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HEALTH LAW VITALS

A Healthcare Newsletter from Haynes and Boone, LLP

JULY 2016

QUICK SHOTS

U.S. Supreme Court issued its long-awaited decision addressing the implied certification theory of False Claims Act liability. **Read more.**

U.S. Supreme Court to determine whether False Claims Act cases should be dismissed for violations of the statute's seal requirements. **Read more.**

HHSC releases provider letter regarding minimum requirements for granting physician privileges to be member of medical staff of a freestanding emergency medical care facility. **Read more.**

HHSC receives extension from CMS for 1115 Waiver to fund innovative ways to deliver healthcare services. **Read more.**

OIG revises guidance on exclusion of individuals or entities who have engaged in certain prohibited conduct from participation in federal healthcare programs. **Read more.**

Texas Continues to Expand Telemedicine and Telehealth Opportunities with New Rule for Occupational Therapy Services

Michelle "Missy" D. Apodaca and Lissette Villarruel

Michelle "Missy" Apodaca

Lissette Villarruel

Support for telemedicine and telehealth services continues to gain traction in Texas, as evidenced by the Texas Health and Human Services Commission's ("**HHSC**") willingness to consider the use of telemedicine services to increase access to care and the adoption of rules allowing for occupational therapy services to be delivered via telehealth ("**Rules**").

Network Adequacy

During the HHSC Medicaid Forum held on June 6, 2016, HHSC released a draft proposal of recommendations to implement new rules issued by the Centers for Medicaid and Medicare Services ("**CMS**") and Senate Bill 760, 84th Legislature. Part of the CMS rules require states to consider a number of specific factors—including the use of telemedicine—when establishing provider access standards. Accordingly, HHSC emphasized its commitment to continuing to research and develop innovative access standards and methods to increase access to care, specifically identifying telemedicine. To develop appropriate standards for such innovative means of delivering care, HHSC requested feedback from stakeholders on these types of services, including recommendations for establishing standards and monitoring the services provided through telemedicine.

Occupational Therapy Services – Adopted Rules

On June 3, 2016, the Texas Board of Occupational Therapy Examiners ("**BOTE**") adopted the Rules to include telehealth as a mode of delivering occupational therapy services. The Rules outline the parameters within which telehealth services may be offered in occupational therapy settings. Specifically, telehealth services must be provided using "visual and auditory, synchronous, real-time, interactive electronic information/communications technologies." Thus, while telehealth occupational therapy need not be provided face-to-face and in-person, telehealth services must still feature simultaneous interactions between the client and the occupational therapy practitioner.

Further, the Rules require that a licensed occupational therapy practitioner still provide and supervise the telehealth services. In particular, the occupational therapist is in charge of making the initial determination on whether any aspect of the occupational therapy services can be conducted via telehealth. However, the initial evaluation for a medical condition can be conducted only in person—not via telehealth. Otherwise, an occupational therapist may provide an evaluation or intervention via telehealth, provided that the therapist has real-time interaction with the client during the process.

The Rules also specify that the occupational therapist must be on-site and present for the initial application of devices requiring sustained skin contact with the client. Finally, while supervising occupational therapy aides, the occupational therapist must be able to respond immediately to the needs of the client. While supervising other non-licensed personnel, the occupational therapist must maintain line of sight, even while providing services via telehealth.

The Rules have been adopted amidst Texas' growing support for telemedicine and telehealth services as a method of improving access to healthcare. Earlier this year, the HHSC adopted a **new Medicaid rule** clarifying that physicians must be reimbursed for telemedicine services provided in certain school-based settings. As the Texas House of Representatives and Senate committee meetings continue to address interim charges related to telemedicine and telehealth services, opportunities for healthcare providers to engage in telemedicine and telehealth services will likely continue to expand.

