CMS Issues Changes to Stark and EMTALA Regulations and Revisits the DFRR in FY 2009 IPPS Final Rule

On July 31, 2008, the Centers for Medicare and Medicaid Services (“CMS”) issued the Hospital Inpatient Prospective Payment Systems final rule for 2009 (“FY 2009 IPPS Final Rule”). In addition to certain payment and reimbursement changes, the FY 2009 IPPS Final Rule contains revisions to the regulations promulgated pursuant to the Stark Law. Many of these changes were forecast in proposals published by CMS in the summer and fall of 2007 but due to a continued evolution of CMS’s thinking on this subject, the FY 2009 IPPS Final Rule contains a number of surprises for those who have financial relationships with referring physicians. In part, CMS offers some helpful retraction in response to industry reaction to the unwelcome complexity of the “stand in the shoes” and other concepts introduced last year. A large portion of the rule changes, however, is targeted directly at physician-owned entities that provide equipment, services or personnel to hospitals through one or more forms of compensation arrangements. Careful review and likely restructuring of a number of these relationships will be necessary well in advance of the effective dates of the FY 2009 IPPS Final Rule.

The FY 2009 IPPS Final Rule also contains final changes to the regulations governing the Emergency Medical Treatment and Active Labor Act (“EMTALA”) and revisits the implementation of the Disclosure of Financial Relationships Report (“DFRR”), which is used to report financial relationships between hospitals and physicians. Finally, CMS finalizes certain disclosure requirements for physician-owned hospitals.

Overview
In the FY 2009 IPPS Final Rule, CMS revises the Stark regulations, such that:

Effective October 1, 2008:

• Physician owners (other than titular owners, e.g. owners in “friendly PC” models) are required to stand in the shoes (“SITS”) of their physician organizations, and non-owner physicians are permitted but not required to SITS;

• Parties can rectify temporary noncompliance with a Stark exception due to a missing signature by obtaining such a signature in 90 days (if inadvertent) or 30 days (if not inadvertent);

• The exception for OB malpractice subsidies may be satisfied by an alternative set of requirements that hospitals, federally qualified health centers, and rural health clinics may meet;

1 These revisions address and adopt certain changes to the Stark Law proposed by CMS in April 2008 (“FY 2009 Proposed IPPS Rule”) and in the July 2007 proposed 2008 Physician Fee Schedule rule (“CY 2008 Proposed PFS Rule”), as well as certain changes finalized in September 2007 (“Stark Phase III”).
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• In any appeal of a denial of payment for a designated health service (“DHS”) on the basis that the service was furnished pursuant to a prohibited referral, the burden of proof at each level of appeal is on the entity submitting the claim;

• Outer limits to the period of disallowance for a noncompliant financial relationship exist (beginning no sooner than the time the financial relationship fails to meet a Stark exception and ending no later than the date the relationship meets an exception and any excess compensation or underpayment has been paid), though parties may argue for a shorter time frame on a case-by-case basis;

• Only an interest in an entity arising from a retirement plan offered by that entity to the physician through the physician’s employment with that entity is excluded from the definition of “ownership or investment interest”; and

Effective October 1, 2009:

• Per-click or per-use payments from entity lessees to physician lessors (and vice versa, if the entity is a DHS entity that refers patients to the physician lessee) are prohibited (i.e., such arrangements cannot fall within the exceptions for space and equipment leases, nor can they be used to rent equipment under the fair market value or indirect compensation exceptions);

• Percentage-based arrangements tied to revenue earned, billed, collected, or otherwise attributable to services performed or the business generated through the use of leased space or equipment do not satisfy the “set in advance” standard; and

• The definition of “entity” is expanded to include persons or entities performing the DHS.

In addition to Stark:

• CMS revisits the DFRR. CMS proposes to send the form to 500 hospitals (both general acute care hospitals and specialty hospitals) and solicits comments on this number, revises the estimated time of completion from 31 hours to 100 hours, revises the estimated cost per hospital from $1,550 to $4,080, requires completion within 60 days, and re-publishes a copy of the proposed DFRR form.

• CMS outlines several requirements for physicians and physician-owned hospitals regarding the disclosure of such physician’s ownership interest at the beginning of a patient’s hospital stay or outpatient visit, or at the time that a physician refers a patient to the hospital. CMS may terminate a provider agreement if a physician-owned hospital fails to comply with these provisions.

