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HEALTH LAW VITALS

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Regulatory/Compliance:

CMS Unveils Draft Quality Measure Development Plan for New Payment Models

Billy Marsh

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On December 18, 2015, the Centers for Medicare and Medicaid Services ("**CMS**") released its draft Quality Measure Development Plan ("**QMDP**"). The QMDP offers an overarching framework for the development of quality measures used to effect payment adjustments to providers in the Merit-based Incentive Payment System ("**MIPS**") and Alternative Payment Models ("**APMs**") created by The Medicare Access and CHIP Reauthorization Act of 2015 ("**MACRA**").

MIPS consolidates and replaces existing quality-based incentive programs such as the Physician Quality Reporting System, the Value Modifier, and the "Meaningful Use" program. The QMDP provides that, beginning in 2019, CMS will adjust payments based on a score assigned to the provider in four performance categories: (1) quality; (2) resource use; (3) clinical practice improvement activities; and (4) meaningful use of certified electronic health record technology.

APMs allow Health and Human Services and CMS to offer incentive payments to providers for participation in authorized programs, such as Accountable Care Organizations ("**ACOs**"), Patient Centered Medical Homes, and bundled payment models. MACRA requires that quality measures used in APMs be comparable to those used in MIPS.

While the QMDP does not propose any specific quality measures, it provides the principles that will guide their development. CMS states in the QMDP that its goal is to create a "patient-centered measure portfolio" that will do the following:

- follow patients with chronic conditions across the continuum of care;
- emphasize outcomes;
- address the patient experience, care coordination, and appropriate use of resources;
- promote multiple levels of accountability;

QUICK SHOTS

OIG Advisory Opinion regarding non-profit organization's financial assistance with medical costs for patients receiving treatment for certain diseases

Read more.

HHS' final rule modifying HIPAA to allow certain entities to disclose to NICS identities of individual disqualified from possessing a firearm

Read more.

- apply to multiple types of providers;
- account for low-volume providers;
- align with other payment models and reporting systems, including those from the private sector and other government-payor programs; and
- rely on data generated from electronic health records.

In the QMDP, CMS commits to "collaborate with specialty groups and associations to develop measures that are important to both patients and providers and that represent important performance in the targeted quality domains." CMS further states throughout the QMDP that it will listen to and involve all stakeholders in further developing quality measures for MIPS and APMs.

The comment period on the QMDP ends March 1, 2016. CMS will post the final QMDP that incorporates edits based on comments received from the public by May 1, 2016. Specific details regarding the quality measures CMS will use in implementing MIPS must be published in the Federal Register by November 1, 2017. CMS will begin payment adjustments under MIPS on January 1, 2019, based on the 2018 performance period.

Healthcare Technology:

New Year, New Stark Law Provisions

Phil Kim

Phil Kim

To be applied to all services furnished under the Medicare Physician Fee Schedule ("**PFS**") on or after January 1, 2016, the Centers for Medicare & Medicaid Services ("**CMS**") has implemented the final CY 2016 PFS rule ("**the Final Rule**") in response to health care delivery and payment systems reform and in the hopes of

UPCOMING EVENTS

17th Annual Conference on Emerging Issues in Healthcare Law
Addressing the Compliance Challenges of Tomorrow Today

Sean McKenna
March 2, 2016
San Diego, California.

20th Annual Compliance Institute
Effective Compliance: Lessons Learned from the Past and Preparing for the Future

Sean McKenna
April 20, 2016
Las Vegas, Nevada.

28th Annual Health Law Conference
Texas Medicaid: The 1115 Waiver and Other Provider Initiatives

Michelle Apodaca
April 21, 2016
Houston, Texas.

reducing the burden on providers and facilitating compliance with the Stark regulations. This marks the first set of substantial changes to the Stark regulations since the "Phase IV" changes were issued in 2009.

The Final Rule's major changes include updates to the payment policies, payment rates, and quality provisions for services covered by the PFS. It also updates the Stark regulations with two new exceptions to the physician self-referral prohibition, changes the requirements for physician-owned hospitals, and offers several clarifications to the Stark regulations.

