

# Federally Qualified Health Center and Rural Health Center Telemedicine Compliance and Legal Issues

**Michael A. Dowell**

## **FQHCs, RHCs, AND TELEMEDICINE**

Federally qualified health centers (FQHCs) and rural health centers (RHCs) are vital sources of care for vulnerable populations, as they provide high-quality, affordable primary and preventive health care to uninsured and medically underserved individuals. FQHCs and RHCs are required to provide comprehensive primary care services to all patients in need, regardless of insurance status, and to charge uninsured patients on an income-based, sliding scale basis.

The Health Resources and Services Administration (HRSA), which provides oversight over FQHCs and RHCs, promotes the use of telehealth technologies for health care delivery, education, and health information services. HRSA defines telemedicine as “*the use of electronic information and telecommunications technologies to support and promote long-distance clinical health care, patient and professional health-related education, public health and health administration. Technologies include videoconferencing, the internet, store-and-forward imaging, streaming media, and terrestrial and wireless communications.*”<sup>1</sup> HRSA is currently sponsoring numerous telemedicine initiatives, including but not limited to the: (1) Telehealth Network Grant Program; (2) Substance Abuse Treatment Telehealth Network Grant Program; (3) Tele-Behavioral Network Grant Program; (4) Telehealth Resource Center Program; (5) Telehealth Centers of Excellence; (6) Flex Rural Veterans Health Access Program; (7) License Portability Grant Program; and (8) Telehealth Focused Rural Health Research Center Cooperative Agreement.



**Michael A. Dowell** is a partner and member of the Health Care Law Group at Hinshaw & Culbertson LLP in downtown Los Angeles. Mr. Dowell counsels federally qualified health centers, rural health centers, non-profit health care organizations, and other health care entities on telemedicine and general health care law regulatory matters. He can be reached at 213/614-7341 or [mdowell@hinshawlaw.com](mailto:mdowell@hinshawlaw.com).

## **Increasing Use of Telemedicine**

FQHCs and RHCs have added telemedicine services to the array of services offered, with the objective of reducing inequities in health care access while improving the

cost-effectiveness and quality of health care.<sup>2</sup> Telemedicine may incorporate both synchronous and asynchronous patient visits, remote monitoring, and various forms of mobile phone/tablet application communication; what each of these applications has in common is the exchange of clinical information across locations and between multiple providers, or between providers and patients.

Data on the use of telemedicine at FQHCs and RHCs indicates that its use has rapidly expanded in the past few years. As of 2017, 44 percent of FQHCs and RHCs had begun using telemedicine, and another 12 percent were in the process of implementing a telemedicine program or were actively exploring its feasibility.<sup>3</sup> FQHCs and RHCs with a telemedicine program are using telemedicine primarily for behavioral health (52 percent), specialty care (27 percent), chronic disease management (25 percent), and primary care (23 percent).<sup>4</sup> The medical specialties most frequently used for telemedicine include: teleaudiology, telecardiology, teledentistry, teledermatology, telenursing, teleophthalmology, telepathology, telepharmacy, telepsychiatry, teleradiology, and telerehabilitation.<sup>5</sup>

### **Telemedicine Benefits**

Telemedicine presents many benefits, such as improving access to care, promoting care coordination, fostering patient engagement, and reducing costs. Telemedicine has been identified as a promising solution to meet some of the needs of rural and underserved areas that lack sufficient health care services, including specialty care, and has been shown to improve access to needed care, increase the quality of care, and reduce costs by reducing readmissions and unnecessary emergency-department visits.<sup>6</sup> “Telemedicine can also be useful alternatives for those with mobility challenges, such as patients who cannot drive or who require a wheelchair.”<sup>7</sup> Telemedicine has proven to increase access to specialist

care, decrease referral wait times, better outcomes for patients, making it a crucial tool to deliver quality health care for all populations.<sup>8</sup>

Telemedicine programs can and have been implemented in a variety of ways, such as facilitating remote second opinions, on-demand and scheduled appointments, and triage in emergency departments, as well as promoting provider-to-provider communications. Specialty physician eConsults are one of the fastest-growing and popular uses for telemedicine. The provider-to-provider service gives primary care physicians access to specialists for difficult cases, usually on an asynchronous telemedicine platform.

### **TELEMEDICINE MODALITIES**

Telemedicine is not a type of health care service but rather a “modality” to deliver multiple types of health care services. It is important to understand the modality of telemedicine being provided because some states and payors will only permit the use of certain telemedicine modalities.

#### **Synchronous (Real-Time Video and Audio)**

FQHCs and RHCs can interact with patients by videoconferencing in real time with live video, telephone, or HIPAA-compliant chat/text to provide diagnoses and treatment options. This modality is used often in telepsychiatry, telehomehealthcare, telecardiology, and remote consults with specialists.