• Finally, CMS revises the EMTALA regulations to clarify that, if a patient has been admitted to a hospital but has not been stabilized and requires a transfer to another hospital, the recipient hospital does not incur any EMTALA obligations in accordance with such transfer. CMS also finalizes requirements that hospitals must meet to participate in a community call plan to share on-call responsibilities and comply with EMTALA.

Stark Law Changes Effective October 1, 2008

Stand in the Shoes

In the FY 2009 IPPS Final Rule, CMS emphasizes its goal of “simplicity” and revises the SITS concept, such that only physician owners (other than titular owners) are required to SITS of their physician organizations. CMS defines “titular owner” as a physician without the ability or right to receive any financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment. These titular owners and other non-owner physicians are allowed to SITS of their physician organizations and, accordingly, can achieve compliance with the Stark law by one of the two following methods: (a) SITS of their physician organization and comply with a direct exception, or (b) not SITS of the physician organization and, if the remaining relationship is an indirect compensation relationship under Stark, comply with the indirect compensation exception. CMS further clarifies that the SITS provisions do not apply to an arrangement that satisfies the requirements of the Stark exception for academic medical centers.

CMS finalizes the revised definitions of “physician” and “physician organization” proposed in the FY 2009 Proposed IPPS Rule that clarify that a physician and the professional corporation (“PC”) of which he or she is the sole owner are treated the same under the Stark 2

2 The SITS concept was introduced in the CY 2008 Proposed PFS Rule, finalized in Stark Phase III, delayed with respect to a portion in November 2007, and revisited with new proposals in the FY 2009 Proposed IPPS Rule.
Law, and that a physician that SITS of his or her PC also SITS of his or her physician organization.

CMS declined to adopt either of the entity SITS proposals as set forth in the CY 2008 Proposed PFS Rule and the FY 2009 Proposed IPPS Rule. CMS highlights, however, that any arrangement that attempts to evade the Stark law by interposing shell organizations is highly suspect and will be scrutinized closely.

Amendments versus Termination: CMS Commentary

In commentary, CMS revisits its statements, which were made in commentary accompanying the Stark Phase III rule, that, in order to comply with “set in advance” requirements, revisions to lease and personal services agreements required that such agreements be terminated and new agreements subsequently entered into. In the FY 2009 IPPS Final Rule commentary, CMS reverses this position and states that amendments to agreements between a DHS entity and physician (or physician organization) are consistent with “set in advance,” provided that (1) all of the requirements of a Stark exception are met, (2) the compensation or the compensation formula is determined prior to implementing the amendment and is sufficiently detailed such that it can be objectively verified, (3) such formula does not take into account the volume or value of referrals or other business generated by the referring physician, and (4) the amended rental charges remain in place for a period of one year or more from the date of the amendment. CMS further clarifies that these four requirements apply to amendments executed under agreements meeting any Stark exception containing a one year term requirement.

Alternative Method for Compliance with Signature Requirements in Certain Exceptions

The FY 2009 IPPS Final Rule includes a new exception (42 C.F.R. §411.353(g)) for arrangements that involve temporary noncompliance with the signature requirements of certain exceptions. This exception is narrower than CMS’s original proposal, found in the CY 2008 PFS Proposed Rule, for an exception covering temporary noncompliance with various procedural requirements. The final exception applies differently depending on whether the failure to comply with the signature requirement is inadvertent or not inadvertent. If the failure is inadvertent, the exception applies as long as the parties acquire the signatures within ninety (90) consecutive days following the date of noncompliance (regardless of whether referrals exist between the parties) and the compensation arrangement fits all other requirements of the applicable exception. If the failure is not inadvertent, the parties must obtain signatures within thirty (30) days of the date of noncompliance (regardless of whether referrals exist between the parties) and the compensation arrangement must fit all other requirements of the applicable exception. This new exception may only be utilized once every three (3) years with respect to the same referring physician. Significantly, CMS did not adopt the self-disclosure requirement that had been previously proposed, recognizing that such a requirement would be burdensome on providers.

