LHA IMPACT LAWBRIEF

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Louisiana Hospital Association

Volume 33, No. 4 – June 2018 **Connect with LHA:**

Headlines:

- **HIPAA Privacy, Security Rules Front and Center Following M.D. Anderson Breach Ruling**
- **Justice Department Files Brief in Texas Lawsuit Supporting Challenge to the Constitutionality of the ACA**
- **BLUE VALLEY HOSPITAL UPDATE – Kansas District Court Dismisses Case, BVH Medicare Provider Agreement Terminated for Failing to be "Primarily Engaged"**
- **LDH Licensing "Express Lane" Coming Soon**
- **CMS Requests Feedback on Regulatory Burdens of the Stark Law**

Notices:

CALL FOR SPEAKERS: The 2018 Health Law Symposium will be held this year on November 20 at the LHA Conference Center in Baton Rouge. We are currently seeking speakers and topic suggestions for this event. We want your input! Please share your suggestions with us through this online survey: https://www.surveymonkey.com/r/2018HealthLaw.

ARTICLE SUBMISSION: The LHA Society of Hospital Attorneys encourages its members to submit articles on topics of interest. Writing an article that is published in *Lawbrief* is a great way to promote your name in the healthcare community and advertise your knowledge. If you have written an article and would like to have it considered for publication in *Lawbrief*, please email it in Word format (no PDFs please) to LHA Advocacy Coordinator Meaghan Musso at mmusso@lhaonline.org.

LEGAL & REGULATORY EDUCATION PROGRAMS & WEBINARS:

- July 10 Auditing Evaluation and Management Coding Compliance (Webinar)
- July 10 HIPAA Audit & Enforcement Update: How to Prepare for Reviews & Avoid Penalties (Webinar)
- July 12 Meeting CMS, CAH CoPs, DNV and TJC Requirements on Dietary, Food and Nutrition Services (Webinar)
- July 17 Advance Directives: Ensuring Compliance with CMS and TJC (Webinar)
- July 19 Electronic Health Records: Auditing Quality & Compliance (Webinar)
- July 23 2018 LHA Summer Conference & Annual Meeting (Orange Beach, AL)
- July 25 Medical Staff Bylaws Update (Webinar)
- Aug. 1 Joint Commission Infection Control 2018 Update (Baton Rouge)
- Aug. 7 Medicare Cost Report and the Chargemaster: The Medicare Cost Report & Cost-to-Charge Ratios (Webinar)
- Aug. 21-22 Human Resource Professional Symposium (Baton Rouge)
- Aug. 23 Cybersecurity and Ransomware "Train the Trainer" (Baton Rouge)
- Aug. 30 **NEW DATE** Payor Day Series - Medicare/Medicare Advantage Plans (Baton Rouge)
- Sept. 12-13 Infection Prevention Boot Camp (Brochure Coming Soon)

Articles:

HIPAA Privacy, Security Rules Front and Center Following M.D. Anderson Breach Ruling
By: Cindy Amedee

On June 18, 2018, the U.S. Department of Health and Human Services, Office of Civil Rights (OCR) announced a $4.3 million penalty against M.D. Anderson Cancer Center for three breaches of unprotected personal health information (PHI) that occurred in 2012 and 2013. One breach involved theft of an unencrypted laptop, and the other two breaches involved theft of unencrypted thumb drives, all of which contained personal health information. The breaches affected more than 33,000 patients.

The Department found that M.D. Anderson did not encrypt all its electronic health information, despite having a written policy regarding encryption. OCR stated that the amount of the penalty is based on the number of patients that were affected and the amount of time that M.D. Anderson was out of compliance with HIPAA. M.D. Anderson argued that it was not responsible for encrypting all the data and that not all of the data included personal health information and, therefore, was not subject to HIPAA. The Office of Civil Rights did not agree with these arguments.

On June 15, 2018, the United States District Court for the District of Columbia fell in line with other courts when it ruled that a patient has no private right of action under HIPAA against his or her health care provider for a breach of health information. A patient may file suit under some other theory of law, but the court will dismiss claims that rely on HIPAA. Patients' sole remedy for breach of health information under HIPAA is the filing of complaints with the Secretary of the U.S. Department of Health and Human Services and/or a State's attorney general's office.

