all plans offered by issuers that participate in those Marketplaces that receive Federal financial assistance).

This memorandum will focus on the finalized policies that impact the implementation and enforcement of Section 1557’s prohibition of discrimination on the basis of disability.

Background on Section 1557 of the ACA

Section 1557 applies to any health program or activity that receives Federal financial assistance, any program or activity that is administered by an executive agency under Title I of the ACA, and any entity established under Title I of the ACA.² This provision prohibits discrimination on

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² Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1557, 124 Stat. 119, 260 (2010) (codified at 42 U.S.C. § 18116).

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any grounds prohibited by the following statutes, including:³

- Title VI of the Civil Rights Act of 1964 (race, color, and national origin);⁴
- Title IX of the Education Amendments of 1972 (sex);⁵
- The Age Discrimination Act of 1975 (age);⁶ and
- Section 504 of the Rehabilitation Act of 1973 (disability).⁷

On May 18, 2016, HHS finalized its first set of regulations implementing Section 1557 at 45 C.F.R. Part 92.⁸ Several states and religiously-affiliated health care organizations subsequently filed lawsuits challenging certain aspects of the regulations, particularly the prohibition of discrimination on the basis of gender identity and termination of pregnancy—this litigation is ongoing.⁹ In June 2020, the Trump Administration revised the Rule and posted it in the Federal Register “with preamble language that was inconsistent with the Supreme Court’s *Bostock* Opinion,” which held that discrimination based on sexual orientation and gender identity constitute discrimination under Title VII.¹⁰ Several litigants challenged aspects of the regulation, and those lawsuits are currently stayed pending the Department’s review of the 2020 Rule.¹¹ In 2022, HHS proposed to revise the 2020 Rule to reinstate regulatory protections consistent with the statutory text of Section 1557 and Congressional intent, although the proposed rule also addressed other aspects of the regulations.¹²

Change in Interpretation on Section 1557 Applicability to Medicare Part B

- **Proposed Rule:** HHS’s longstanding position has been that Medicare Part B funding does not meet the definition of “Federal financial assistance” for purposes of title VI, title IX, section 504, the Age Discrimination Act, and section 1557 of the ACA.¹³ In the 2022 Section 1557 proposed rule, HHS proposed to change that position after evaluating the Part B program and the definition of “Federal financial assistance,” such that Part B funds will be considered Federal financial assistance when received by providers and suppliers. HHS sought comment on the impact that this change in position may have on recipients that receive only by Part B funds but do not receive any other form of Federal financial assistance from HHS. HHS also invited comment on the amount of time that should be

³ *Id.*

⁴ 42 U.S.C. § 2000d *et seq.*

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¹⁰ Proposed Rule at 47,827.

¹¹ *Id.*

¹² *Id.* at 47,828.

¹³ 81 FR 31375, 31383 (May 18, 2016)

allowed for recipients of Part B funds to come into compliance with the applicable statutes and their implementing regulations.

- **Rehabilitation Stakeholder Comment:** Stakeholder feedback on this proposal was mixed. Some commenters objected to the proposal, claiming that interpreting Part B as meeting the definition of “Federal financial assistance” would reduce access to care because forcing these providers to implement new requirements would discourage them from participating in federally funded health care programs. Other commenters were supportive of proposed change in interpretation. Supporting commenters noted that because funds received under Medicare Part A and Part B are fundamentally similar and Medicare Part A payments have long been considered Federal financial assistance, it is reasonable for HHS to similarly consider Part B payments as Federal financial assistance. Therefore, the commenters argued, considering Part B payments to be Federal financial assistance would allow individuals with disabilities additional options to bring discrimination claims against discriminatory conduct in all health care settings.
- **Final Rule:** HHS is finalizing this proposed change in interpretation without modification. HHS agreed with commenters that because Part B payments, like those of Medicare Part A, are Federal funds directly or indirectly received by providers, they squarely meet the definition of “Federal financial assistance.” HHS states that this position provides uniformity across the various Parts of the Medicare program, but also ensures that HHS is applying the definition of “Federal financial assistance” consistently across all federally funded programs. HHS believes that because many recipients of Part B funds are already recipients of some other form of Federal financial assistance, this change will not impose excessive burdens on those covered entities. HHS also acknowledges that recipients will require time to come into compliance as a result of this change in position. Therefore, while the revised interpretation is effective upon publication in the Federal register, the new regulatory interpretation will have a one-year delayed applicability date. As such, compliance by entities whose Federal program participation has been limited to Part B must be in compliance with title VI, title IX, section 504, the Age Act, and section 1557 no later than May 6, 2025.