Obstetrical Malpractice Insurance Subsidies

In the CY 2008 PFS Proposed Rule, CMS expressed concern that the current exception for obstetrical malpractice insurance subsidies, which incorporates by reference the anti-kickback safe harbor applicable to the same, may be too narrow, and thus proposed revising the exception (but did not propose actual text) to list specifically the conditions that are appropriate to safeguard against program or patient abuse when an obstetrical malpractice insurance subsidy is provided to a physician.

In the FY 2009 IPPS Final Rule, CMS revises §411.357(r) to retain the provisions of the current exception (renumbered as §411.357(r)(1)), and to provide an alternative set of requirements under which hospitals, federally qualified health centers, and rural health clinics may provide obstetrical malpractice insurance subsidies (new §411.357(r)(2)). CMS indicates that it did not eliminate the current exception because it applies to subsidies provided by a “hospital or other entity.” and CMS had not proposed in the CY 2008 PFS Proposed Rule to limit the types of entities that may provide subsidies under the exception. As indicated above, the newly added exception is limited to particular entities. The regulation places

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3 The signature requirements to which the new exception applies are found in § 411.357(a)(1), 411.357(b)(1), 411.357(d)(1)(i), 411.357(e)(1)(i), 411.357(e)(4)(i), 411.357(e)(3)(1), 411.357(p)(2), 411.357(q), 411.357(r)(1), 411.357(r)(2)(ii), 411.357(r)(2)(iii), and 411.357(v)(7)(i) and 411.357(w)(7)(i).
strict parameters on the provision of the subsidies. Highlights include—

- The physician’s medical practice (through which he or she routinely engages in obstetrical practice) must be (1) located in a primary care health professional shortage area (“HPSA”), a rural area, or an area with demonstrated need for the physician’s obstetrical services, as determined by CMS in an advisory opinion; or (2) comprised of patients, at least 75 percent of whom reside in a medically underserved area (“MUA”) or are members of a medically underserved population (“MUP”).

- For each coverage period (not to exceed 1 year), at least 75 percent of the physician’s obstetrical patients treated under the coverage of the obstetrical malpractice insurance during the prior period (not to exceed 1 year) must have (1) resided in a rural area, HPSA, MUA, or an area with a demonstrated need for the physician’s obstetrical services as determined by CMS in an advisory opinion; or (2) been part of a MUP.

- The arrangement must be set out in a signed, written agreement; must not be conditioned on referrals by the physician to the entity providing payment; and must provide for payment to the organization that is providing the malpractice insurance (rather than the physician).

- A restriction of the “costs of malpractice insurance premiums” that may be subsidized in the context of physicians who engage in obstetrical practice on less than a full time basis.

**Burden of Proof**

In the FY 2009 IPPS Final Rule, CMS finalizes the proposal that it made in the CY 2008 PFS Proposed Rule to “clarify” that, consistent with CMS’ existing procedures for administrative appeals relating to claim denials, in any appeal of a denial of payment for a DHS that was made on the basis that the service was furnished pursuant to a prohibited referral, the burden of proof at each level of appeal is on the entity submitting the claim to establish that the service was not furnished pursuant to a prohibited referral.

In response to comments concerning the difficulty of being required to “prove a negative” for certain exceptions, such as lack of requisite intent to violate the anti-kickback statute, CMS adds language to the regulation to clarify that while the burden of production on each issue at each level of appeal is initially on the claimant, this burden may shift to CMS or its contractors during the course of the proceeding, depending upon the evidence submitted by the claimant.

CMS notes that this burden of proof rule is not applicable to appeals of civil monetary penalties, exclusions or other remedies imposed because of a determination that a DHS entity or a physician knowingly violated the self-referral statute or regulations.

**Period of Disallowance for “Tainted Claims”**

CMS provides in the FY 2009 IPPS Final Rule that the “period of disallowance” associated with a non-compliant financial relationship:

- Begins no sooner than the time the financial relationship fails to meet all of the requirements of an applicable exception; and

- Ends no later than the date the relationship meets all of the requirements of an applicable exception and any excess compensation or underpayment has been paid.

CMS states that the purpose of the final rule is to set outer time limits during which DHS providers can be guaranteed that billing is permitted. CMS emphasizes that parties to a prohibited arrangement can argue, on a case by case basis, that the period of disallowance is a shorter period of time (e.g., because the financial relationship ended).