Health information sharing, and the rules and regulations of software, licensing and technology issues, are important issues to our health care clients, and these issues are coming to the forefront as more is being done to try to curb record hacking with the advances of technology. In keeping with Taylor Porter's commitment to its health care clients to actively monitor the latest state and federal regulatory developments within the health care industry, our firm wants to make clients aware of these two noteworthy stories this week that focus on the growing concern of health information technology issues.

According to an article in the *HIPAA Journal*, "Report: Healthcare Data Breaches in Q1, 2018," there have been 77 healthcare data breaches reported to the Department of Health and Human Services' OCR. Those breaches have impacted more than one million patients and health plan members – almost twice the number of individuals that were impacted by healthcare data breaches in Q4, 2017. The *Journal* reported that the main cause of breaches in Q1, 2018 was unauthorized access/disclosures – 35 incidents; followed by 15 breaches involving the loss or theft of electronic devices containing ePHI, all of which could have been prevented had encryption been used.

The two largest breaches of the year to date have affected Oklahoma State University Health Sciences Center (279,865 individual patients affected) and St. Peter's Surgery & Endoscopy Center (134,512). In both cases, hackers gained access to the networks, and viewed and obtained patients' PHI.

Health information sharing, and the rules and regulations of software, licensing and technology issues are important issues to healthcare companies. These issues are coming to the forefront as more is being done to try to curb record hacking with the advances of technology. These first quarter 2018 data breach numbers, the result of the M.D. Anderson breach, and the instances of several other healthcare centers' breaches should encourage administrative leaders to take proactive measures in medical records, e-health issues and HIPAA privacy and security to protect the information of their patients.

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Justice Department Files Brief in Texas Lawsuit Supporting Challenge to the Constitutionality of the ACA

By: Clay J. Countryman, Esq.

Depending on how a Texas federal court rules in a lawsuit filed February 2018, by 20 state attorney generals (including Louisiana), all or part of the Affordable Care Act (ACA) could be declared unconstitutional. On June 7, 2018, the Justice Department filed a brief in Texas v. the United States (N.D. Texas 2018) (the "Texas lawsuit") that largely supported the challenge to the constitutionality of the Individual Mandate in the ACA requiring individuals to maintain essential health insurance coverage.

The Trump administration had previously announced that it will not defend the ACA against the legal challenge in the Texas lawsuit to the ACA's constitutionality, which is break from the executive branch's tradition defending existing statutes. In the brief filed in the Texas federal court and an accompanying letter to the House and Senate leaders of both parties, the Justice Department agrees in large part with the 20 state attorney generals that brought the suit that the Individual Mandate in the ACA requiring individuals to purchase and maintain health insurance was unconstitutional because of the 2017 tax legislation's reduction of the tax penalty formula to zero.

The Justice Department's brief also received considerable attention because of the Justice Department's request that the ACA's guaranteed-issue and community-rating requirements also be declared invalid as of January 1, 2019. Sixteen states and the District of Columbia have intervened in the Texas lawsuit to defend the lawsuit against the ACA since the Justice Department filed its brief in early June.

Background

The Supreme Court ruled in the 2012 landmark decision in *NFIB v. Sebelius,* 567 U.S. 519 (2019), that Congress lacked the constitutional authority to impose a mandate on individuals to obtain health insurance which required that most Americans "shall" insure that they are "covered under minimum essential coverage." The Supreme Court rejected the Obama administration's argument that Congress was authorized to impose the Individual Mandate under its constitutional power to regulate interstate commerce. However, the Supreme Court also ruled that the Individual Mandate and the tax penalty imposed on individuals for not having coverage was a lawful exercise of Congress's taxing power. A majority of the Supreme Court noted in the *Sebelius* decision that the court's decision under Congress's taxing-power interpretation was only *"fairly possible"* because the tax-penalty raised "at least some revenue for the Government."

In December 2017, Congress enacted the Tax Cuts and Jobs Act of 2017 (2017 Tax Act), which in part reduced the tax penalty under the Individual Mandate to zero for not having health starting in January 2019. Subsequently, on February 26, 2018, the Texas lawsuit was filed by the 20 state attorney generals arguing that the ACA and the Individual Mandate are unconstitutional now that Congress has repealed the tax-based penalty that supported the constitutionality of the ACA under the *Sebelius* ruling as a valid exercise of Congress's taxation power.