Ensuring the Availability of Accessible Medical Diagnostic Equipment

- **Proposed Rule:** HHS solicited feedback regarding whether existing standards developed by the U.S. Access Board on accessible medical diagnostic equipment (“MDE”) should be incorporated as an enforceable standard for covered entities under Section 1557, and whether lack of access to accessible MDE constituted discriminatory benefit design or network inadequacy.
- **Rehabilitation Stakeholder Comment:** Stakeholders strongly encouraged OCR to incorporate the Access Board’s standards as a requirement for entities covered under Section 1557, and to standardize these requirements across other areas of the Department’s regulatory scope. Stakeholders also urged OCR to ensure that the Section 1557 regulations consider the full range of medical equipment that must be made accessible, including at-home diagnostic tools, telehealth equipment, and other equipment frequently used in the health care setting.

- **Final Rule:** On September 14, 2023, OCR issued a proposed rule to update HHS’s section 504 regulations.¹⁴ In that proposed rule, OCR proposed specific accessibility standards, scoping requirements, and time periods for compliance for MDE used by recipients of Federal financial assistance. Accordingly, while OCR recognizes the importance of ensuring that all people, regardless of disability status, receive effective preventative care, OCR has decided to not address the MDE Standards in regulatory text of this Section 1557 Final Rule. OCR will continue to enforce existing nondiscrimination obligations and will adopt enforceable standards for accessible MDE under Section 504.

Accessibility of Information and Communication Technology for Individuals with Disabilities

- **Proposed Rule:** In the proposed rule, OCR sought comment on several proposals relating to accessibility of information and communication technology (“ICT”) for people with disabilities. ICT is defined as information technology and other equipment, systems, technologies, or processes, for which the principal function is the creation, manipulation, storage, display, receipt, or transmission of electronic data and information, as well as any associated content. Examples of ICT include, but are not limited to: computers and peripheral equipment; information kiosks and transaction machines; telecommunications equipment; telehealth interfaces or applications; customer premises equipment; multifunction office machines; software; mobile applications; websites; videos; and electronic documents.

The current iteration of the Section 1557 regulations require covered entities to ensure that “their health programs and activities provided through ICT are accessible to individuals with disabilities,” a requirement that OCR proposed to maintain with redesignation. Covered entities under Section 1557 are thus already required to provide accessible ICT unless such provision would result in undue burden or a fundamental alteration of their programs (in such cases, covered entities must then provide reasonable accommodations to ensure that individuals with disabilities can receive the benefits of the program or activity to the maximum extent possible). OCR also proposed to apply these existing requirements applicable to websites to mobile applications as well.

- **Rehabilitation Stakeholder Comment:** Stakeholders urged OCR to include specific, clear, and enforceable ICT accessibility and usability standards in the Section 1557 regulations that align with widely accepted standards that already exist for other entities, such as the Access Board’s Section 508 standards and the international Web Content Accessibility Guidelines (“WCAG”) 2.1 Levels A and AA. Stakeholders referenced that these standards, developed by the international standards body of the Worldwide Web Consortium (“W3C”), are regularly evolving through an expert stakeholder development and consensus process. Stakeholders encouraged OCR to develop regulatory language clarifying that compliance should relate to the currently accepted version of WCAG as well as successor standards as they are finalized and published. Further, stakeholders encouraged OCR to ensure that the regulations continue to make clear that ICT encompasses not only websites, but mobile applications, online systems, and other forms

¹⁴ 88 FR 63392 (September 14, 2023)

of ICT – all of which should be made accessible to individuals with disabilities. Lastly, stakeholders urged OCR to establish and communicate to covered entities clear consequences for failure to comply with and implement these accessibility requirements.