#### **Asynchronous (Store and Forward)**

Digital images, videos, audio, and clinical data are captured and stored on a patient's computer or mobile device and transmitted securely via email, fax, text, or phone voicemail to a provider for later review and analysis. This modality is used often in teledermatology, teleradiology, and telepathology. Artificial intelligence and scientifically based questionnaires have also been

used with the store and forward modality; however, many states and various payors do not accept the use of such.

### **Remote Patient Monitoring**

FQHCs and RHCs can use telemedicine technology to collect medical data from patients while they are at home and then interpret and use that data to offer a diagnosis or deliver medical care. Patients use a system that captures and feeds data/information from sensors and monitoring equipment or an external monitoring center so that providers can monitor patients. Remote monitoring includes technology that allows providers to monitor health indicators related to conditions such as diabetes, asthma, cardiac arrhythmias, and pulmonary diseases. Data that are generated by remote monitoring can be transmitted to health care professionals in real-time for analysis and follow-up care.

### **FQHC TELEMEDICINE LEGAL ISSUES**

Many legal issues are raised by the practice of telemedicine, particularly the impact of fraud and abuse laws. An inconsistent patchwork of laws and regulations make it difficult for providers to understand when they can provide telemedicine services and how they will be paid for delivering health care via telemedicine. Legal issues include but are not limited to the following.

#### **Licensure**

Telemedicine provider licensure is important because reimbursements can result in false claims if the telemedicine provider is not licensed appropriately. Health care professionals who provide services via telemedicine modalities generally are subject to the licensure rules of: (1) the state(s) in which their patients are physically located; and (2) the state(s) in which they (the professionals) are practicing. In addition, many states have special telemedicine licensing or permitting requirements for currently licensed physicians seeking to commence telemedicine activities within

the state.<sup>9</sup> Twenty-five states are now part of the Interstate Medical Licensure Compact, which gives physicians an expedited means of applying for a license to practice telemedicine in member states.

### **Fraud and Abuse Laws (Anti-Kickback, Stark, and False Claims)**

Telemedicine arrangements must comply with federal and state fraud and abuse laws. In general, the use of telemedicine may be subject to fraud and abuse laws if the use directly or indirectly generates reimbursement from a federal health program, with the majority of fraud and abuse issues implicated by the infrastructure, equipment, and support necessary to implement a telemedicine project. Exceptions/safe harbors to fraud and abuse laws may apply; however, careful assessment is required to ensure compliance.

Anti-kickback law safe harbors most likely to be utilized in telemedicine are: space rental, equipment rental, personal services and management contracts, bona fide employees, e-prescribing, electronic health record (EHR) software, information technology, and training. Stark exceptions related to FQHC or RHC participation in telemedicine may include: the employee exception, rental of office space, rental of equipment, personal service arrangements, group practice arrangements, e-prescribing, and EHR arrangements. Anti-kickback and Stark law risk also can be mitigated through: (1) documentation of the business purpose for the telemedicine arrangement; (2) a fair market value analysis of compensation and ownership arrangements; and (3) avoiding compensation methodologies that link compensation to the volume or value of patient referrals.

#### **Continuity of Care**

If a patient receives telemedicine from one service provider, but chooses another provider for his next patient visit, then the

second physician may not have all the information she needs to diagnose the patient's problem. Failure to coordinate continuity of care may result in quality of care and/or medical malpractice issues. Most state Medicaid programs require the telemedicine provider to be available for follow-up care or to otherwise ensure continuity of care, and identification and/or referral of telemedicine patients in the event of an emergency.

### **Scope of Practice/Valid Physician Patient Relationship**

Traditionally, establishing a physician-patient relationship has required at least an initial in-person encounter between a physician and a patient. Many payor reimbursement schemes do not permit a provider to establish a new physician-patient relationship via telemedicine. The degree of contact required to establish the physician-patient relationship varies by state. The general telemedicine industry standard is to permit establishment of a physician-patient relationship with a live, two-way, audio-video interaction between the physician and the patient.

### **Internet Prescribing**

Physicians can only prescribe medication pursuant to a valid physician-patient relationship, and some states prohibit remote prescribing unless the physician has performed an appropriate history and in-person physical examination of the patient and has made a diagnosis based upon the examination and medical tests consistent with medical practice standards. Multiple states have Internet prescribing rules that prohibit a physician from prescribing medication based on Internet questionnaire patient visits only.