New Exceptions

The two new exceptions to the Stark law involve the recruitment of non-physician practitioners and timeshare arrangements.

Recruitment of Non-Physician Practitioners

In adding the exception for the recruitment of non-physician practitioners, CMS acknowledged significant changes to health care delivery and payment systems, as well as the projected shortages in primary care providers, by finalizing a new exception for remuneration from a hospital, federally qualified health center ("**FQHC**"), or rural health center ("**RHC**") to a physician in order to assist the physician in recruiting and compensating an employee or independent contractor non-physician practitioner ("**NPP**") who furnishes "substantially all" primary care services or mental health services to patients of a physician's practice. For purposes of the new exception, NPPs include clinical social workers, clinical psychologists, physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse midwives. However, NPPs do not include certified registered nurse anesthetists, dieticians and physical therapists.

The amount of the remuneration may not exceed fifty percent of the actual aggregate compensation to the NPP (including any signing bonus and benefits), and the exception may be used only once in a three-year period for the same physician. Additionally, the exception is not available for indirect compensation arrangements, which must satisfy the indirect compensation arrangement exception. For example, the exception cannot be used to provide assistance to a physician who contracts with a staffing company that will provide an NPP to the physician's practice.

Timeshare Arrangements

CMS also finalized a new exception to protect timeshare arrangements between hospitals or physician organizations (the licensor) and physicians (the licensee) for the non-exclusive use of the hospital's or physician organization's space, equipment, personnel, supplies, or services if they meet specified requirements, including:

- the arrangement must specify the equipment, personnel, supplies, or services, and it must be in writing and signed by the parties;
- compensation over the course of the term of the arrangement must be set in advance, consistent with fair market value and commercially reasonable without taking into account the volume or value of referrals;
- compensation must not use a formula based on a percentage of revenue raised, earned, billed, collected, or otherwise attributed to the services provided or a formula based on a per-unit of service fee that is not time-based if the fees are for services referred to the licensor or the licensee;
- the premises must be used predominantly for evaluation and management ("**E/M**") services, and any equipment must be located in the same building where the E/M services and designated health services ("**DHS**") are furnished; and
- all locations included in the arrangement for furnishing E/M and DHS services must be on the same schedule.

CMS finalized the new exception to address concerns that timeshare arrangements, which are fairly common and beneficial in some circumstances, could generally fail to satisfy existing exceptions. For example, oftentimes, timeshare arrangements cannot meet the space and equipment arrangement exceptions, which require "exclusive use" when used by the lessee, or the fair market value exception, which is not available for space leases.

Clarifications

The Final Rule also includes clarifications and modifications to existing Stark law exceptions, including the following provisions:

- Written Agreement Requirement
- Definition of Remuneration
- "Stand in the Shoes"
- Temporary Noncompliance with Signature
- Holdover Arrangements for Space, Equipment, and Personal Services
- Fair Market Value
- "Incident To"

For details of these clarifications, please click here.

In addition to the above new exceptions and clarifications, CMS is planning on issuing a report to Congress to determine if additional rulemaking may be necessary in light of evolving payment models integrating physicians and other health care entities to achieve population health and reduce costs.

Innovative Trends/Models of Care:

Texas Telemedicine 2015 Year in Review

Lisa Prather

Lisa Prather

The regulations regarding telemedicine in Texas were a frequent topic of discussion in 2015. While the telemedicine rules currently in effect for Texas are the same as they were this time last year, over the course of the past year there were amendments to the rules, litigation to enjoin enactment of those amendments, and legislation related to the rules.

The use of telemedicine in Texas dates back to 1998, when Texas' Medicaid program started offering telemedicine services to those in medically underserved areas. Thereafter, the Texas Legislature took several steps to expand the types of services, providers, and locations eligible for reimbursement for telemedicine services.

In October 2010, the Texas Medical Board ("**TMB**") amended several provisions of its telemedicine rules, including: revising the definition of "telemedicine" to require consultations using advanced telecommunications technology so that providers could see and hear the patient in real time; requiring that providers establish a proper physician-patient relationship via physical, face-to-face, examination of the patient; and prohibiting the prescription of controlled substances via telemedicine. These changes initiated the first disconnect between the TMB and companies providing medical services solely via telecommunications, particularly a Dallas-based telehealth company known as Teladoc that provides round-the-clock patient care through Internet real-time telephone and video consultations.