CMS also provides no assurances as to the period of disallowance (1) if the reason for non-compliance is never corrected (e.g. no repayment is made or the compensation fluctuates with the value or volume of referrals) or (2) in a situation in which the excess compensation (or underpayments) could be construed as either payment for referrals that (a) pre-date a non-compliant relationship or (b) will occur after the end of the term of the non-compliant relationship. CMS states that the period of disallowance will be determined on a case-by-case basis in those situations.

**Ownership or Investment Interest in Retirement Plans**

In §411.354(b)(3)(i), CMS adopts its proposal from the CY 2008 PFS Proposed Rule and excludes from
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the definition of “ownership or investment interest” only an interest in an entity arising from a retirement plan offered by that entity to the physician (or an immediate family member of the physician) through the physician’s (or immediate family member’s) employment with that entity. CMS’s intent appears to be to close a perceived loophole through which it suspects that some physicians use retirement plans to purchase or invest in entities to which they refer patients for DHS.

Stark Law Changes Effective October 1, 2009

Unit of Service (Per-Click) Payments in Lease Arrangements

The FY 2009 IPPS Final Rule (a) adopts CMS’s proposal in the CY 2008 Proposed PFS Rule that arrangements in which a physician lessor receives a unit-of-service (per-click or per-use) payment from an entity lessee be excluded from the Stark exceptions for space and equipment leases, and (b) expands this prohibition to include a prohibition on per-click lease payments to a DHS entity that refers patients to the physician lessee. Also prohibited are payments based on a percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated through the use of the equipment. Similar changes were made to the fair market value and indirect compensation exceptions when equipment or space rental is a part of the arrangement.

CMS responds to a significant amount of comments relating to physician-owned companies that provide lithotripsy services and equipment to hospitals on a per-use basis. On the one hand, CMS says clearly that lithotripsy equipment may not be leased/rented to a hospital on a per-use basis if the lessor is a physician or physician organization that orders services performed on the leased equipment. On the other hand, CMS confirms that at the present time it does not consider lithotripsy to be a DHS, even if provided under arrangement by a physician-owned entity to a hospital and billed by the hospital. This means that CMS believes that lithotripsy, unlike other referring physician services that no longer can be provided under arrangement to hospitals, can continue to be owned by referring physicians under the final rule and still billed by the hospital as hospital services.

The issue then becomes whether the compensation arrangement between the hospital and the lithotripsy physician/physician organization meets an applicable compensation exception, as those exceptions are revised in the final rule. A question remains, not clearly answered in final rule commentary and worthy of further clarification, as to whether CMS intends to permit a physician-owned company to provide lithotripsy services on a turnkey, per-use basis to a hospital, or whether a per-use, under arrangement venture that includes the provision of equipment now fails to meet all applicable compensation exceptions as finalized.

In response to comments suggesting that the new rule will limit access to technology for patients, CMS states that (a) current leasing arrangements can be restructured (e.g., on a block time basis), (b) hospitals can purchase equipment and contract with other hospitals to provide the services under arrangements, thereby sharing the cost of the equipment, or (c) providers can contract with non-physician-owned suppliers of equipment. Providers should be cautious in restructuring current leasing arrangements, as CMS notes in commentary that certain other structures (for example, “on-demand” lease arrangements) are problematic.

Services Provided “Under Arrangements”

Prior to the FY 2009 IPPS Final Rule, only the person or entity that billed Medicare for the DHS was considered the DHS “entity.” CMS expands this definition of entity in the FY 2009 IPPS Final Rule to include those who perform DHS. Thus, the “furnishing” of DHS includes performing services that are billed as DHS to the Medicare program, irrespective of whether the claim is submitted by the entity performing the services or some other entity (such as a hospital providing the services “under arrangements”).

In commentary, CMS compares a physician ownership interest in a joint venture that provides services “under arrangements” to a hospital, and to which the physician refers patients for services billed by the hospital, to a physician ownership interest in a department or subdivision of the hospital. Accordingly, CMS appears to take the view that hospital-physician

4 In the CY 2008 Proposed PFS Rule, CMS had proposed to revise the definition of “entity” so that a person or entity is considered to be furnishing DHS if it is the person or entity that (1) has performed the DHS; (2) presented a claim for Medicare benefits for the DHS; or (3) caused a claim to be presented for Medicare benefits for the DHS. CMS did not adopt prong (3) in its final rule.
joint ventures for “under arrangements” services are prohibited, unless the physician ownership interest meets the requirements of the Stark exception for ownership in rural providers. As discussed above, CMS has acknowledged another exception in this area as it relates to ownership of under arrangement lithotripsy services.