### **Informed Consent**

Currently, 38 states include some sort of telemedicine informed consent requirement in their statutes, administrative

codes, and/or Medicaid policies.<sup>10</sup> Informed consent requirements often regulate when informed consent must be obtained, the format in which informed consent is delivered and obtained, and/or the content of the informed consent. The level of detail associated with the informed consent process should depend on the complexity and risks of the procedure or treatment involved.

FQHCs and RHCs should consider addressing the following issues (in addition to any state-required information) in informed consent policies and procedures: (1) information regarding all involved health care providers with their credentials and locations, as well as any other staff that may help facilitate the telemedicine service; (2) a description of the telemedicine service that will be performed and the technology that will be used; (3) alternative options for treatment and care; (4) any risks specifically related to the electronic nature of the care delivery (*e.g.*, technology disruptions, failures, or limitations); (5) specific security and privacy measures that have been implemented, as well as any increased privacy risks relative to the telemedicine technology; (6) a plan for ongoing care, including details about who is responsible for various aspects of the patient's care; and (7) a plan for alternative care in the case of an emergency or technological malfunction.

### **Medical Recordkeeping**

Most state medical records laws require that any electronic records or other documents created during or as a result of a telemedicine act become part of the patient's permanent medical record and are subject to all other general requirements of patient medical records, including privacy and confidentiality requirements.<sup>11</sup> Telemedicine encounters must be documented in accordance with state medical recordkeeping requirements, including recording of synchronous patient visits if required by state law. Telemedicine providers should consult

with health care law counsel to ensure that telemedicine recordkeeping requirements comply with applicable state law, including storage of the medical records. Telemedicine providers should have access to medical records, must document each encounter via telemedicine, and should state the telemedicine modality and technology used.

### **HIPAA and State Law Privacy, Confidentiality, and Security**

The Health Insurance Portability and Accountability Act (HIPAA) security rule requires covered entities to implement technical safeguards to protect against unauthorized access to protected health information (PHI) that is transmitted over an electronic network. Text, email, and video are not inherently HIPAA compliant (because the transmission isn't encrypted), leaving the health care organization and its business associates open to a data breach and HIPAA violation. Any system of communicating ePHI at a distance must be set up so that communications can be monitored and remotely deleted if necessary.

### **Medical Malpractice**

Many states require telemedicine activities to be performed in accordance with the appropriate standard of care, and some states make a presumption that a physician breaches the standard of care by remotely prescribing medications based solely on a medical questionnaire completed by the patient. Existing state malpractice case law, tort law, and civil procedure will govern telemedicine malpractice issues not directly addressed by specific state telemedicine statutes or regulations.<sup>12</sup>

Federal Tort Claims Act (FTCA) medical malpractice coverage generally only covers FQHC and RHC employees or full-time independent contractors; therefore, telemedicine providers are not likely to be covered by the FTCA. FQHCs and RHCs should use adequate and

reliable telemedicine technology in order to reduce the risks of privacy breaches and malpractice issues. In addition, malpractice insurance may not cover services provided via telemedicine and may pose new malpractice risks, particularly in matters of jurisdiction, choice of law, procedure, and duty of care concerns. FQHCs and RHCs will need to purchase telemedicine insurance if their existing insurance coverage excludes coverage for telemedicine services.

## **MEDICARE AND MEDICAID TELEMEDICINE PAYMENT AND COVERAGE**

---

### **Medicaid Payment and Coverage**

States decide whether to provide telehealth and the type of telehealth services they will authorize for payment. This flexibility results in significant program variation across state Medicaid programs.<sup>13</sup> Specifically, state Medicaid programs may decide on (1) the type of telemedicine service (equipment) to cover; (2) the types of telemedicine providers that may be covered and reimbursed; (3) how much to reimburse for telemedicine services, as long as such payments do not exceed federal upper payment limits; and (4) other conditions for payment.<sup>14</sup>

Almost every state Medicaid program provides reimbursement for synchronous (interactive live video) telemedicine visits; however, only 15 states reimburse for asynchronous or store-and-forward services other than teleradiology.<sup>15</sup> In addition, the types of services that can be reimbursed, the types of providers that can be reimbursed, permissible patient originating sites, and the level of reimbursement provided for Medicaid telemedicine services varies widely from state to state. Some state Medicaid programs have included documentation and/or confidentiality, privacy, and security guidelines within their Medicaid reimbursement rules and regulations. As of September 2018, a 50-state survey of state

telehealth laws and Medicaid program policies reported the following:

- 49 states and the Washington D.C. Medicaid programs reimburse for some form of interactive live video.
- 15 state Medicaid programs require reimbursement for asynchronous store-and-forward.
- 24 state Medicaid programs require reimbursement for remote patient monitoring.
- 23 state Medicaid programs limit the type of facility that can serve as an originating site.
- 6 state Medicaid programs have some form of geographic restriction.
- 34 state Medicaid programs reimburse for either a transmission fee, facility fee, or both.<sup>16</sup>

