EPSTEIN BECKER GREEN

EBG Q&A Follow Up
to
"ACA Section 1557: Will You Meet the October 16 Deadline?" Webinar
of
October 6, 2016

Presented by Frank C. Morris, Jr. and Nathaniel M. Glasser
Epstein Becker & Green, P.C.

DEFINITION OF COVERED ENTITY GENERALLY

Q1: Are those who participate in Medicaid programs, or who receive funds through Medicaid, considered "covered entities"?

A1: Yes. Medicaid is considered receipt of federal funds and thus makes the recipient a "covered entity." 81 Fed. Reg. 31384.

Q2: Are plans that receive the Retiree Drug Subsidy subject to Section 1557?

A2: Yes. Because the Retiree Drug Subsidy is funded by CMS, we believe that OCR will consider this Federal financial assistance and thus makes the plan a "covered entity." *See* 81 Fed. Reg. 31445.

Q3: Would a pediatric physician practice not treating Medicare patients be considered a covered entity?

A3: It depends. It is entirely possible that the practice would not be a covered entity if the physician practice receives no Federal financial assistance including, but not limited to, no reimbursement from CHIP and other Medicaid plans and no federal funding or subsidies for research. Such a practice should carefully review all income/funding sources with legal counsel to make a definitive determination.

Q4: Does non-Medicare Part B Federal assistance for private physicians include Medicaid and/or meaningful use payments?

A4: Yes. 81 Fed. Reg. 31445.

Q5: Is a physician who takes only Part B payments a covered entity?

A5: It depends. As noted in the question above, Medicaid and meaningful use payments (for EHR adoption and use) are considered Federal financial assistance so providers must look beyond Part B to evaluate all potential sources of Federal financial assistance. If, however, a physician accepts only Medicare Part B payments, and no other form of Federal financial assistance, the physician should not be a covered entity. 81 Fed. Reg. 31445-46.

Q6: Is a nursing home with a self-funded plan a covered entity?

A6: Nursing homes are expressly identified as examples of covered entities in the Final Rule. 81 Fed. Reg. 31412, 31449. Additionally, the Final Rule notes that for an entity principally engaged in providing or administering health service – such as a nursing facility – "all of its operations are considered part of the health program or activity…" 45 C.F.R. § 92.8 (definition of "health program or activity"); 81 Fed. Reg. 31385.

To determine whether it is a covered entity, the nursing home would first need to look at all sources of income and Federal financial assistance to determine whether it is a covered entity. If the nursing home receives Federal financial assistance from HHS (excluding Medicare Part B), the nursing home is a covered entity and all of its operations will be considered part of the health program or activity. If the nursing home otherwise does not receive Federal financial assistance, but its group health plan receives Federal financial assistance, the self-funded group health plan would be a covered entity. If neither the nursing home nor the group health plan receives Federal financial assistance, the nursing home should not be a covered entity. 45 C.F.R. § 92.208; 81 Fed. Reg. 31432.

Q7: Is a long-term care and rehabilitation facility with a self-funded plan and a third-party administrator a covered entity?

A7: See Q6/A6, above. *See also* 81 Fed. Reg. 31445.

Q8: Do third-party payments to retail pharmacies as part of individuals' prescription drug coverage constitute Federal financial assistance under Section 1557?

A8: This depends on the source of the "third-party payments." If the third-party payments are from the federal government, then yes, such payments would constitute Federal financial assistance. If the third-party payments are from a private payor, then no, such payments likely would not constitute Federal financial assistance.

Q9: Are subcontractors of covered entities, including those that do not provide medical services, required to comply with Section 1557?

A9: In the preamble, HHS rejected certain commentators' request that a contractor should become a recipient of Federal financial assistance, and thus covered by Section 1557, simply by virtue of a contract with an issuer. 81 Fed. Reg. 31383. HHS correctly pointed out that case law applying other civil rights laws does not support such a broad application. However, subcontractors may be covered entities in their own right if they receive Federal financial assistance.

Q10: Is a student health center, associated with a large university that operates a medical center, required to comply with Section 1557?

A10: It depends on the sources of funding for the student health center. Even though, in this scenario, the university operates a medical center, we do not believe that HHS would consider the university to be "principally engaged" in providing or administering health services. Thus, a fact specific inquiry regarding the sources of funding for the student health center would be required to determine if it is a covered entity.

GROUP HEALTH PLANS AND THIRD PARTY ADMINISTRATORS

Q11: Are self-insured health plans offered by health care providers, such as hospitals, required to comply with Section 1557? Does the analysis change if the group health plan does not independently receive Federal financial assistance?

A11: Yes. If the organization is a covered entity, all of the organization's activities and programs are required to comply with Section 1557, including its self-insured group health plan. 45 C.F.R. § 92.208 (definition of "health program or activity"). The analysis does not change even if the group health plan does not independently receive Federal financial assistance.