[1] The Rules became effective on July 1, 2016. Through these Rules, the Texas Board of Occupational Therapy Examiners ("**BOTE**") adopted amendments to § 362.1, concerning definitions, with changes to the proposed text as published in the March 18, 2016, issue of the Texas Register. *See* 41 Tex. Reg. 4046 (2016) (to be codified at 40 Tex. Admin. Code § 362.1). The BOTE also adopted amendments to § 372.1, concerning provision of services, and § 373.1, concerning supervision of non-licensed personnel and occupational therapy assistants, without changes to the proposed text as published in the March 18, 2016, issue of the Texas Register. The rule will not be republished. See 41 Tex. Reg. 2142 (2016), *adopted* 41 Tex. Reg. 4050 (2016) (to be codified as an amendment to 40 Tex. Admin. Code § 372.1); 41 Tex. Reg. 2144 (2016), adopted 41 Tex. Reg. 4052 (2016) (to be codified as an amendment to 40 Tex. Admin. Code § 373.1). To view the adopted Rules, **click here**.

UPCOMING EVENTS

UT Southwestern - Greater Dallas Healthcare Diversity Summit

Improving Diversity Across Hospital Boards and Healthcare Governance

Kenya Woodruff

July 13, 2016 | Dallas, Texas

Texas Society of CPAs - Advanced Health Care Conference

Health Care Fraud: Current Government Investigations

Sean McKenna

July 17, 2016 | San Antonio, Texas

Multiple New Regulations Push for Healthier Foods

Suzie Trigg

Suzie Trigg

Earlier this year, we wrote about the spotlight on food labeling in 2016. Halfway through the year, the changes to food and beverage labeling show no signs of slowing down.

The U.S. Food and Drug Administration ("**FDA**") recently released its long-awaited Final Guidance on compliance with the menu labeling rule, as well as its final rules on updated nutrition facts and supplement facts labels and changes to serving sizes of common foods. The FDA has also requested input on the use of the term "natural" and on its standards related to health claims, indicating that we may see future rulemaking in these areas, and it has pressed the industry to cut salt content in food over the next decade. In addition, as of July 1, 2016, Vermont's GMO labeling law will take effect, sending a ripple effect through the food industry as manufacturers adjust their packaging. Finally, local laws—such as Philadelphia's tax on sodas and San Francisco's health warnings on advertisements for soda—continue to shake up affected product manufacturers, even as many wonder whether such laws violate First Amendment rights and challenges to the laws continue.

Menu labeling and the revised nutrition facts panels, supplement facts panels, and serving size rules represent just a few, but perhaps the most significant, new standards for food companies that will take effect in the coming year.

Menu Labeling

The April 2016 release of the FDA's Final Guidance on compliance with the federal menu labeling rule restarted the one-year clock for covered establishments to achieve compliance. The restaurant chain-centric statute was originally part of the 2010 Patient Protection and Affordable Care Act in an effort to combat the growing obesity epidemic in the United States. Six years later, the rule has yet to be enforced. Barring further action from Congress, the timeline is now set and covered establishments should finalize and implement their menu labeling plans by May 2017.

Restaurants, or similar retail food establishments in which the primary business activity is the sale of food to consumers, that are part of a chain with twenty or more locations doing business under the same name, and that offer for sale substantially the same menu items, must provide calorie information for standard menu items, as well as additional nutrition information for such items, upon request. Calories must be displayed clearly and prominently on all menus and menu boards, along with the term "calories" or "cal." Calories for variable menu items (i.e., combination meals) must be displayed in ranges. Calories must be listed per item or per serving on a sign next to foods on display or self-service foods (i.e., a salad bar). Menus and menu boards must also contain a conspicuous, succinct statement indicating suggested daily caloric intake (*i.e.*, "A 2,000 calorie diet is used as the basis for the general nutrition advice; however individual calorie needs may vary."). And the FDA has stated that establishments must have a "reasonable basis" for determining nutrient values, which may involve utilizing nutrient databases, published cookbooks that contain nutritional information for recipes in the cookbook, nutrition information determined by laboratory analyses, or any other reasonable means.