## Medicare Reimbursement Rules

### Medicare Part B

The Medicare fee-for-service (FFS) program is the basis for telemedicine payments under Medicare Part B.<sup>17</sup> Federal law limits most Medicare payment for telehealth services to those that are furnished via a telecommunications system by a physician or certain other types of practitioners to an eligible individual who is not at the same location. Federal law generally requires that Medicare pay for certain services, including office visits, consultations, and office psychiatry services, that are furnished using an interactive audio and video telecommunications system that permits real-time communication between a Medicare beneficiary and a physician or certain other practitioner.<sup>18</sup> The provider receives the same reimbursement as he would have received had the services been furnished face-to-face. The originating site, where the patient is located, receives a nominal fee.<sup>19</sup> The use of telemedicine in Medicare Part B is low; however, it has grown rapidly in recent years, as Medicare Part B telemedicine has increased by more than 500 percent from 2008 to 2014, and

increased another 79 percent from 2014 to 2016.<sup>20</sup> Medicare beneficiaries using telehealth services tend to be under age 65, disabled, and dually eligible for Medicare and Medicaid; reside in rural areas; and disproportionately have chronic mental health conditions.<sup>21</sup>

Federal law only permits Medicare to pay for telehealth services<sup>22</sup> that are furnished to a beneficiary who is present in an originating site located in certain types of geographic areas: a rural health professional shortage area (HPSA), a county outside of a metropolitan statistical area (MSA), or a site that is participating in a federal telemedicine demonstration project approved by (or receiving funding from) the Secretary of Health and Human Services (the Secretary) as of December 31, 2000. An originating site is the location of an eligible Medicare beneficiary at the time a telehealth service is furnished. In addition, federal law only allows certain types of health care settings to serve as originating sites: offices of physicians or practitioners, hospitals, critical access hospitals, rural health clinics, federally qualified health centers, hospital-based critical access hospital-based renal dialysis centers (including satellites), skilled nursing facilities, and community mental health centers.

The statute only allows certain types of practitioners to furnish and receive Medicare payment for telehealth services: physicians, nurse practitioners, physician assistants, nurse-midwives, clinical nurse specialists, certified registered nurse anesthetists, clinical psychologists, clinical social workers, and registered dietitians or nutrition professionals. The practitioner furnishing the telehealth service is located at a separate site from the beneficiary, known as the distant site.

The Bipartisan Budget Act of 2018 expanded the coverage of telehealth services under the physician fee schedule to include the treatment of strokes in urban areas, expanded telemedicine coverage

to patient homes and independent renal dialysis facilities, allows providers to give free at-home telemedicine technology/equipment to dialysis patients if certain requirements are met, permitted Medicare Advantage plans to include some of the costs of telehealth services in their annual plan bid amounts, and permitted accountable care organizations that accept financial risk to bill Medicare for telehealth services originating from the patient's residence and urban areas. In the 2019 Medicare Payment Rules, the Centers for Medicare & Medicaid Services (CMS) authorized Medicare Part B reimbursement for virtual check-ins (brief telemedicine check-ins to assess whether a patient needs to come in for an office visit), remote evaluation of pre-recorded patient information (store and forward, including interpretation with verbal follow-up from the patient within 24 hours), and interprofessional Internet consultations (telemedicine consultations provided by a consulting physician to a treating physician), for which reimbursement is not subject to the geographic and site limitations/restrictions set forth above for physician consultations, office visits, and psychiatry services.

### **Medicare Part C**

Medicare Advantage (MA) plans must cover the same telemedicine services that are covered under Medicare Part B, but they can also use rebate dollars to offer additional telemedicine services, subject to general CMS guidelines.<sup>23</sup> CMS has recently updated its Value-Based Insurance Design model of care to allow telemedicine to replace certain in-person medical visits in MA plans. Starting in 2020, participating MA plans can provide telemedicine services as a replacement for in-person visits, as long as the MA plans continue to cover face-to-face appointments for the same issues. In addition, the plans can design benefits

to target beneficiaries with certain conditions or socioeconomic statuses, such as low-income subsidies and special plans for those who are dually eligible for Medicare and Medicaid. MA payments are determined through a comparison of a plan's estimated cost and the maximum amount Medicare will pay a plan.<sup>24</sup> MA plans have delivered telemedicine services to beneficiaries via telemonitoring, and web-based and telephone consultations.<sup>25</sup>