Q12: Do employers offering self-insured group health plans have to comply with Section 1557?

A12: If the employer is a "covered entity" principally engaged in health care services and receives Federal financial assistance, then as stated in Q6/A6 and Q11/A11, the employer must comply with Section 1557. If the employer is not a health care provider, however, then the Section 1557 regulations do not apply to the design of the self-insured group health plan, but do apply indirectly, to its operations and administration. If the employer uses a TPA or Administrative Services Organization (ASO) that also is an issuer, the TPA/ASO is a covered entity and must administer the group health plan in a nondiscriminatory manner in accordance with Section 1557. If the plan design or terms are alleged to be discriminatory, Section 1557 does not apply but OCR may refer the matter to EEOC for investigation of the employer.

Q13: Is a third-party administrator a covered entity if it does not contract with another covered entity?

A13: The Final Rule does not exclude third party administrator (TPA) services, even when the third party administrator does not contract with another covered entity. Thus, if an entity receives Federal financial assistance and is principally engaged in providing health insurance, the law will apply to its TPA services.

If the TPA does not receive Federal financial assistance, HHS will engage in a case-by-case analysis to determine whether the TPA is subject to the rule – according to statements in the Proposed Rule which were not rejected in the Final Rule. 81 Fed. Reg. 31432.

Under the Final Rule, if discrimination in a plan is alleged, OCR will investigate the TPA when the alleged discrimination is in the administration of the plan. If the alleged discrimination is in benefit design, OCR will process the complaint against the employer/plan sponsor, if it is a "covered entity." The OCR lacks jurisdiction over employers that are not "covered entities" and in such cases, the OCR may refer the matter to EEOC for processing as a Title VII matter. 45 C.F.R. § 92.208.

Q14: If a third party administrator contracts with a covered entity, do the compliance requirements extend to its contracts with non-covered entity clients?

A14: For the reasons stated above in Q13/A13, if the TPA is a covered entity, then the compliance requirements likely extend to all of its operations, including its contracts with non-covered entity clients.

Q15: Does a self-insured health plan's compliance with Section 1557 depend on the third party administrator (TPA) or whether the TPA receives federal health benefits?

A15: Not necessarily. If the employer is a "covered entity," e.g., a health care provider, then all of the employer's operations must comply with Section 1557. If the employer is not a "covered entity," then whether and to what extent the group health plan must comply with Section 1557 depends on whether the TPA is a covered entity. Whether the TPA is a covered entity will be determined on a case-by-case basis by HHS. 81 Fed. Reg. 31432.

Q16: Does a third party administrator that receives federal funding for some but not all clients need to include notices in significant communications for all of its members?

A16: Yes. The rule interprets "health program or activity," which encompasses administering group health plans, to uniformly cover all of the operations of any entity receiving Federal financial assistance and that is 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.

Q17: Is a health insurance issuer that is not a qualified health plan issuer, but does participate in the reinsurance program, considered a covered entity?

A17: Because the rule is written broadly, and the health insurance issuer may obtain reimbursement through the program, an argument may made that this reimbursement is a form of "Federal financial assistance," bringing a health insurance issuer that participates in the reinsurance program within the coverage of Section 1557. However, we have seen no guidance discussing participation in a reinsurance program and how it affects compliance with Section 1557.

Q18: When will self-insured plans who do not receive Federal financial assistance be at risk for HHS turning the plans over to the EEOC?

A18: If an employer or self-insured group health plan that is not a "covered entity" allegedly discriminates in the benefit design, then HHS may refer the matter to the EEOC. 45 C.F.R. § 92.208. One example based on the final regulations is an exclusion from coverage of all transgender services under a group health plan. Note, however, that coverage as to transgender individuals is a coverage issue still subject to litigation under Title VII.

Compliance with Section 1557 Requirements

Q19: Do the requirements of Section 1557, such as the taglines and notice requirements, apply to all aspects of issuers and insurers' business, such as medical, dental, vision, etc.?

A19: Yes. The rule interprets "health program or activity" to uniformly cover all of the operations of any entity receiving Federal financial assistance and that is 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. 45 C.F.R. § 92.208 (definition of "health program or activity"); 81 Fed. Reg. 31383. The Final Rule does not provide an exception for HIPAA-excepted benefits such as limited scope dental, vision, etc., because those benefits are engaged in the scope of health programs or activities.

Q20: In how many languages does a covered entity have to be able to provide translation services?

A20: While the number of languages in which a covered entity is required to provide language assistance services is not made explicit in the rule, it can be inferred that a covered entity must be prepared to provide such services in at least the top 15 languages in the state or states in which it operates. Considering that covered entities must post a tagline indicating that language assistance services are available in each of the 15 listed languages, covered entities should provide language assistance services in at least those languages. OCR may, however, take the position that LEP services need to be provided in additional languages where necessary for effective communication on key medical services.

