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A window into compliance efforts in the real world

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Office of Counsel to the Inspector General
U.S. Department of Health and Human Services

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by Christopher Fete, JD, MHA; Alianna Goff; and Nathaniel M. Lacktman, JD, CCEP

Telemedicine service arrangements and fair market value assessments

» The use and implementation of telemedicine is growing.
» Important compliance issues should be considered when entering into telemedicine arrangements.
» Fair market value (FMV) and commercial reasonableness are important pieces of the puzzle.
» Telemedicine arrangements vary by service type and organizational objective.
» The structure of the arrangement impacts the assessment of FMV and commercial reasonableness.

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Telemedicine has spread rapidly over the past several years due to strides in technology, growing commercial insurance coverage, and the continued shortage in the supply of physicians. Consumers increasingly turn to telemedicine as an alternative or addition to in-person medical care. Telemedicine is used by hospitals, health systems, provider groups, and entrepreneurial start-ups across the world to connect directly to patients in their own homes and on their own schedule. Through virtual consultations and digital health applications, providers can extend their reach to offer remote monitoring and medical consultations to a larger patient base. The benefits to patients and providers are evident.

Despite new advances in healthcare technology and innovations in service delivery, telemedicine providers and entrepreneurs must still heed traditional federal and state healthcare compliance laws, such as the Stark Law and Anti-Kickback Statute (AKS). An important, but not-so-obvious, element of structuring a compliant arrangement is to ensure the compensation between the parties is consistent with fair market value (FMV) and the terms are commercially reasonable. This article discusses the importance of FMV and commercial reasonableness assessments, specifically related to telemedicine service arrangements, and applies the concepts to four example telemedicine offerings.


Fete


Goff


Lacktman

What is FMV and commercial reasonableness for healthcare arrangements?

Government regulators expect that any contract or arrangement between parties who may potentially refer healthcare items or services to each

other should be consistent with FMV and commercially reasonable. These are two separate, but related, concepts. Both are typically assessed together when the overall service relationship is evaluated (see Figure 1 on page 61).

With regard to FMV, the federal Stark Law (aka, the physician self-referral law) defines it as "the value in arm's-length transactions, consistent with the general market value, i.e.:

> the price that an asset would bring as the result of *bona fide* bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of *bona fide* bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement.[1]

The federal Anti-Kickback Statute guidance generally aligns with the Stark Law definition and the IRS' definition under federal Treasury regulations.[2] OIG hospital guidance states, for example:

> any remuneration flowing between hospitals and physicians should be at fair market value for actual and necessary items furnished or services rendered based upon an arm's-length transaction and should not take into account, directly or indirectly, the value or volume of any past or future referrals or other business generated between the parties.[3]

According to OIG, arrangements:

> under which hospitals (i) provide physicians with items or services for free or less than fair market value, (ii) relieve physicians of financial obligations they would otherwise incur, or (iii) inflate compensation paid to physicians for items or services pose significant risk. In such circumstances, an inference can arise that the remuneration may be in exchange for generating business." Thus, OIG recommends hospitals have a process "for making and documenting reasonable, consistent, and objective determinations of fair market value and for ensuring that needed items and services are furnished or rendered.[4]

With regard to commercial reasonableness, CMS guidance states an arrangement will be considered "commercially reasonable" if the arrangement would make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician (or family member or group practice) of similar scope and specialty, even if there were no potential DHS [designated health services] referrals.[5]

Why conduct a FMV and commercial reasonableness assessment?

An assessment is useful for compliance purposes under the federal Stark Law, the federal AKS, and IRS rules for 501(c)(3) entities. Most exceptions under the Stark Law, and many safe harbors under the AKS, require the compensation to be FMV in a commercially reasonable arrangement. Similarly, 501(c)(3) entities that have arrangements above FMV can risk running afoul of private inurement and excess benefit rules due to their tax-advantaged status. One way providers can determine, ahead of time, if an arrangement is FMV and commercially reasonable is to have it assessed as part of the initial due

diligence process. Even telemedicine providers and companies treating exclusively self-pay or commercial insurance patients can benefit from a FMV assessment, because over half the states in the U.S. have "all-payer" anti-kickback laws which apply regardless of the source of payment (e.g., they govern cash pay medical services as well).