The Texas Lawsuit

In the Texas lawsuit, the complaint filed by the 20 state attorney generals argues that "Because the tax penalty raises $0 after the enactment of the 2017 Tax Act, the Individual Mandate lacks "the essential feature of any tax," and the interpretation by the Supreme Court in Sebelius to save the Individual Mandate from its unconstitutionality is no longer "fairly possible". The complaint further argues that if the Individual Mandate is unconstitutional then the remainder of the entire ACA is also unconstitutional.

The Texas lawsuit asks the court to: (1) declare the ACA, as amended by the 2017 Tax Act, unconstitutional; (2) declare all rules and regulations promulgated under the ACA to be unlawful; and (3) to enjoin the government from implementing and enforcing the ACA.

The Justice Department Brief Filed in the Texas Lawsuit

In the brief filed in the Texas lawsuit, the Justice Department takes the position that "As of 2019, the Individual Mandate will be unconstitutional under controlling Supreme Court precedent (from the *Sebelius* case) holding that "the Federal Government does not have the power to order people to buy health insurance". Thus, the Justice Department essentially agrees with the plaintiffs in the Texas lawsuit that the Individual Mandate is unconstitutional absent the collection of any revenue under the tax penalty because of the Tax Act of 2017, except that the Justice Department asserts that the Individual Mandate will not be unconstitutional until the tax penalty becomes zero on Jan. 1, 2019.

The Justice Department also argued in its brief the guaranteed-issue and community-rating provisions of the ACA are not severable from the minimum coverage provisions, and therefore are also invalid. However, contrary to the plaintiffs' argument in the Texas lawsuit, the Justice Department also argues that the remainder of the ACA is severable from the Individual Mandate and should remain intact. The Justice Department noted that the ACA's other major provisions, such as various insurance regulations, health insurance exchanges and associated subsidiaries, the employer mandate and Medicaid expansion, and reduced federal healthcare reimbursement rates for hospitals, are severable from the Individual Mandate.

While the Texas lawsuit has to play out from here, the position of the Justice Department in its brief does raise the possibility that the ACA, or at least the Individual Mandate and other major provisions could be struck down and no longer enforceable.

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BLUE VALLEY HOSPITAL UPDATE – Kansas District Court Dismisses Case, BVH Medicare Provider Agreement Terminated for Failing to be "Primarily Engaged"
By: Jacob S. Simpson and Dani Borel

As reported in last month's LHA article, Blue Valley Hospital (BVH) recently filed a lawsuit seeking to restrain and enjoin the United States Department of Health and Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS) from terminating BVH's Medicare certification and provider contracts. In the lawsuit filed with the United States District Court for the District of Kansas (Kansas District Court), BVH argued that if the Temporary Restraining Order (TRO) and injunction were not granted, BVH would lose nearly all of its revenue while the administrative appeal was pending, which would force BVH to close and would result in irreparable harm. At the time of the prior article, it was unclear how the Court would rule and whether the BVH Medicare provider agreement would be terminated.

On June 7, 2018, the Kansas District Court dismissed the BVH case for lack of subject matter jurisdiction because BVH had not exhausted its administrative remedies. BVH's Medicare provider agreement was subsequently terminated by CMS in a Public Notice of Termination effective June 15, 2018. Hospitals should carefully analyze the requirements to be "primarily engaged" that are summarized below, and make any necessary adjustments to meet those requirements prior to the arrival of surveyors. As the BVH case illustrates, the administrative process can be slow and the courts are not likely to grant injunctive relief to protect against termination of a hospital's provider agreement while the hospital pursues its administrative remedies.

Background

The "Primarily Engaged" Requirement: In summary, Survey and Certification Memo: 17-44-Hospitals (S&C 17-44) states that to be a hospital, a facility must be "primarily engaged" in providing certain services **to inpatients**. For the surveyors to determine whether or not an entity meets the "primarily engaged" requirement, hospitals must have two inpatients at the time of the survey, as well as an average length of stay (ALOS) and average daily census (ADC) of two over the past twelve months.