Q21: What would be considered a "significant publication" for a retail pharmacy? Does it include all marketing materials?

A21: The Finale Rule intends "significant publication" to be interpreted broadly. While HHS acknowledges that "each covered entity is in the best position to determine which of its communications and publications with respect to its health programs and activities are significant," and notes that HHS intends for covered entities to have flexibility in complying with the rule, examples of significant publications are provided. The list expressly includes "marketing materials" for the public. 81 Fed. Reg. 31402. It is important for covered entities to consider the nature of the information included in the publication. Publications that relate to health care or health coverage access, rights and benefits, consent, grievances, outreach, and education should be considered significant and should comply with the requirements of Section 1557.

Q22: Does not providing language assistance services constitute national origin discrimination under Title VI?

A22: Yes, failure to provide language assistance services may constitute national origin discrimination under Title VI of the Civil Rights Act of 1964 depending on the particular facts. Under Title VI, persons with limited English proficiency must be afforded a meaningful opportunity to participate in programs that receive federal funds. This would include offering language assistance services at least where required for effective communication.

Q23: What assistance must a retail pharmacy provide for patients with vision and speech disabilities?

A23: Accessibility accommodation determinations can be made on a case-by-case basis, but effective communication must be provided when needed. In the case of a visually-impaired individual, effective communication might include auxiliary aids and services such as having a competent staff member read the document to the patient in a HIPAA compliant location, or making a TTY number available, or, as with translations to other languages, making the document available in Braille or large print. In the case of an individual with speech impairments, effective communication could include offering the individual a communication board or flashcards. Due weight must be given to the preference of the individual with a disability.

Q24: Does Section 1557 mean care must be gender neutral, or that discrimination cannot occur based on gender?

A24: Section 1557 requires providing equal access to health care without discrimination based on sex, which includes gender and sexual orientation. OCR's position is that medically appropriate care decisions can consider biological sex, but health care programs and activities may be sex-specific only when the covered entity can demonstrate an "exceedingly persuasive justification" for the sex-based classification. An exceedingly persuasive justification requires showing at least that the classification

serves important health-related or scientific objectives and that the discriminatory means employed are substantially related to the achievement of those objectives. Justifications cannot be overbroad, hypothesized, or invented post hoc, and must be supported by accepted professional standards, research literature, objective evidence, and empirical data, if available. 81 Fed. Reg. 31377, 31408-09.

Q25: Are covered entities required to post the notice of non-discrimination and 15 taglines on patient portals?

A25: If the patient portal is accessed from the covered entity's home page that includes a link in a conspicuous location immediately directing the individual to the content of the notice elsewhere on the website, then no. If the patient portal is being accessed independently from the covered entity's home page, then yes, the patient portal will likely need to include a notice of nondiscrimination and taglines in the 15 top languages from the state. The purpose of Section 1557 is to provide equal access to health care and coverage. A patient portal is a key point of access and in OCR's view would likely be considered a "significant communication" within the meaning of the Final Rule.

Q26: Are covered entities required to inform OCR of Section 1557 grievances the covered entities directly receive?

A26: No. Self-reporting is not a requirement included in the Final Rule.

Q27: Are marketing videos or billboards subject to notice requirements?

A27: "Significant communications" may include marketing materials, including those for the public. Whether certain videos or billboards are subject to notice requirements will be fact-specific, and HHS says it will take a broad view but allow for a flexible approach from covered entities. It is important for covered entities to consider the nature of the information included in the publication. Publications that relate to health care or health coverage access, rights and benefits, consent, grievances, outreach, and education generally should be considered significant and comply with the requirements of Section 1557.

Q28: Can hospitals satisfy the "significant publication" requirement by providing the notice of nondiscrimination with taglines upon each encounter with a patient, rather than updating all of these "significant" documents?

A28: No. While HHS acknowledged that compliance with the notice requirement in "significant publications and communications" may impose some "limited" burdens, HHS feels those burdens are outweighed by the benefits compliance will generate for individuals with limited English proficiency. However, HHS will allow entities to exhaust their current stock of hard copy publications rather than requiring a special printing of the publications to include the new notice.

Q29: Does posting the notice of nondiscrimination in a medical waiting room suffice, or must it be in each patient exam room as well?

A29: Posting in a medical waiting room should suffice as long as the notice is conspicuous.

Q30: Is the NYS Patient Bill of Rights sufficient to satisfy the nondiscrimination notice with the addition of contact information for the Section 1557 compliance officer and OCR?