Updated Nutrition Facts, Supplement Facts, and Serving Sizes

The FDA's final rules on updated nutrition facts and supplement facts labels, as well as serving sizes, take effect in July 2016. Companies with greater than $10 million in sales annually will have until July 2018 to change product labels to comply with the new rules, while companies with less than $10 million in sales annually will have until July 2019 to change product labels to comply with the new rules. The FDA's rules represent the first major overhaul of the nutrition facts panel since its introduction in the early 1990s and aim to reflect the most current nutrition science and consumer habits. The rules also track current trends—for example, removing "Calories from Fat" (since fat was a big focus in the early 1990s) and placing greater focus on sugar by requiring the declaration of added sugars.

Food and supplement manufacturers should consider the far-reaching impact of the new rules. Every food and supplement product label will be affected. Beyond that, however, the FDA has also, for the time being, left other affected regulations, such as those relating to nutrient content claims and health claims, the same. Therefore, products that currently qualify to make such claims may no longer qualify. For example, under current regulations, the recommended daily intake ("**RDI**") for Vitamin C is 60 mg. With the new rule, the FDA has updated the RDI for Vitamin C to 90 mg. Therefore, products that currently may claim that they are "high in Vitamin C" or a "good source of Vitamin C" may no longer qualify for such claims, since the percentages upon which such claims are based remain unchanged in the FDA's other regulations.

Because nutrient content claims and health claims may change for many products, food and supplement companies should also be aware of ancillary material that the FDA may consider part of product labeling, such as information on websites, social media, and blogs. Romance copy (*i.e.*, copy that elaborates on what a product is, what it does, and how a consumer can use it, and often contains implied claims about a product), vignettes, and even product trademarks that are express or implied claims, may also need to change. Food and supplement companies should note the FDA's continued focus on the overall impression given by a product's labeling, suggesting that this will continue to be a hot area for enforcement activity.

Finally, because the new rule indicates the FDA has departed from considering only the properties of a food that can be tested, in a move toward considering the impact of certain ingredients (like added sugar and dietary fiber) on health, the new labeling rule comes with significant recordkeeping requirements. Food and supplement companies should plan early and thoroughly to obtain such information from ingredient manufacturers and should have a strategy in place to protect highly sensitive information, like product formulations. In short, two or three years will pass quickly, so food and supplement companies would be well served to establish working groups now to plan for updates to product labeling and claims.

* The author would like to thank Kayla Johnson, a student at Southern Methodist University School of Law, for her contributions to this article.

OSHA's New Recordkeeping Rule Impacts the Healthcare Industry

Punam Kaji and Matthew Deffebach

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On May 11, 2016, the Occupational Safety and Health Administration ("**OSHA**") issued a final rule, which is slated to go into effect January 1, 2017. As a result of the new rule, certain

employers must electronically submit to an OSHA website the injury and illness data contained in their various OSHA logs. This information will become publicly available on the OSHA website. The new rule specifically targets the healthcare industry. As explained in the chart below, the new rule applies to two categories of employers: (1) employers with 250 or more employees, and (2) employers with 20 to 249 employees in specific "high-risk industries" listed in Appendix A. ***Many healthcare industries are specifically named in Appendix A.***
View the full list of Appendix A.

Healthcare industries and corresponding NAICS code impacted by the rule:

- Ambulatory healthcare services (6219);
- General medical and surgical hospitals (6221);
- Psychiatric and substance abuse hospitals (6222);
- Specialty (except psychiatric and substance abuse) hospitals (6223);
- Nursing care facilities (6231);
- Residential mental retardation, mental health, and substance abuse facilities (6232);
- Community care facilities for the elderly (6233); and
- Other residential care facilities (6239).

The following chart further describes the rule's requirements.