### **OIG ADVISORY OPINION GUIDANCE ON TELEMEDICINE ARRANGEMENTS**

The Office of Inspector General (OIG) advisory opinions provide guidance, with respect to similar factual situations, on the OIG's interpretation of the federal anti-kickback law. To date, the OIG has approved six telemedicine-related advisory opinions. The OIG has issued advisory opinions (the "opinions"): (1) permitting an ophthalmologist to sublease imaging equipment to an optometrist, and provide telemedicine consultations to the optometrist's patients<sup>26</sup>; and (2) an arrangement wherein a health system's stroke center and its neurology stroke specialist would provide neurology emergency clinical protocols and immediate telemedicine consultation to participating community hospitals, and the health system would also provide, at its own expense, telemedicine hardware and software to each participating hospital's emergency department.<sup>27</sup> Other OIG advisory opinions regarding FQHC and/or RHC involvement in telemedicine services are summarized below.

### **OIG Advisory Opinion 99-14 Allows Health System to Operate Rural Health Center Telemedicine Network**

In Advisory Opinion 99-14,<sup>28</sup> the OIG addressed a proposal by a health system that operated a telemedicine network

pursuant to a federal telemedicine grant. The health system wanted to continue to develop, operate, administer, and fund the network once the grants expired. The OIG determined that the proposed arrangement potentially provided a benefit to the physicians receiving telemedicine services in the form of subsidized line charges, free equipment, and additional opportunities to earn fees. The OIG concluded, however, that the relatively small remuneration was outweighed by the fact that the arrangement furthered congressional intent to promote telemedicine networks in rural areas, and by the benefits actually received by the community. These benefits included improved access to essential health care services and decreased health care costs in rural areas.<sup>29</sup>

### **OIG Advisory Opinion 04-07 Allows a Health System to Provide Telemedicine Services to School-Based Clinics**

Advisory Opinion No. 04-07<sup>30</sup> analyzed a proposed arrangement between a health system and school-based clinics in low-income rural areas, where the health system had developed a telemedicine program for specialist physician consultation services. The health system provided free telecommunication equipment and free physician consultations for the school-based clinic patients. Nurses at the school-based clinics would conduct screening tests, and then health system physicians would provide telemedicine consultations, if needed. If a student required a referral to a physician, the student would be sent to his or her primary care provider or be given a list of primary care providers in the community.

The OIG acknowledged that the arrangement created the potential for referrals to the health system from the school and the consulting practitioners, and self-referrals by the patients, but concluded that no sanctions would be imposed. The OIG determined that the provision of

non-reimbursable screening services that were not tied to reimbursable services would not violate the federal prohibition on inducements.<sup>31</sup>

### **OIG Advisory Opinion 18-03 Allows FQHC to Provide Telemedicine Information Technology Items and Services to County Clinic**

The OIG recently approved an arrangement regarding a federally qualified health center look-alike<sup>32</sup> proposal to provide information technology items and services, without charge, to a county Department of Health's clinic to facilitate telemedicine encounters (the "proposed arrangement").<sup>33</sup> The opinion provides insight into the OIG's position regarding telemedicine equipment donation and is the first OIG advisory opinion that authorizes the billing of a federal program for services provided with donated telemedicine equipment.

Under the proposed arrangement, the FQHC would furnish the clinic with certain items, including a computer, webcam, microphone, telemedicine videoconferencing software, and a webcam camera used in telemedicine examinations. Nothing inherent to the telemedicine items would: (i) limit or restrict the use or compatibility of the telemedicine items with different information technology systems, software applications, or networks; or (ii) inhibit the ability of any users of the telemedicine items to communicate or exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks. The FQHC would remain financially responsible for all aspects of installing, maintaining, and updating the telemedicine system. These services would include maintaining Internet connectivity required by the system and providing technical assistance for its use. The FQHC would also train clinic staff on the telemedicine items and facilitate access to telemedicine services.<sup>34</sup>



The clinic would use the telemedicine equipment to facilitate consultations and follow-up with clinic patients related to HIV prevention, specifically consultations regarding prescriptions for pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP). While the clinic currently offers testing and evaluations for sexually transmitted infections, its scope of services is limited to legally mandated services, which do not include PrEP and PEP services.

The FQHC is located 80 miles from the county clinic, and there was limited availability of the PrEP and PEP services in the county clinic's service area. The FQHC operates a pharmacy where patients could fill prescriptions for PrEP and PEP medications, but patients would not be required to fill prescriptions there; furthermore, the pharmacy is 80 miles from the clinic and does not offer mail-order services. The telemedicine items and services provided by the FQHC would be funded by a State Department of Health (DOH) HIV prevention grant, and the DOH would retain actual title to the items used in the arrangement.