A30: HHS permits covered entities to combine the content of the Section 1557 nondiscrimination notice with the content of other notices as long as the content of the combined notice still clearly informs individuals of their civil rights under Section 1557. Certain requirements for the Section 1557 nondiscrimination notice, such as explicitly making clear that auxiliary aids and services are available for both individuals with disabilities and individuals with limited English proficiency and how to obtain those services, are not included in the NYS Patient Bill of Rights. To combine the notices, all such differences would have to be reconciled.

Q31: What should be included on an 8.5"x11" page wellness flyer?

A31: Although not explicit in the rule, OCR seems likely to find that an 8.5"x11" flier will constitute a "large-size" publication, which requires publication of the full notice of nondiscrimination, plus taglines in 15 languages.

Q32: Can the nondiscrimination notice be in English as long as the taglines pertaining to language services access are in the top 15 languages for large scale publications?

A32: Yes.

Q33: Does the covered entity have to include the specific name of the Civil Rights Coordinator in the notice, or is the title and contact information enough?

A33: The Final Rule requires covered entities to provide the "identification of, and contact information for" the Civil Rights Coordinator. 45 C.F.R. § 92.8(a)(5). The rule, however, does not say whether "identification" includes the specific name of the Civil Rights Coordinator. While the sample language from OCR (Appendix A to the Final Rule) includes a place holder for the specific name of the Civil Rights Coordinator, it is possible that, depending on the circumstance, OCR would determine that it is burdensome on the covered entity to change the notice each time the Civil Rights Coordinator changes and thus not require the specific name in the notice. We would suggest evaluating the burden on a case-by-case, publication-by-publication basis.

Q34: Do covered entities need to provide language assistance to visitors in inpatient settings?

A34: It depends. OCR looks to whether it is necessary for effective communication and access to health care. If visitors or companions are making or assisting in decisions for patients and need information about health status or procedures communicated to them as part of that decision-making, language assistance services should be provided. For deaf companions this would likely include American Sign Language interpretation whether live or by video remote interpreting which must meet certain technical standards.

Q35: How can you make a website more accessible for sight-impaired individuals?

A35: Effective communication through a website for sight-impaired individuals typically includes addressing issues such as: alt attributes/accurate descriptions, skip navigation/by-pass blocks, methods of navigation, focus, order of content, forms/tables, resizing text, contrast, pdfs, captioning/narrative description of pictures or images, language, and control of moving content.

Q36: Does the notice have to be mailed or emailed to all employees, in both union and non-union settings?

A36: No. The notice has to be included in conspicuous physical locations where the entity interacts with the public, in a conspicuous location on the website, and in significant publications or communications. A separate mailing is not required.

Q37: If a large, multi-site organization cannot have a single phone number for coordinating language assistance services, can the tagline directions be more general?

A37: The Final Rule does not require the tagline to include a single phone number, but the tagline directions must make clear that language assistance services are available and how they can be accessed.

OTHER

Q38: Are there Congressional lobbying efforts afoot by the Chamber of Commerce, etc., to negate these regulations?

A38: The Chamber of Commerce submitted comments in response to the Notice of Proposed Rulemaking regarding Section 1557. However, we are not aware of any current efforts by the Chamber of Commerce or others to lobby Congress to negate these regulations.

We note that on August 23, 2016, eight plaintiffs – including Texas, Wisconsin, Nebraska, Kentucky, and Kansas – filed a federal lawsuit in the Northern District of Texas, challenging the interpretation of "sex" in the Final Rule and seeking to invalidate the regulation.

Q39: If the statute merely incorporates other statutes, and other statutes don't adopt Section 1557 theories, how can theories stand alone in this narrow realm of activity?

A39: While Section 1557 incorporates provisions of 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 794 of Title 29, the statute does not expressly limit individuals' rights to those provided under those statutes. Further, the statute authorizes the Secretary to promulgate regulations to implement Section 1557.

DISCLAIMER OF ALL LIABILITY AND RESPONSIBILITY

This Question & Answer memorandum ("Q&A") is presented as an informational source only. It is intended to assist readers as a learning aid. It is not intended and should not be construed to constitute legal or other professional advice. It is not written (nor is it intended to be used) for purposes of assisting clients, nor to promote, market, or recommend any transaction or matter addressed. Given the purpose of the Q&A, it may omit discussion of exceptions, qualifications, or other relevant information that may affect its utility in any legal situation. Due to the rapidly changing nature of the law, information contained in this memorandum may become outdated. In no event with the authors or their law firm be liable for any direct, indirect, consequential, or other damages resulting from and/or related to the use of these materials.

This Q&A does not create an attorney client-relationship between the authors (and/or the authors' law firm) and any reader. You should consult an attorney to obtain advice with respect to any particular matter and/or any fact-specific situation under federal law and the applicable state or local laws that may impose additional obligations on you and your organization. No reader of this Q&A should act or refrain from acting on the basis of information contained herein without first seeking legal advice from counsel in the relevant jurisdiction(s).