If a hospital does not have at least two inpatients at the time of the survey, a survey will not be conducted at that time and surveyors will review the ADC and the ALOS data over the past 12 months. If the facility does not have a minimum ADC of two inpatients and an ALOS of two over the last 12 months, the guidance to surveyors is that the facility is most likely not primarily engaged in providing care to inpatients. The State Agency (SA) or Accrediting Organization (AO) must immediately contact the CMS Regional Office (RO) to inform them that a survey could not be completed. The RO will consider certain enumerated additional factors in determining whether to conduct a second survey. After considering those factors, the RO will determine whether a second survey should be conducted. If the CMS RO determines a second survey should be conducted but the facility does not have two inpatients, the survey will not be conducted. Instead, the facility will be cited for non-compliance with 42 CFR § 482.1. For initial applicants, the RO will then deny the applicant's certification in the Medicare program. For hospitals currently participating in Medicare, the RO will proceed with termination of the provider agreement, after considering all the circumstances, including access to care concerns.

The BVH Survey: On Nov. 13-14, an unannounced survey was conducted at BVH. At the time of the survey, BVH had no inpatients. The surveyors reviewed the ADC and ALOS data for BVH from Nov. 1, 2016 to Oct. 31, 2017. The Hospital Database Worksheet reviewed by the surveyors showed an ADC of .48. BVH reported an ALOS of 1.2. The survey report also found that nearly every patient was discharged prior to the weekend; BVH performed 309 outpatient surgical procedures for the prior year compared to 146 inpatient surgical procedures; BVH advertised that it performed laparoscopic procedures where most patients are able to return to their home the day after surgery; and BVH recently added 5 off-campus locations to its Medicare provider number, none of which provided inpatient services. Based on that information, the surveyors concluded BVH was not "primarily engaged" in providing services to inpatients. BVH submitted a plan of correction, but the CMS RO determined the POC lacked specific dates as to when the hospital would come into compliance and was "aspirational only." CMS subsequently sought to terminate the BVH Medicare provider agreement.

The BVH Appeal and Lawsuit for Injunctive Relief: As a result, BVH requested an expedited hearing with the HHS Departmental Appeals Board and filed suit in the Kansas District Court to restrain and enjoin the HHS and CMS from terminating its Medicare certification and provider contracts. BVH sought an injunction to continue operating and treating patients while pursuing its administrative appeal and judicial review if needed.

BVH alleged the ADC and ALOS requirements were contrary to and directly conflicted with CMS' own definition of "inpatient." Specifically, a patient is considered an inpatient if formally admitted as an inpatient "with the **expectation** that he or she will require hospital care that is expected to span at least two midnights." However, the ADC and ALOS requirements of S&C 17-44 mandate an ADC of two inpatients and ALOS of two midnights. BVH argued that many of its inpatients have an expected stay of two midnights, but because of the high quality of care received, are able to go home earlier than expected. In addition, BVH argued CMS violated the rule-making requirements by failing to provide a notice and comment period for the new ADC, ALOS and two inpatient minimum requirements.

Kansas District Court Opinion

In a June 7, 2018, Memorandum and Order, the Kansas District Court dismissed the BVH motion for a preliminary injunction for lack of subject matter jurisdiction concluding BVH had not exhausted its administrative remedies. The Court explained in detail the legal requirement for exhaustion of administrative remedies under the Medicare Act, ultimately finding that BVH could not seek injunctive relief through the Court when BVH had not exhausted the proscribed remedies. The Court did not reach the substantive issues presented by BVH. However, there are a few noteworthy takeaways from the Court's opinion that hospitals should be aware of:

1. **CMS' Resurvey Resulted in 37 Page Statement of Deficiencies:** While the Motion for TRO and Preliminary Injunction was pending, CMS resurveyed BVH on April 22-25. According to the Court, the 37-page Statement of Deficiencies from this resurvey included:

    - Admissions by BVH's leadership acknowledging that BVH knew it was not in compliance.

- To get its numbers up, a discount was offered to employees and their friends and families to incentivize them to have surgery so BVH could increase its census numbers.
- Interviews with former employees suggest they quit working at BVH because they were told to falsify medical records to make it appear that the patient needed to stay two nights, so BVH could justify keeping patients longer to inflate their inpatient numbers.
- Numerous patient safety concerns, including concerns with medication administration.

2. **BVH's Argument that S&C 17-44 Violated "Notice and Comment" Rulemaking Requirement Was Not Convincing:** BVH argued that S&C 17-44 failed to give adequate notice or opportunity to comply. The Court noted, however, "it does not appear the memo creates a new rule or standard…As Defendants argued at the May 11 hearing and in their supplemental briefing, S&C Memo 17-44 sets out the non-exhaustive criteria used to evaluate the statutory standard of whether a facility is "primarily engaged" in inpatient care."