Many telehealth providers find guidance in Advisory Opinions issued by the Office of Inspector General (OIG). All OIG opinions are inherently limited based on the unique facts and circumstances of the proposed arrangement. Not only do most Advisory Opinions address traditional (non-telemedicine) services, the telemedicine industry and its related business relationships have evolved at breakneck speed over the last decade. The financial and transfer arrangements are becoming much more complex and include many more elements, because the technology readily allows scalability across states and across various providers (e.g., hospitals, primary care, pharmacy, durable medical goods [DME], home health), as well as the enhanced role IT support and software plays in such services arrangements. Telemedicine services are no longer limited to mere pilot programs, and building compliant arrangements, including FMV and commercial reasonableness standards, is important.

Although law firms can assess and advise on the structure of an arrangement, they often are unable to provide FMV or commercial reasonableness opinions, because such work typically requires specifically trained health consulting professionals. Going through the process of conducting a FMV and commercial reasonableness assessment, and adhering to the valuation opinion when executing the arrangement, can go a long way to protect the parties and document their diligence and commitment to building a compliant arrangement.

Assessment standards for telemedicine providers/services

Although federal laws and rules do not mandate a single methodology to use when conducting FMV and commercial reasonableness assessments, valuation firms typically adhere to professional standards and guidelines for their review process. A multitude of factors influence FMV and commercial reasonableness, and the process is a highly fact-specific analysis (see Figure 2 on page 62).

With regard to telemedicine services, FMV can be impacted by the delivery model selected, the time/availability requirements of the rendering professionals, the structure of the services being provided, and the payer environment. Telemedicine compensation arrangements can take several forms, such as between hospitals and employed physicians, hospitals and independent contractors, hospitals to hospitals ("hub and spoke models" between urban centers and rural care providers), or management services agreements between a provider group and a management company (e.g., in friendly PC models). In all cases, the FMV assessment should be based on the facts and circumstances of the specific arrangement (e.g., structure, duties and expectations, burden on the provider, reimbursement environment).

Considerations for service offerings

The following sections identify some telemedicine service offerings and highlight the corresponding FMV and commercially reasonableness considerations associated with each offering.

Telemedicine emergency (on-demand) specialty services

Telemedicine services can assist with specialty Emergency Department (ED) coverage services. Similar to traditional on-call arrangements for ED coverage,

Figure 1: Checklist for Fair Market Value and Commercial Reasonableness

Fair Market Value: Things to Consider – Drivers of Value

- ☐ **Modality to be used for services**
  - ☐ Emergency (On Demand) Specialty Services
  - ☐ Subspecialty (Scheduled) Consultation Services
  - ☐ Direct to Consumer Services
  - ☐ Provider to Provider Consultation Services
- ☐ **Overall scope of telemedicine services provided under agreement**
  - ☐ Multiple models (see above) implemented leveraging infrastructure
  - ☐ Number of specialties and subspecialties
  - ☐ Assess the burden placed on the telemedicine provider
  - ☐ Contracting for coverage of defined period or availability (e.g., 24/7/365)
  - ☐ Coverage schedule/frequency by specialty
  - ☐ Response requirements (by phone, by live video)
  - ☐ Frequency of activations for provided services
  - ☐ Limitations on where technology can be activated
  - ☐ Estimated time to complete consultations/observations
  - ☐ How many providers available in rotation
  - ☐ Audience for telemedicine services (provider to provider or provider to patient interaction)
  - ☐ Type/Level of Services provided (back-up support for on-site providers v. constant patient monitoring and intervention)
- ☐ **Level of intensity/average patient acuity of the services provided** (e.g., trauma v. specialty care consult support)
- ☐ **What party is providing the equipment and support staff?**
  - ☐ Capabilities and Infrastructure of the client hospitals.
  - ☐ Related costs to provide telemedicine support at client hospital
- ☐ **Third-party payor environment** (parity, negotiated commercial contracts, direct to consumer flat fee)
- ☐ **Which party is retaining the right to bill and collect for the professional services rendered**
- ☐ **Marketing and branding initiatives**

Commercial Reasonableness: Things to Consider – Key Issues

Commercial reasonableness, which can be done internally or via an external resource, is a broad and somewhat abstract concept. As a result, a first step in ensuring regulatory compliance with this requirement is to develop a framework for evaluating each arrangement. The list below represents a summary of key considerations when addressing commercial reasonableness for telemedicine arrangements.