According to the OIG, the FQHC would not limit or restrict the ability of the telemedicine equipment and software to be used with other systems or prevent users from doing so. The clinic would not require its patients to receive telemedicine services from the FQHC and would advise them of the availability of services from other providers, either in person or via telemedicine. Furthermore, the clinic's patients could receive such services from other remote providers using the equipment and software provided by the FQHC.<sup>35</sup>

The OIG concluded that, although the proposed arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of federal health care program business were present, the arrangement poses a low risk

of fraud and abuse, based on the presence of adequate administrative safeguards related to patient steering, no increase in costs to federal health care programs, and the promotion of a significant community benefit.<sup>36</sup>

### **OIG Advisory Opinion 19-02 Allows Pharmaceutical Manufacturer to Loan Smartphones to Indigent Patients for Telemedicine Remote Monitoring**

The OIG recently approved an arrangement allowing a pharmaceutical manufacturer to temporarily loan smartphones to indigent patients who lack smartphone technology required to receive telemedicine remote monitoring adherence data from a sensor embedded in a prescribed antipsychotic medication ("the proposed arrangement").<sup>37</sup>

Advisory Opinion 19-02 addressed an unspecified drug developed by the manufacturer for which drug non-adherence posed a problem in certain patient populations. The manufacturer indicated that non-adherent patients increased utilization of other health care services, resulting in increased costs to the health care system. The Food and Drug Administration (FDA) recently approved a Digital Medicine (DM) version of the drug, which consists of a tablet of the drug embedded with an ingestion event marker (IEM), a sensor paired with a smartphone application (App) for use by the patient. The sensor then records and transmits adherence data and other health care data to an application accessed through the patient's smartphone. The information from the application is then transmitted to a secure cloud-based server where health care providers can access it with patient consent.<sup>38</sup>

Under the proposed arrangement, the requestor would loan a limited-function smartphone capable of running the required App to patients who: (1) have been prescribed a specific medication; (2) meet certain criteria as specified

by the patient's insurer; (3) have an annual income below a certain level; (4) do not already possess a technology device capable of running the App; and (5) are U.S. citizens or legal permanent residents. The program would not be advertised to patients but would be described to prescribers. All smartphone features except the application necessary to monitor adherence and make domestic phone calls would be disabled. The smartphone would only be provided to the patient for a maximum of two 12-week periods and would then be disabled. The manufacturer certified that telephone capability is necessary for patients to access support for the DM drug, and the manufacturer would maintain an umbrella voice and data plan for the loaner smartphone.<sup>39</sup>

Under the anti-kickback statute, the OIG considered whether the remuneration might influence a beneficiary to select a preferred provider, practitioner, or supplier, and whether it could influence a person to select an item or service that is reimbursable by federal health care programs. Under the CMP law, the OIG acknowledged that the smartphones constitute remuneration under the civil monetary penalties (CMP) law, but the OIG concluded that the proposed arrangement satisfied the "Promotes Access to Care Exception" to remuneration.<sup>40</sup> The OIG concluded that the remuneration would pose a low risk of harm by (i) being unlikely to interfere with clinical decision making, (ii) being unlikely to increase costs to federal health care programs or beneficiaries through overutilization or inappropriate utilization, and (iii) not raising patient safety or quality-of-care concerns.<sup>41</sup>

## CONCLUSION

The OIG recently published a report on its review of Medicare payments for telemedicine services. The objective of the OIG review was to determine whether or

not CMS paid practitioners for telemedicine services that met Medicare requirements. The report concluded that, of the sampled claims reviewed by OIG, 31 percent did not meet the Medicare conditions for payment for telemedicine services.<sup>42</sup>

The OIG made another recent announcement that it would be reviewing state Medicaid payments for telemedicine and other remote services to confirm that providers are billing properly for telemedicine health reimbursements. "Medicaid pays for telemedicine, telehealth, and telemonitoring services delivered through a range of interactive video, audio or data transmission (telecommunications)," the OIG announced. "Medicaid programs are seeing a significant increase in claims for these services and expect this trend to continue. We will determine whether selected States' Medicaid payments for services delivered using telecommunication systems were allowable in accord with Medicaid requirements."<sup>43</sup>

As the result of the report's findings, FQHCs who bill the Medicare and/or Medicaid programs for telemedicine services should expect to have their claims audited or reviewed to confirm that their telemedicine programs and claims comply with Medicare requirements, including coverage, coding, and documentation rules. In light of the heightened scrutiny, FQHCs and RHCs must adopt and implement effective telemedicine compliance programs that incorporate telemedicine program best practices identified by the OIG in its telemedicine advisory opinions.