Starting in 2011, a series of warning letters, lawsuits, injunctions, and countersuits were exchanged between the TMB and Teladoc, and 2015 saw renewed legal battles between the parties. In January 2015, the

TMB passed an emergency measure to prohibit the prescribing of drugs without an initial in-person visit, so Teladoc filed a federal antitrust suit and sought a preliminary injunction to prevent the new rule taking effect.

Just two months later, in March 2015, TMB proposed official amendments to the telemedicine rules, which were approved by the TMB in April 2015 and scheduled to take effect on June 3, 2015. The revised rules required "establishing a diagnosis through the use of acceptable medical practices, including documenting and performing patient history, mental status examination, and physical examination *that must be performed as part of a face-to-face or in-person evaluation….*" (22 Tex. Admin. Code 174.8(a), emphasis added).

While the revised rules included some changes which may help expand telemedicine services, such as exceptions for mental health services and for situations where the patient is currently at a health facility and is attended by another healthcare professional, many saw the face-to-face or in-person requirement as impeding the use of technology and hindering the expansion of telemedicine. TMB's position is that the revised rules aim to strike a balance between patient safety and the use of advanced technology. Teladoc feels that the changes restrict access to healthcare and prevent patients from having a more convenient and affordable option for their medical needs, so Teladoc once again filed suit.

On May 29, 2015, less than a week before the revised rules would take effect, the U.S. District Court in Austin granted Teladoc's request for an injunction against TMB's new rules. Most recently, on December 14, 2015, a federal judge rejected TMB's motion to dismiss Teladoc's antitrust suit. Most likely, there will be further motions and rulings in 2016, but there may not be full resolution until February 2017, when the case regarding the new rules is set for trial.

Texas is not the only state trying to find the correct balance between the practice of medicine and the use of technology. As Medicare, Medicaid and other payors continue to add aspects of telemedicine that qualify as reimburseable services, most states are taking some type of action related to telemedine.

Several other states, including Arizona, Colorado, Connecticut, Florida, Kentucky, Maine, Montana, Nebraska, New Hampshire, New Mexico, Oklahoma and Tennessee, have enacted legislation to regulate a variety of telemedicine activities. These states, like Texas, tend to be viewed as having heightened requirements for telemedicine. Twelve states have joined the Interstate Medical Licensure Compact ("**IMLC**"), whose goal is to expedite licensing of physicians seeking to practice in multiple states and improve access to healthcare through the use of telemedicine technologies. Texas has not yet joined the IMLC, but it and seven other states have introduced legislation related to the IMLC.

Texas politicians have also taken action in this area. More than 10 telemedicine bills were filed during the 84th Texas Legislature, and, by the time the legislature adjourned in June 2015, only one bill, House Bill 1878, had passed. This legislation allows Medicaid reimbursement for school-based telemedicine if certain requirements are met.

Further, the Texas political leadership recognized the significance of the telemedicine topic related to access to care and issued "Interim Charges" to study the issue in 2016. The Interim Charge designation indicates the potential for the issue to become priority legislation during the next legislative session, which will reconvene in January 2017.

As 2016 begins, Texas will most likely continue to experience (and possibly cause) some static as it works to find the right connections between providers and patients via the use of telemedicine.

FDA/Emerging Products:

Supporting Health through Healthier Food Choices: A Spotlight on Food Labeling in 2016

Suzie Trigg

Suzie Trigg

The FDA's Proposals on the Revision of the Nutrition and Supplement Facts Labels

In early 2014, first lady Michelle Obama announced upcoming changes to the FDA's Nutrition Facts label, and in March 2014, the FDA issued a proposed rule on the revision of Nutrition and Supplement Facts labels "to assist consumers in maintaining healthy dietary practices." The FDA's proposed rule, along with a supplemental proposed rule issued in July 2015 regarding added sugar, mark the first changes to the Nutrition Facts panel since the 2003 *trans fat* rulemaking and the first overhaul of the Nutrition Facts panel in the 20 years since implementation.