- ☐ **Qualitative Considerations**
  - ☐ What is the specific purpose for entering a telemedicine arrangement?
  - ☐ Whether the arrangement is necessary in addition to the services already available.
  - ☐ Whether the telemedicine arrangement has a specific operational objective (profit contribution, service-line expansion, increase access to care).
  - ☐ Whether the telemedicine arrangement will address an identified community/patient need (access to specialties or services, less transfers).
  - ☐ Whether the telemedicine arrangement can/will be used to provide training and support services for other providers.
  - ☐ Whether additional considerations exist that may affect the decision of entering into a telemedicine arrangement (market conditions, provider shortages, etc.)
- ☐ **Quantitative Considerations**
  - ☐ Whether the cost of providing telemedicine services which is causing losses to a hospital's service line on a sustained basis.
  - ☐ Whether the payment rates for telemedicine services and technology provided are reasonable and documented as FMV.
  - ☐ Whether there is sufficient utilization of telemedicine services to offset the losses of a particular service offering.
  - ☐ Whether the staffing and equipment that are leveraged in the telemedicine model are higher than necessary (e.g., what are the alternatives).
  - ☐ Whether there are less expensive alternatives for the services (recruitment, program development).

SAMPLE CHECKLIST ONLY – FOR EDUCATIONAL PURPOSES/DOES NOT CONSTITUTE LEGAL ADVICE

telemedicine services provide a benefit to facilities that lack the required bench of specialists. These arrangements offer access to specialists who can help deliver appropriate and quality care, and this can potentially lead to a decrease in the transfer of patients to other facilities. The immediacy and rapid responsiveness of these arrangements offer real benefits to patients in need. One example is telestroke service arrangements with rural hospitals.

In terms of structuring FMV payments for these types of arrangements, there are several things to consider. The key is to identify and outline exactly what the entity is contracting with the physician or other organization to provide. One approach is to structure the

Figure 2: Telehealth Compliance Checklist

Professionals

- ☐ Are the telehealth professionals licensed in the state where patient located?
- ☐ Are there practice standards for patient examinations and remote prescribing?
- ☐ Are professionals documenting and maintaining patient records of the encounters?
- ☐ Does insurance policy cover telehealth services?
- ☐ Is insurance carrier licensed in every state where services are provided (patient located)?

Medicare/Medicaid

- ☐ Do services qualify as covered telehealth services?
- ☐ Are services being coded to properly reflect the place of service?
- ☐ Is the telehealth service provider located internationally?

Commercial Insurance, Medicare Advantage, and Medicaid Managed Care

- ☐ Does the state require commercial coverage of services provided via telehealth?
- ☐ Does the provider's contracts reflect said coverage and include negotiated payment amounts?
- ☐ Has reimbursement other than FFS been evaluated, such as PMPM, capitation add-ons, or hybrid risk-bearing?

Consent

- ☐ Does the informed consent form account for services provided via telehealth?
- ☐ Does is recognize patient freedom of choice?

Fraud & Abuse

- ☐ If Medicare/Medicaid, does the arrangement comply with the federal Anti-Kickback Statute? (Check provider/vendor arrangements and patient incentive programs)
- ☐ If Medicare/Medicaid, does the arrangement comply with the federal Civil Monetary Penalties Law? (Check provider/vendor arrangements and patient incentive programs)
- ☐ Does the arrangement comply with the Stark Law? (Check all physician benefits, including software and equipment tech, to ensure they meet a Stark exception)
- ☐ Does the arrangement comply with state patient brokering laws and anti-kickback statutes? (Check provider/vendor arrangements and patient incentive programs)
- ☐ Does the arrangement comply with state corporate practice of medicine rules? (Check not just where the brick & mortar facility is located, but where the patients are located)
- ☐ If capitated or PMPM compensation, does the arrangement comply with state insurance laws? (Check if exempt and, if not, conduct risk assessment)

Credentialing

- ☐ Is there a credentialing by proxy agreement in place that meets all the elements?
- ☐ Does the hospital relying on proxy credentialing have such provisions in its bylaws?
- ☐ Are the hospitals engaging in periodic re-credentialing assessments and reporting?

Privacy & Security

- ☐ Are there privacy and security protocols for the telehealth offerings?

SAMPLE CHECKLIST ONLY – FOR EDUCATIONAL PURPOSES/DOES NOT CONSTITUTE LEGAL ADVICE

arrangement similar to a standard emergency call arrangement. Key factors to consider include: physician specialty, average acuity of services (e.g., trauma center designation), response time, which party elects to bill and collect for the services rendered, the payers willingness to reimburse for the services provided, limitations on where technology can be activated, how often the service is being activated, types of consults/services being provided, estimated time to complete consultations or observations, number of providers available in the rotation, understanding of the overall burden placed on the physician(s) providing the services, and the capabilities and infrastructure of the client hospital. From a valuation perspective, these are all aspects that can influence the FMV of an arrangement.