## Key Elements of Telemedicine Compliance Programs

FQHCs and RHCs must develop policies and procedures that acknowledge and promote their commitment to compliance and that address specific areas of potential

noncompliance with applicable laws and regulations. Policies help form the basis of expectation for conduct by FQHC and RHC employees. Procedures are the documents that implement their standards of conduct.

### **Written Policies and Procedures**

FQHC and RHC policies and procedures should address the guidance provided by all applicable regulatory authorities and should be designed to prevent and detect violations of applicable law, regulations, rules, and ethical standards by employees, agents, and others. The policies and procedures should be measured by employee accountability, as reflected in performance review and disciplinary actions. The failure to properly develop, disseminate, and train employees on telemedicine compliance policies and procedures may result in exposure to a variety of legal liabilities as well as fines, penalties, loss of revenue, and corporate reputational damage.

The following list of policies and procedures are included in recommendations made in a recent American Health Information Management Association (AHIMA) Practice Brief on telemedicine policies and procedures: (i) introduction to telemedicine; (ii) scope of telemedicine program; (iii) orientation/training of staff; (iv) using the telemedicine equipment; (v) confidentiality/privacy; (vi) video recording of telemedicine services; (vii) clinical record keeping; (viii) prescriptions; (ix) appropriate telemedicine services; (x) technical quality of telemedicine; (xi) prioritization of clinical telemedicine; (xii) monitoring; (xiii) payor reimbursement; and (xiv) billing modifiers, codes, and explanations.<sup>44</sup> FQHCs and RHCs also should establish policies and procedures regarding medical records documentation, contingency plans in the event of a technology failure, continuity of care referrals to local providers, and quality of care oversight and monitoring for telemedicine visits.

### **Workforce Training**

All FQHC/RHC staff should be made aware of the telemedicine policies and procedures and their roles in the process. A workforce training program should include review of the telemedicine policy and procedure requirements, and other applicable requirements. FQHCs and RHCs should conduct periodic staff training and updates about the telemedicine program.

### **Payor Billing and Collections**

Billing for services must be in compliance with state and federal laws as well as in accordance with any third-party payer's requirements. These laws and requirements vary by state. Reimbursement for telemedicine services is dependent on the documentation, billing, and codes (payer specific), state licensing, and/or organization-specific documentation requirements.<sup>45</sup> FQHCs and RHCs should ensure that the services qualify as covered telemedicine services and that the services are being coded properly.

### **Confidentiality/Privacy**

FQHCs and RHCs must implement privacy and security protocols for telemedicine services, including the use of HIPAA-compliant messaging, voice and file transfer, and information storage. Transmitting PHI including, but not limited to, patient records, diagnostic results, and videotapes must be secure on both the transmitting and receiving ends. FQHCs and RHCs must obtain business associate agreements from various parties, including but not limited to, telemedicine hardware vendors; telemedicine software vendors; medical device vendors; and external providers/clinics where patients may utilize their Internet services for telemedicine.<sup>46</sup>

### **Consent**

Patient consents are required documentation prior to the encounter. The provider requesting the telemedicine services at the

originating site must advise the patient about the proposed use of telemedicine, any potential risks, consequences, and benefits, and obtain the patient's or the patient's legal representative's consent. To ensure freedom of choice, a patient should be given the option of not participating in telemedicine without affecting his or her right to future care or treatment. Once the patient understands, the FQHC or RHC should obtain and maintain documentation of his or her understanding prior to providing telemedicine services.

### **Medical Records Documentation**

Providers must document all telemedicine services, provide that documentation to the originating site when applicable, and maintain a copy in the facility's medical record. The physical location of the patient as well as the physical location of the provider must be documented as well as everyone involved in the clinical encounter, including those who may be off camera. Additional documentation needs are dictated by the service or procedure performed. Complete and accurate documentation for the patient condition is a requirement to ensure proper reimbursement for services provided.

### **Fraud and Abuse**

FQHCs and RHCs should consult with competent health care law counsel to ensure that telemedicine arrangements comply with the federal anti-kickback, Stark, and civil monetary penalties law, and comparable state law requirements. The initial costs associated with the development and implementation of telemedicine programs can be expensive and are frequently funded by community benefit grant agreements, which also must comply with applicable fraud and abuse laws.