The FDA's proposed Nutrition Facts label changes have received extensive attention – and comment – from industry and the public alike. The food industry estimates that a significant amount of resources will be required to implement the changes, and many companies are concerned about maintaining their brand's image in light of increased serving sizes and the labeling of "added sugar." As to serving sizes, the FDA has attempted to more accurately reflect the amount that consumers eat in a sitting, rather than what consumers *should* eat in a sitting. Therefore, the total calories of many products, in addition to appearing in a larger font, will also appear to consumers to increase. As to added sugar, the industry has questioned the FDA's scientific basis for mandating such disclosure, particularly since there is no distinguishable difference between sugars in a food and added sugars in a food.

In short, while many aspects of the FDA's proposed updates to Nutrition Facts labels are hotly debated, it is likely that the FDA will interpret the comments that it has received to release a final rule in 2016. From there, it remains to be seen whether the FDA will allow two years for implementation or more time, as certain industry stakeholders have requested. Meanwhile, the food industry is already preparing for revisions, given the long lead time needed to reanalyze products and potentially reformulate certain products.

GE, GMO, Bioengineered – Which to Use or Not Use?

Vermont's hotly contested Act 120 – the nation's first significant law relating to the labeling of food produced with genetic engineering ("**GE**") – remains the subject of a lawsuit brought by the Grocery Manufacturers Association ("**GMA**"). GMA has argued that Vermont's law, which requires food product manufacturers to label foods sold in Vermont after July 1, 2016 as "produced with genetic engineering" (if containing genetically engineered ingredients), is unconstitutional and confusing to consumers. More recently, the FDA has released its own guidance revealing its position on the labeling of genetically engineered foods.

The FDA's Guidance on Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants reaffirms the FDA's position that the FDA does not view genetic engineering, alone, as a material fact that warrants mandatory inclusion on food labels. However, the FDA recognized the interest in this information and suggested the use of statements such as:

- "Not bioengineered."
- "Not genetically engineered."
- "Not genetically modified through the use of modern biotechnology."
- "We do not use ingredients that were produced using modern biotechnology."
- "This oil is made from soybeans that were not genetically engineered."

- "Our corn growers do not plant bioengineered seeds."

Notably, the FDA cautioned against the use of the term "GMO," as such term describes full organisms and not ingredients.

Labeling Foods as Natural

In response to requests from courts, the public, and industry, the FDA may be one step closer to more fully defining the parameters under which a food can be labeled as "natural." The FDA is currently seeking comments on the use of the term "natural" on food labeling. The comment period ends on May 10, 2016.

With significant changes to mandatory food labeling on the way, along with new developments with respect to voluntary labeling of foods, 2016 promises to be a year in which food companies should closely watch developments and weigh in to promote their interests.

Employment/Benefits:

What Does the DOL's New Guidance on Worker Classification Mean for Healthcare Staffing Agencies in Texas?

LaToya Alexander

LaToya Alexander

Recently, the Department of Labor ("**DOL**") issued an Administrator's Interpretation ("**Interpretation**") on the standards for determining whether a worker is an employee or independent contractor under the Fair Labor Standards Act ("**FLSA**"). According to the Interpretation, "most workers are employees under the FLSA's broad definitions." This may potentially include healthcare staffing agency hires.

The Interpretation's Economic Realities Test

In order to determine whether one is an employee, many courts utilize the "economic realities" test—an analysis which focuses on whether a worker is economically dependent on the alleged employer, rather than in business for herself. A worker who is economically dependent on an employer is suffered or permitted to work by the employer and is therefore an employee. The economic realities test is typically based on six common factors: (1) whether the work is an integral part of the employer's business; (2) whether her managerial skill can affect her profit and loss; (3) the nature and extent of her relative investment in comparison to the employer's investment; (4) whether work requires business skills, judgment, and initiative; (5) whether the relationship is permanent or indefinite; and (6) the nature and degree of the employer's control of the worker. In applying these factors, the Interpretation states the analysis should be guided by the FLSA's statutory directive that the scope of the employment relationship is very broad and that no one factor is determinative of a worker's status. "Ultimately, the goal is not simply to tally which factors are met, but to determine whether the worker is economically dependent on the employer (and thus its employee) or really in business for himself or herself (and thus its independent contractor)."