	Employers with **250 or more employees** (at any time during the previous calendar year)	Employers with **20 to 249 employees** (at any time during the previous calendar year) **and classified on an industry list** (App. A) to the revised regulations
Annual Electronic Submission Requirement	Must electronically submit the information from 300A (Summary of Work-Related Injuries and Illnesses), 300 (Log of Work-Related Injuries and Illnesses), and 301 (Injury and Illness Incident Report)	Must electronically submit the information from 300A (Summary of Work-Related Injuries and Illnesses)
What information must be submitted?	Everything on the 300A, 300, and 301 except for: **From the OSHA Form 300** • Employee Name (Column B) from 300. **From the OSHA Form 301** • Employee Name (Field 1); • Employee Address (Field 2); • Name of Physician (Field 6); • Facility Name and Address where obtained treatment (Field 7).	Everything on the 300A
Where is the information submitted?	According to OSHA, it will provide a secured website for the electronic submission.	According to OSHA, it will provide a secured website for the electronic submission.
When must information be submitted?	For the first two years (namely, 2017 and 2018), by July 1st. Thereafter, by March 2nd.	For the first two years (namely, 2017 and 2018), by July 1st. Thereafter, by March 2nd.

If an employer is not included in the two categories above, does it have to submit injury and illness data electronically? No, unless an employer receives a notification from OSHA that the employer must submit the data. This is similar to the regime that existed before this change where employers would only submit data if they received OSHA's annual survey form.

If an employer currently is exempted from keeping 300, 301, or 300A logs, does this change anything? No; if already exempted under Section 1904.1 or 1904.2 of the recordkeeping regulations, an employer only submits data if requested by OSHA to do so.

What will OSHA do with the data? OSHA intends to post the establishment-specific injury and illness data it collects under this final rule on its website. The publication of specific data fields will be in part restricted by applicable federal law, including the Freedom of Information Act, as well as specific provisions within part 1904 of the existing regulations. OSHA does not intend to post any information online that could be used to identify individual employees.

What is the new employee access rule? Previously, employers were required to provide "limited" access to injury and illness records to their employees and their representatives. The revised regulation removes the word "limited."

What are the new rules regarding encouraging the reporting of work-related injuries and illnesses? Employers previously had to inform employees on how to report injuries and illnesses, but now they must also ensure that the procedure for doing so is "reasonable." According to OSHA, a procedure is not reasonable if it would deter or discourage a reasonable employee from accurately reporting a workplace injury or illness.

What additional notice requirements are imposed on employers? In addition to being advised as to the procedures for reporting work-related injuries and illnesses, employers must also specifically inform employees that: (i) employees have the right to report work-related injuries and illnesses; and (ii) employers are prohibited from discharging or in any manner discriminating against employees for reporting work-related injuries or illnesses.

Beyond the Bathroom: The ACA Nondiscrimination Rules' Effect on Health Care Services and Health Insurance

Christopher Beinecke

Christopher Beinecke

Background

Section 1557 of the Affordable Care Act ("**ACA**") prohibits covered entities from discriminating in certain healthcare programs and activities on the basis of race, color, national origin, sex, age, or disability. The U.S. Department of Health and Human Services ("**HHS**") issued final rules under Section 1557, which specify gender identity discrimination and sexual stereotyping as forms of sex discrimination. The rules' financial impact should be small, but they will affect a number of businesses regarding the delivery of healthcare and coverage.

A "covered entity" under Section 1557 is:

1. An entity that operates a health program or activity, any part of which receives federal financial assistance (*e.g.*, healthcare systems or providers who accept Medicare Part A or Medicaid and insurance carriers and third party administrators ("**TPA**") receiving federal funding through participation in the health insurance marketplace)

2. An entity established under ACA Title I that administers a health program or activity (*e.g.*, a state-run health insurance marketplace)

3. Health programs or activities administered by HHS itself (*e.g.*, the federal health insurance marketplace)

A covered entity does not include an employer who merely provides benefits to its own employees but is not primarily engaged in the business of providing or administering a health program or activity. So, who is affected and how?

Healthcare systems and providers as covered entities

Healthcare systems and providers who accept Medicare Part A and/or Medicaid are covered entities, and, as such, must provide transgendered individuals equal access to facilities and services and must treat transgendered individuals consistent with their gender identity. Hospitals and providers are not required to expand the services provided to patients, but are prohibited from denying transgendered individuals medically necessary services within their scope of practice without a compelling justification. For example, a physician who performs breast examinations cannot refuse to perform a clinical breast examination for a transgendered man with a BRCA mutation.