One issue that remains unclear is whether providing only some of the components of DHS (such as equipment or billing services) is considered “performing” DHS. CMS declines to provide a specific definition of “perform” and, instead, states that the term should have its common meaning. There is a helpful illustration used by CMS in the commentary that indicates a service has been “performed” by a physician or physician organization if it does all the medical work such that it “could bill for the service” but has contracted with a hospital to bill for the service instead. CMS goes on to state in commentary, however, that it does not consider an entity that (a) leases or sells space or equipment used for the performance of the service, (b) furnishes supplies that are not separately billable but used in the performance of the medical services, or (c) provides management, billing services, or personnel to the entity performing the service, to perform DHS. It remains somewhat unclear as to exactly when any combination of these services (falling short of completing whatever is needed to bill for the service) can be provided by the outside entity before it has “crossed the line” and “performed” the service under the FY 2009 IPPS Final Rule.

Percentage-Based Compensation

In the FY 2009 IPPS Final Rule, CMS adds a requirement to the space lease, equipment lease, fair market value, and indirect compensation arrangements exceptions prohibiting percentage arrangements tied to the revenue earned, billed, collected, or otherwise attributable to services performed or the business generated through the use of leased space or equipment. In doing so, CMS took a narrower approach than found in the CY 2008 Proposed PFS Rule, which would have only permitted percentage compensation arrangements related to revenues from personally performed physician services (excluding, e.g. percentage gain-sharing arrangements). Nonetheless, in commentary, CMS indicated that other types of percentage compensation arrangements (e.g. billing and management fee arrangements) would continue to be reviewed closely and may be subject to future rule-making.


The DFRR is a form designed by CMS to collect information concerning financial relationships between hospitals and physicians. CMS originally intended to send the DFRR to 500 hospitals in September 2007. Two-hundred ninety of the hospital recipients were to be those that had failed to respond to a voluntary survey previously sent by CMS as part of its investigation into physician-owned specialty hospitals, as mandated by the Deficit Reduction Act of 2006. The DFRR process has been delayed due to Paperwork Reduction Act (“PRA”) requirements related to agency information collection requests, including receipt of Office of Management and Budget (“OMB”) approval. CMS has revised its time estimate for, and burden associated with, completing the form a number of times and does so yet again through the FY 2009 IPPS Final Rule, as discussed below. In the FY 2009 IPPS Proposed Rule, CMS again proposed to send the DFRR to 500 hospitals (both general acute care hospitals and specialty hospitals), solicits comments regarding the same, and re-publishes a copy of the proposed DFRR form. The form includes eight separate worksheets designed to capture detailed information regarding all financial relationships the hospital has in place with physicians.

In commentary, CMS makes a number of significant announcements with regard to the DFRR. In the FY 2009 IPPS Proposed Rule, CMS estimated that the average number of hours required to complete the DFRR was 31. In response to numerous comments it received regarding this issue, CMS revises the estimate to 100 hours. Recognizing that many hospitals may choose to involve accounting staff and attorneys in preparing and reviewing the form, CMS increases its estimate of the costs associated with completing the DFRR from $1,550 to $4,080 per hospital, for a revised total burden for 500 hospitals of $2,040,000.

CMS adopts its proposal from the FY 2009 IPPS Proposed Rule to require that the DFRR be returned within 60 days of the date that appears on the cover letter or e-mail transmission of the DFRR. CMS reminds hospitals that § 411.361(f) provides that failure to submit timely the requested information concerning an entity’s financial relationships may result in civil monetary penalties of up to $10,000 for each day
beyond the deadline established for disclosure. CMS reiterates, however, that it will seek not to invoke this authority. Prior to imposing a civil monetary penalty, CMS would issue a letter to any hospital that does not return the completed DFRR, inquiring as to why the hospital did not return timely the completed DFRR. In addition, a hospital may, upon a demonstration of good cause, receive an extension of time to submit the requested information.