3. **Court Found the Government's Interest in Expeditious Provider Termination Procedures Is Strong:** The Court noted that it if it were to allow pre-termination hearings in each instance where a provider's rights are terminated, it would create an administrative burden. Because BVH was tagged with numerous deficiencies, including compromise of patient care, "the government interest in protecting patients through an expeditious provider-termination procedure is quite strong."

4. **A Request for Collateral Relief Must be *Entirely* Collateral.** By arguing multiple due process violations, including the lack of notice and comment to the rules being enforced by the agency, BVH's violation of due process allegation lost its collateral nature. The *Elridge* exception to the requirement to exhaust all administrative remedies before judicial action requires an "entirely collateral" request. While BVH stated that it had not been provided with a review in a meaningful time and manner, the Court found this was not the focus of BVH's due process arguments.

The Court held BVH's request for an injunction was not collateral—sufficient to sidestep the exhaustion of administrative remedies requirement—because BVH was attacking the constitutionality of S&C 17-44, which was being enforced. These arguments were the same arguments used by BVH in the administrative proceeding to oppose the termination decision. A true collateral action cannot include an attempt to reverse the agency's decision. Finding the issue of the constitutionality of S&C 17-44 as "inextricably intertwined" with the substantive challenge to the termination decision, BVH's request was deemed not to be collateral.

However, the Court still addressed BVH's due process for lack of hearing argument. This argument was found to be not colorable because there was no proscribed procedure in which BVH was due a hearing before the termination of its Medicare provider agreement. Stated plainly, there was no rule that required the hearing BVH sought, so the agency could not have violated BVH's due process rights. Finding no exception to the exhaustion of administrative remedies requirement, the matter was dismissed for lack of subject matter jurisdiction.

This decision should be contrasted with the United States Fifth Circuit decision discussed in May's article **Patience is a virtue; an administrative hearing is a right: fifth circuit creates possibility of enjoining recoupment.** In that case the Fifth Circuit found the provider's injunction request was entirely collateral because it requested an injunction based on the failure of the administrative court to provide a hearing within 90 days, as required by the applicable procedural rules. Noteworthy, the provider did not make any arguments related to the merit of the underlying administrative decision.

Conclusion

Hospitals should know that it's not necessarily over for BVH—while BVH may have a difficult legal road ahead, the organization still has the opportunity to appeal through the HHS Departmental Appeals Board and ultimately to seek review in the court system. However, this recent Court opinion alerts hospitals to this significant threat that hospitals may not be able to seek an injunction while pursuing their

administrative remedies and judicial review. Additionally, hospitals with low ADC and ALOS should thoroughly review S&C 17-44 and begin preparing for surveyors now. Hospitals should consider:

- Will the hospital have two inpatients when surveyors arrive? BVH had no inpatients at their initial survey.
- Does the hospital routinely schedule surgeries early in the week such that patients are discharged prior to the weekend? The BVH survey report showed that nearly every patient was discharged prior to the weekend.
- Does the ADC consistently drop to zero on Saturdays and Sundays (suggesting that the facility is not consistently and primarily engaged in providing care to inpatients)? Again, the BVH survey report showed that nearly every patient was discharged prior to the weekend.
- For "surgical" hospitals, are procedures mostly outpatient? BVH performed approximately twice as many outpatient procedures as inpatient procedures.
- How many provider-based off-campus emergency departments? A large number may suggest that a facility is not primarily engaged in inpatient care and is instead primarily engaged in providing outpatient emergency services.
- What is the number of inpatient beds in relation to the size of the facility and services offered? BVH recently added 5 off-campus locations to its Medicare provider number, none of which provided inpatient services.
- What is the volume of outpatient surgical procedures compared to inpatient procedures? BVH performed 309 outpatient surgical procedures for the prior year compared to 146 inpatient surgical procedures.
- Does the hospital website suggest most surgeries are outpatient surgeries? BVH advertised that it performed laparoscopic procedures where most patients are able to return to their home the day after surgery.
- Others:
    - Do the staffing patterns suggest the facility is primarily engaged in outpatient operations? Or, are nurses, pharmacists, physicians, etc. scheduled to work to support 24/7 inpatient care?
    - Is the facility advertised as a "specialty" hospital or "emergency" hospital? Does the name of the facility include terms such as "clinic" or "center" as opposed to "hospital?"