Interpretation v. Fifth Circuit

In the Fifth Circuit, the economic realities test differs from the Interpretation's in part because the courts typically do not utilize the "integral" factor. Though there are not many Fifth Circuit cases regarding the status of healthcare staffing agency workers, a Texas district court case involving a Home and Community-Based Service provider is instructive for comparing the Interpretation's analysis of the economic realities test to the Fifth Circuit's test.[1] In *Chapman v. A.S.U.I. Healthcare of Texas, Inc.*, the court granted summary

judgment to two direct care specialists, who were hired to be with clients in group residences, determining they were employees as a matter of law. In that case, the plaintiffs were interviewed by ASUI, were classified as independent contractors for tax purposes, provided their own uniforms, and typically worked in residents' homes daily from 3 p.m. to 9 a.m., though they were not paid from 10 p.m. to 6 a.m. while clients were asleep.

Profit and Loss

The court concluded this factor weighed in favor of employee status because plaintiffs' hours and rate of pay were determined by ASUI. This analysis is slightly different than the Interpretation's, which focuses on whether the worker's managerial skill can affect an employee's profit and loss. According to the DOL, this factor is determined not by whether the worker has the potential to work more hours, but instead on whether the worker exercises her managerial skill (e.g., negotiating contracts, deciding which jobs to perform, and hiring helpers to assist).

Relative Investment

The court determined this factor weighed in favor of employee status because the plaintiffs' investment of purchasing uniforms was "negligible" in comparison to ASUI's investment in contracts, management of clients and payroll, and operation of a "Dayhabilitation Center." This analysis is directly in line with the Interpretation's guidance that the relevant inquiry is how the worker's investment compares to the employer's overall business, rather than the employer's investment on a particular job.

Skill and Initiative

Because plaintiffs' jobs required no prior experience and their duties were to cook, clean, and interact with clients, the court concluded this factor weighed in favor of employee status since plaintiffs did not need special training or a unique skill. Though the conclusion would likely be the same, this is somewhat different from the Interpretation in that the DOL focuses on a worker's business skills, judgment, and initiative, not his technical skills, in order to determine whether a worker is economically independent.

Permanency

The court determined this factor weighed in favor of employee status because the plaintiffs worked continuously for ASUI and did not concurrently perform work in a similar capacity for another employer, a conclusion which is likely in line with the Interpretation's note that an independent contractor typically works "one project for an employer and does not necessarily work continuously or repeatedly for an employer." According to the DOL, the key is whether the "lack of permanence or indefiniteness is due to operational characteristics intrinsic to the industry, or the worker's own business initiative."

Control

Finally, the court determined the control factor weighed in favor of employee status because plaintiffs "had little to no control over the meaningful aspects of the business." ASUI assisted plaintiffs in finding clients, controlled their hours, assigned them to houses, and called them to cover other specialists who were absent. Such a determination is directly akin to the Interpretation's control factor guidance. Indeed, the Interpretation's example of the control factor regarding employee nurses on a nurse registry is quite similar to the facts in *Chapman*.

Effect on Healthcare Staffing Agencies

The Interpretation sends a message that the DOL will consider most workers employees under the FLSA, and the *Chapman* court's analysis suggests that many of the factors used to determine whether staffing agency hires are employees in the Fifth Circuit are analyzed in the same manner as the Interpretation. Though it is not clear whether Texas courts will change their worker classification analysis based on the Interpretation, whether a staffing agency hire goes through training, has to adhere to staff agency supervision regarding whether she will accept an assignment, can take on other jobs while working for the staffing agency, works on a project short term, and/or has a comparably larger monetary investment than the staffing agency are all factors likely to be considered.

[1] *Chapman v. A.S.U.I. Healthcare of Texas, Inc.*, No. CIV.A. H-11-3025, 2012 WL 3614187 (S.D. Tex. Aug. 21, 2012), *aff'd sub nom. Chapman v. A.S.U.I. Healthcare & Dev. Ctr.*, 562 F. App'x 182 (5th Cir. 2014).

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

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