Telemedicine subspecialty (scheduled) consultation services

Although a rural community may have a need for a subspecialist, there is not always sufficient patient volume to sustain a local, full-time subspecialist in the area. These experts are often very low in supply and high in demand, and naturally reside in densely populated areas. Historically, patients in rural areas have been forced to travel significant distances in order to receive the care they need. Telemedicine subspecialty consults can help solve that problem.

The arrangements aid larger community hospitals and health systems use the current supply of subspecialist physicians more efficiently, connect specialists to patients and physicians at rural hospitals, and enable access to a wider pool of experts. It can help subspecialists make better use of their time by treating more patients (e.g., less travel to outreach clinics). Patients can more easily obtain specialty services while remaining in their local communities and not traveling long distances. Patients can also be diagnosed and treated earlier, which can contribute to improved outcomes and a lower total cost of care. Hospitals can save money, because the remote experts help to prevent unnecessary transfers, advise on less expensive modes of transfer, and represent an overall lower cost overhead compared to hiring a full-time subspecialist. For that reason alone, many hospitals choose a telemedicine subspecialist arrangement over alternatives, such as locums tenens coverage or contracting for physicians to provide services on an outreach basis.

Under these arrangements, consults are more typically scheduled in advance, rather than on-demand. Or, if not pre-scheduled, the subspecialist has a designated amount of time to respond to the hospital's request for a consult. Key factors to consider when determining FMV include: physician specialty, structure of the arrangement (predominantly scheduled services or more of an on-call/back-up call situation), frequency the specialty service is used/scheduled, estimated/average duration of each activation/appointment, and the ability of the provider to bill and collect for the services rendered.

Direct-to-consumer telemedicine services

Consumers are turning to retail clinics as a convenient, low-cost avenue to receiving primary care physician (PCP) services. Remote telemedicine services, often through a free-standing kiosk or similar arrangement, are one such avenue. Pharmacies, grocery stores, and other national retailers are beginning to offer these services in-store by leasing space to telemedicine providers.

The inherent referral relationship between the retailer as landlord and the telemedicine provider as lessee creates potential FMV issues. In opining to what constitutes FMV for an in-store lease of this nature, one question that arises is the appropriate classification of the lease when

determining its market value. Leases for retail and healthcare/medical office spaces have distinctly different values in a given market. Which is appropriate? On one hand, the services being offered within the leased space are healthcare in nature. On the other hand, the benefits realized by the lessee include higher customer traffic and increased exposure more often associated with traditional retail leases. Additional factors to consider in these valuations include the marketing opportunities and brand credibility from being associated with a well-known, trusted national retailer; the square footage of the lease space; the local real estate market; and the building class where the lease space is located.

Provider-to-provider telemedicine consultation services

Provider-to-provider telemedicine consultations offer tremendous benefits to individual practitioners and their patients. Provider-to-provider consults are interactions between a specialist or expert and a patient's primary care physician (PCP) who lacks access to a specialist or expert in a specific field. The consultation is designed to augment the PCP's ability to treat his/her patient.

These services often are structured in two ways: real time (synchronous) interactions or store-and-forward (asynchronous) interactions. Real time consultations are live audio-video streams in which the consulting physician interacts with the PCP. Through this service, community physicians can interact with specialists or experts to advise on appropriate care for the patient. The consulting physician can assist with establishing the most appropriate care plan for the community physician's patient and is available to answer questions and provide insight in a timely manner. With store-and-forward interactions, the PCP captures information from the patient and transmits it to the specialist. The consulting physician reviews the information sent by the PCP and offers recommendations. The PCP can review the specialist's recommendations and draw upon it to develop a care plan for the patient.

Assessing FMV payments for these services can often be simpler than other telemedicine service arrangements, because there are fewer variables and the burden (from an on-demand availability standpoint) is less because these consultations can easily be scheduled in advance. Key factors to consider include the ability to bill and collect from third-party payers, the consulting physician's specialty, and the time it takes the consulting physician to perform the consult. For these types of arrangements, if the consulting provider is not able to bill and collect for the services provided, flat fee or hourly rate approach may be considered.

Conclusion

There are an ever-increasing variety of new, innovative ways to use technology to deliver healthcare services. One constant, however, is the importance of ensuring that such arrangements are compliant with healthcare fraud and abuse laws. Providers should take reasonable steps to review their arrangement to ensure the compensation is consistent with FMV and the terms are commercially reasonable.

1. 42 CFR §411.351.
2. 26 CFR § 53.4958-4(b).
3. 70 FR 4858, 4866 (January 31, 2005).
4. Id. at 4863.
5. 69 FR 16054, 16093 (March 26, 2004).