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LDH Licensing "Express Lane" Coming Soon
By: Jacob S. Simpson

Hospitals and other healthcare providers may soon find relief from the long licensing wait times. Effective May 15, 2018, the Governor signed into law House Bill 539 (Act No. 324) which authorizes the Louisiana Department of Health (LDH) to establish an expedited licensing process for healthcare facilities and providers that LDH licenses. Getting in the "express lane" will not be cheap, however. LDH may assess fees for the expedited licensing process up to $7,500.

The final version of the law does not specify certain provider types or licensing applications which will be available for expedited processing, but the original proposed bill suggested the expedited process would apply to an adult day health care facility, ambulatory surgical center, home health agency, hospice, hospital, nursing facility, rural health clinic, intermediate care facility for people with developmental disabilities, end stage renal disease facility, outpatient abortion facility, psychiatric residential treatment facility, pediatric day health care facility, therapeutic group home, crisis receiving center, home and community based service provider, and adult residential care provider. In the final version, the expedited licensing process applies to "healthcare facilities and providers that the department licenses."

Once LDH receives and approves a completed expedited licensing application, LDH must conduct the expedited licensing survey within ten working days of the readiness date indicated by the facility. If LDH is unable to do so, they must refund the licensing fee. The law specifically states LDH may not utilize

existing employees who conduct regular licensing surveys to conduct expedited licensing surveys, suggesting new employees will be hired to operate the "express lane."

While the fees may be steep, many facilities may find it's a small price to pay to avoid the wait. The law requires LDH to promulgate any rules necessary to provide for the expedited licensing process, so be on the lookout for additional details in the Louisiana Administrative Code.

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CMS Requests Feedback on Regulatory Burdens of the Stark Law
By: Clay J. Countryman

The Centers for Medicare & Medicaid Services (CMS) is seeking public feedback regarding the regulatory impact and burdens of the Physician Self-Referral Law (commonly known as the Stark Law). On Monday, CMS published in the Federal Register a Request for Information Regarding the Physician Self-Referral Law (RFI). This is an opportunity to inform CMS through this open solicitation the significant problems and issues the Stark Law has caused for Hospitals, and recommended changes to ease those obstacles.

According to the RFI, CMS has identified some aspects of the Stark Law as a potential barrier to coordinated care and is seeking public comment on the impact and burden of the Stark Law and whether the Stark Law prevents or inhibits care coordination. CMS plans to issue guidance or revise regulations to address obstacles such as certain portions of the Stark Law, as well as to encourage and incentivize coordinated care. In the RFI, CMS has asked for stakeholders' comments on the following areas:

- The structure of arrangements between parties that participate in alternative payment models or other novel financial arrangements;
- The need for revisions or additions to exceptions to the Stark Law; and
- Certain terminology used in the context of healthcare delivery, payment reform, and the Stark Law.

In the RFI, CMS asked for public feedback on 20 questions that address the above areas. Some of the areas and questions include:

1. What existing or potential arrangements involving alternative payment models do you participate in that involve a designated health services entity and referring physician under the Stark Law;

2. What, if any, additional exceptions to the Stark Law are necessary to protect financial arrangements that involve integrating and coordinating care outside of an alternative payment model;

3. Whether the current exception at 42 CFR 411.357(n) for risk-sharing arrangements is effective;

4. Whether the special rule for compensation under a physician incentive plan within the exception for personal services arrangements is useful;

5. Comments on possible approaches to addressing the application of the Stark Law to financial arrangements with participants in alternative payment models.

6. How should the CMS define commercial reasonableness in the context of the Stark Law;

7. Whether the CMS should modify the definition of "fair market value;"

8. When compensation should be considered to "take into account the volume or value of referrals" by a physician or "take into account business generated" between parties to an arrangement;

9. Whether barriers exist to qualifying as a "group practice;"

10. Whether transparency about physician's financial relationships, price transparency or the availability of other data necessary for informed consumer purchasing could reduce or eliminate the harms to the Medicare program and its beneficiaries that the Stark Law is intended to address; and

11. What are the compliance costs for regulated entities, such as physician practices and hospitals.

Any comments and feedback to CMS in response to the Request for Information on the Stark Law must be received by CMS by 5:00 p.m. on August 24, 2018.

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