Impact on employer health coverage

The rules will impact employer health coverage in several ways:

1. Covered entities are subject to the Section 1557 rules for the benefits offered to their own employees. This means a hospital which accepts Medicare Part A and/or Medicaid must comply with the rule with respect to the benefits offered to its own employees. This also applies to insurance carriers and TPAs who participate in the health insurance marketplace.

2. An insurance carrier who is a covered entity must comply with the rules with respect to the health insurance policies it issues to employers, so many employers may notice plan design or other administrative changes to their insurance policies beginning in 2017.

3. HHS does not have the authority to pursue an employer whose self-insured plan design may be discriminatory under Section 1557 and intends to refer these matters to agencies such as the Equal Employment Opportunity Commission ("**EEOC**") who will determine if a situation meets the requirements for an EEOC charge. A TPA is not responsible for an employer's self-insured plan design decisions beyond the TPA's control, although it is liable for administrative actions within its control. Many employers may receive recommendations and some pressure from TPAs, who are frequently also insurance carriers, with respect to their self-insured plans.

4. If an employer is not primarily engaged in providing or administering a health program or activity but maintains an identifiable health program or activity receiving federal financial assistance that isn't solely an employee benefit program, the employer must comply with respect to the employees within that identifiable program or activity. A good example would be a pharmacy operated within a CVS or Walgreens, as these receive payments from Medicare Part D.

There are still questions under the rules. It is not clear what happens if a provider is a covered entity and provides health coverage to its employees through a policy issued by an insurance carrier who is not a covered entity and who does not comply with Section

1557. Can Section 1557 be used to compel the provider to contract with an insurance carrier who does comply?

What does nondiscrimination mean for employer health coverage?

The rules: (i) do not require coverage for any particular treatment; (ii) indicate that reasonable medical management techniques may be used if evidence-based and nondiscriminatory, but they will be subject to careful scrutiny; and (iii) state that a blanket exclusion of all services related to gender dysphoria or transition is discriminatory.

The rules seem to suggest a type of parity requirement through which the plan should provide coverage for services related to gender dysphoria or transition if the plan already covers those services for non-transgendered participants. The rules discuss a hysterectomy as an example, and the same logic should apply to hormone therapy. While plans generally must cover breast reconstruction in connection with a mastectomy, this does not extend to the construction of breasts where none previously existed. Most plans exclude breast implants under other circumstances as cosmetic surgery, barring accident or deformity, so it seems reasonable to believe that a plan would not be required to cover breast implants in relation to gender transition. Similarly, sexual reassignment surgery and tracheal shaves (absent a laryngeal issue) should be excludable.

Religious exemption

The rules do not contain an exemption mechanism for religious organizations and indicate that the ability to object on religious grounds is available under existing laws such as the Religious Freedom Restoration Act. A religious organization that does not intend to comply should consider documenting its objection and the basis for its exemption from Section 1557.

Effective Date and Enforcement

The rules are generally effective on July 18, 2016, but rules that may require changes to a covered entity's health plan design are effective the first plan year beginning on or after January 1, 2017. In addition to enforcement actions and penalties by HHS, individuals may file suit to enforce the provisions of ACA Section 1557 and seek compensatory damages.

CMS Final Rule Aims to Strengthen Incentives for MSSP ACOs

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On June 6, 2016, the Centers for Medicare & Medicaid Services ("**CMS**") issued a new final rule for accountable care organizations ("**ACOs**") participating in the Medicare Shared Savings Program ("**MSSP"**). This final rule (i) revises the benchmarking methodology by phasing in regional factors, (ii) creates a new option for Track 1 ACOs to extend participation agreement in Track 1 for an additional year prior to transitioning to a performance-based risk track, and (iii) defines time frames and other criteria for reopening payment determinations of shared savings and losses. According to CMS, the purpose of these modifications is to "strengthen incentives" for MSSP ACOs.