CMS indicates that is revising Worksheet 7 of the DFRR (dealing with rental, personal service and recruitment arrangements) to permit hospitals to submit one copy of a uniform rental or recruitment agreement. Worksheet 7 also allows parties to submit one copy of a uniform personal services agreement. CMS cautions that it considers an agreement to be “uniform” only if all material terms are the same.

CMS is not adopting a regular reporting process, rather the DFRR will be used for a one-time collection effort. CMS does, however, reserve the right in future rulemaking to propose to use the DFRR or some other instrument as a periodic or regular collection instrument.

CMS indicates that a revised PRA package reflecting the changes to the DFRR has been sent to OMB for its review and approval. Following such approval, a revised PRA notice will be published separately in the Federal Register and will provide for a public comment period of 30 days from the date of display. CMS indicates that, in response to such comments, it could decide to decrease (but not increase) the number of hospitals to which it would send the DFRR. Hospitals should be on the lookout for the PRA notice and consider availing themselves of a final opportunity to comment prior to implementation of the DFRR.

Disclosure Required of Certain Hospitals

The FY 2009 IPPS Final Rule finalizes several proposals regarding the Medicare provider agreement regulations with which all Medicare providers must comply. These finalized rules, effective October 1, 2008, provide:

• Physician-owned hospitals must furnish written notice to patients at the beginning of their hospital stay or outpatient visit that physicians (or immediate family members of physicians) hold ownership or investment interests in the hospital, unless such an owner does not refer patients to the hospital and the hospital maintains a written attestation of such representation in its file.

• A physician-owned hospital must furnish its patients with the list of owners and investors who are physicians (or immediate family members of physicians) at the time the list is requested by, or on behalf of, the patient.

• Physician-owned hospitals must require medical staff members, as a condition of continued membership or admitting privileges, to disclose in writing to patients at the time of any referral to the hospital that they (or an immediate family member) hold an ownership or investment interest in the hospital.

• CMS may terminate a provider agreement if a physician-owned hospital fails to comply with these provisions.

EMTALA

The FY 2009 IPPS Final Rule also revises the EMTALA regulations, codified at 42 C.F.R. §489.24. Perhaps most significantly, CMS clarifies that the EMTALA obligations do not extend to hospitals receiving a transfer from a referring hospital where the patient has been admitted as an inpatient. In the 2003 Final EMTALA rule (68 FR 53243), CMS provided that the EMTALA obligations would not apply once a patient was admitted as an inpatient at a hospital. CMS did not, however, discuss how EMTALA would apply to a situation where a patient was admitted as an inpatient at a facility, could not be stabilized, and was then transferred to another facility that had specialized capabilities and capacity to treat the patient. In the FY 2009 IPPS Proposed Rule, CMS proposed that the EMTALA obligations would apply to a recipient hospital that was asked to accept a transfer from a hospital that had admitted an individual as an inpatient but failed to stabilize the individual before affecting an appropriate transfer. Agreeing with commentators complaining of an increased level of confusion and of the potential for more cases of patient dumping, CMS clarified that once a hospital admits, in good faith, an individual with an emergency medical condition as an inpatient, that hospital has no further EMTALA obligation to that individual, and any hospital with specialized capabilities to which the patient is asked to receive a transfer does not have an EMTALA obligation to accept the transfer.
Additionally, the FY 2009 IPPS Final Rule adds new language in 42 C.F.R. §489.24(j) detailing the requirements that are necessary for hospitals that participate in formal community call plans. The proposed regulations state that such formal plans must: (i) clearly state when each participating hospital will be responsible for providing call coverage, (ii) specifically detail the geographic area to which the plan applies, (iii) be signed by a representative of each participating hospital, (iv) ensure that any applicable EMS protocol includes information on community call relationships, (v) state that hospitals that are not providing call coverage under the community plan must still follow EMTALA obligations (i.e., medical screening examination, stabilizing treatment, and appropriate transfer) with regard to individuals who arrive at their facility, and (vi) provide that participating hospitals must annually assess the community call plans.

K&L Gates will continue to monitor any developments related to Stark, EMTALA, the DFRR, and other related guidance from CMS. If you have any questions regarding the matters discussed in this advisory, please contact:

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