- **Final Rule:** Under the Final Rule, OCR has decided not to adopt specific accessibility standards or a safe harbor at this time. This is in part due to OCR and the Department of Justice recently publishing separate final rules addressing section 504 and title II of the ADA, respectively. These final rules require that recipients of Federal financial assistance and public entities must ensure that their web content and mobile applications comply with set accessibility standards. In this Final Rule, OCR continues to require covered entities to ensure that health programs and activities provided through ICT are accessible to individuals with disabilities sufficient to provide equal access to the health program or activity, unless doing so would impose undue financial and administrative burdens or would result in a fundamental alteration in the nature of the entity’s health program or activity. OCR strongly encourages covered entities that offer health programs and activities through ICT to incorporate current WCAG standards as they take steps to ensure that those programs and activities comply with requirements of this regulation and other Federal civil rights laws.

Meaningful Access for Individuals with Limited English Proficiency (LEP)

- **Proposed Rule:** OCR proposed provisions to effectuate section 1557’s prohibition on national origin discrimination as it is applied to individuals with Limited English Proficiency (LEP) in covered health programs and activities. OCR proposed that covered entities “must take reasonable steps to provide meaningful access to each limited English proficient individual eligible to be served or likely to be directly affected by its health programs and activities.” OCR also proposed that language assistance services must be provided free of charge, be accurate and timely, and protect the privacy and independent decision-making ability of the individual with LEP. Additionally, OCR also proposed specific requirements for qualified interpreter and translation services. Moreover, OCR also proposed regulatory language requiring a covered entity that uses machine translation to have translated materials reviewed by a qualified human translator when the underlying text is critical to the rights, benefits, or meaningful access of an individual with LEP; when accuracy is essential; or when the source documents or materials contain complex, non-literal, or technical language.
- **Stakeholder Comment:** Commenters were generally supportive of these proposed policies, including the requirement that covered entities take reasonable steps to provide meaningful access to “each” individual with LEP eligible to be served or likely to be directly affected by its health programs and activities. Most commenters were supportive of the proposal to require language assistance services free of charge, be accurate and timely, and protect the privacy and independent decision-making ability of the individual with LEP. Many commenters supported the novel proposal to address machine translation in this regulation, with some requesting that machine translation always be checked by a qualified human translator and that patients be advised when a translation has been completed by machine translation due to high error rates.

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Regarding individuals with LEP and their companions, the Final Rule mandates that covered entities provide "meaningful access." While the rule does not explicitly define this term, it allows for flexibility in determining appropriate language assistance services based on individual circumstances. OCR may consider issuing further guidance to supplement existing resources, such as the HHS LEP Guidance and the Language Access Annual Progress Report.

One essential aspect of "meaningful access" is the requirement for covered entities to provide language assistance services that are free, accurate, timely, and respect the privacy of individuals with LEP. This includes using qualified interpreters and translators, providing language assistance without causing undue burden or delay, and ensuring services are available in emergency situations. If an individual with LEP requests that a companion serve as an interpreter, the covered entity should ensure the request is made without the companion present, except in urgent situations. In cases where machine-translation is used, OCR mandates that a qualified human translator checks the translation promptly as soon as practicable or warns the patient in advance that the translation may contain errors.

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Notice of availability of language assistance services and auxiliary aides and services must be provided in English and the top 15 languages in the state. These notices must accompany "Notice of Nondiscrimination," which must be provided annually and on request, in addition to being published on websites and in prominent physical locations in no smaller than 20-point font.

Enforcement of Section 1557

OCR follows established procedures for handling complaints, which may include requiring public entities to make corrective changes such as updating policies and procedures, providing training, and implementing monitoring programs. If an entity refuses to comply, OCR may take further action, such as suspending or terminating federal financial assistance from the Department of Health and Human Services. A private right of action is available under the Final Rule, and non-compliant entities may also be liable to pay compensatory damages. In short, there are real "teeth" to these nondiscrimination regulations.