Revisions to Benchmark Methodology

The final rule makes changes for resetting or rebasing the ACO's benchmark determination for a second or subsequent agreement period beginning on or after January 1, 2017, so that it is incrementally less dependent on the ACO's historical spending and more

reflective of spending in the ACO's region. The former rebasing methodology used historical expenditures from past agreement periods to reset the ACO's benchmark and applied an adjustment for savings generated, which raised concerns that the ACO had to continually beat its own performance and limited the opportunity to produce savings. The changes in the final rule aim to evaluate the ACO's performance in relation to other providers in the same regional market, instead of against its own prior performance.

Some of the changes to the methodology for resetting an ACO's benchmark for a second or subsequent agreement period beginning on or after January 1, 2017, include:

- Replace the national trend factor with regional trend factors for establishing the ACO's rebased historical benchmark and remove the adjustment to explicitly account for savings generated under the ACO's prior agreement period.
- Make an adjustment when establishing the ACO's rebased historical benchmark to reflect a percentage of the difference between the regional fee-for-service ("FFS") expenditures in the ACO's regional service area and the ACO's historical expenditures. A phased approach will be used to transition to a higher weight in calculating the regional adjustment. For those ACOs determined to have spending higher than their region, a lower weight will apply in calculating the regional adjustment the first and second time that their benchmark is rebased under the revised rebasing methodology using the following approach:
    - For higher spending ACOs, the weight placed on the regional adjustment will be reduced to 25 percent (compared to 35 percent for other ACOs) in the first agreement period in which the regional adjustment is applied, and 50 percent (compared to 70 percent for other ACOs) in the second agreement period in which the adjustment is applied.
    - Ultimately a weight of 70 percent will be applied in calculating the regional adjustment for all ACOs beginning no later than the third agreement period in which the ACO's benchmark is rebased using the revised methodology.
- Annually update the rebased benchmark to account for changes in regional FFS spending, replacing the current update, which is based solely on the absolute amount of projected growth in national FFS spending.

For ACOs that started in the program in 2012 and 2013 and that have renewed their participation for a second agreement period beginning in 2016, the revised methodology will apply for the first time in calculating the rebased historical benchmark for their third agreement period (beginning in 2019). For these ACOs' second agreement period (2016 – 2018), the benchmark rebasing methodology established with the June 2015 final rule will continue to apply, including equally weighting the ACO's historical benchmark years and applying an adjustment for savings generated under the ACO's first agreement period.

Extension of Participation Agreement in Track 1

Under the MSSP, ACOs enter a three-year agreement period with CMS under a one-sided (Track 1) or two-sided (Track 2 or Track 3) risk model. ACOs participating in Track 1 have the option to renew for a second, three-year agreement period under Track 1 or under a two-sided risk model. Now, an ACO participating in Track 1 that renews its participation agreement under a two-sided risk model may request

that its participation in Track 1 be extended for one additional year (giving the ACO effectively a four-year agreement period under Track 1). At the end of this additional year, the ACO will transition to Track 2 or Track 3 for a three-year agreement period.

Policies for Reopening Payment Determinations

In the final rule, CMS defined time frames and criteria for reopening a determination of ACO shared savings payments or shared losses owed by the ACO to correct financial calculations. Re-openings are limited to not later than four years after the date of notification to the ACO of the initial determination of shared savings or losses for the performance year for good cause. CMS reserves the right to reopen a payment determination at any time in the case of fraud or similar fault.

According to a CMS press release, "Medicare is moving away from paying for each service a physician provides towards a system that rewards physicians for coordinating with each other." Earlier this year, the U.S. Department of Health and Human Services ("**HHS**") **announced it met its goal** of tying 30% of Medicare payments to alternative payment models that reward quality of care over quantity of services, such as ACOs, by 2016. HHS' new goal is to tie 50% of Medicare payments to alternative payment models by 2018.

ACOs play an important role in this transition, and the recent changes indicate CMS' commitment to making these organizations sustainable.

We'd like to hear your feedback and suggestions for future newsletters. Please contact:

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