### **Compliance Program Best Practices (Safeguards) to Reduce Fraud and Abuse Compliance Risks**

The OIG's favorable opinions were largely based on the arrangement's safeguards

against patient steering and overutilization. The OIG will continue to closely scrutinize partnerships between referral sources to ensure program beneficiaries and the public are protected from high-risk arrangements. Providers contemplating any similar type arrangement must always account for beneficiary choice and access concerns, competitive marketplace advantage concerns, and overutilization concerns that all lead to potential to increase program costs. These concerns will always be paramount in the mind of the OIG and, therefore, paramount to providers. As always, each proposed arrangement must be evaluated on the specific facts of the proposal, and it is always best to seek the counsel and advice of a health care attorney prior to engaging in any arrangement where a provider contemplates providing free items or services to a potential referral source.

FQHCs and RHCs that are looking to expand their telemedicine capabilities and that are interested in entering into arrangements that involve the provision of free items or services should carefully review the OIG's advisory opinions opining on telemedicine arrangements and ensure their arrangements contain the beneficial safeguards identified by the OIG, and that such telemedicine arrangements address the following issues.

#### **Written Agreement between the Parties**

The telemedicine arrangement must be documented in a written agreement between the parties that sets forth all of the services to be provided by each party under the telemedicine arrangement. (OIG Advisory Opinions 98-18, 11-12).

#### **Telemedicine Equipment Leases**

Leases must be in writing and specify the exact equipment subleased for a minimum 12-month term. The lease must provide for a fixed rental payment per month, resulting in an annual aggregate rental payment fixed in advance. The rent to

be paid under the lease must be fair market value in an arm's length value, and the rental charge may not be determined in a manner that takes into account the volume or value of any referrals or business generated between the parties. (OIG Advisory Opinion 98-18).

#### **Patient Referral Requirements**

There should not be any requirement or encouragement that the parties refer patients to specific providers. (OIG Advisory Opinions 04-07, 98-18, 11-12).

#### **No Consideration Regarding the Volume or Value of Referrals**

Neither the volume or value of previous or anticipated referrals, nor the volume or value of any other business generated between the parties, may be a condition of participation in the arrangement. (OIG Advisory Opinion 11-12).

#### **Not Likely to Increase Cost to Federal Health Care Programs of Beneficiaries**

The telemedicine arrangement should not encourage increased utilization of services or increased costs to federal health care program beneficiaries unless required to promote patient care. (OIG Advisory Opinion 18-03, and 19-02)

#### **Not Likely to Interfere with Clinical Decision Making**

The telemedicine arrangement should not interfere with clinical decision making by any of the participants in the telemedicine arrangement. (OIG Advisory Opinion 11-12,19-02)

#### **No Patient Steering**

The telemedicine arrangement should not be operated in a manner to steer patients to specific providers. (OIG Advisory Opinion 04-07 and 18-03)

#### **Marketing and/or Advertising**

The providers should not engage in marketing and advertising that could

induce the selection of the provider. (OIG Advisory Opinion 98-18, 11-12, and 19-02)

#### **Community Benefit or Promote Access to Care**

The arrangement should provide significant community benefit (*e.g.*, improve access to essential health care services, reduce mortality and/or morbidity rates, and/or constrain health care costs). (OIG Advisory Opinions 99-14, 04-07, 11-12, 18-03, and 19-02)

As the use of telemedicine increases, enforcement actions related to the practice of telemedicine will increase. FQHCs and RHCs, therefore, should be vigilant in their compliance efforts to mitigate telemedicine compliance risks and legal issues.

#### **Endnotes**

1. Health Resources and Services Administration, Federal Office of Rural Health Policy. "Telehealth Programs." [www.hrsa.gov/ruralhealth/telehealth](http://www.hrsa.gov/ruralhealth/telehealth)
2. Bashshur RL, Shannon GW, Krupinski EA, Grigsby J, Kvedar JC, *et al.* 2009. National telemedicine initiatives: essential to healthcare reform. *Telemed J E Health.* 15(6), 600-10. PubMed dx.doi.org/10.1089/tmj.2009.9960
3. National Association of Community Health Centers Community Health Center Chartbook (2019) Figure 6-2.
4. *Id.*, Figures 6-3 through 6-7.
5. Telemedicine Toolkit (2017), American Health Information Management Association, page 8. [healthsectorcouncil.org/wp-content/uploads/2018/08/AHIMA-Telemedicine-Toolkit.pdf](http://healthsectorcouncil.org/wp-content/uploads/2018/08/AHIMA-Telemedicine-Toolkit.pdf)
6. Eric Wicklund, Is CMS Giving Telehealth Its Due In Its New Rural Health Strategy? May 11, 2018. [mhealth-intelligence.com/news/is-cms-giving-telehealth-its-due-in-its-new-rural-health-strategy](http://mhealth-intelligence.com/news/is-cms-giving-telehealth-its-due-in-its-new-rural-health-strategy)
7. Note 5, *Supra* at pp. 7.
8. Kvedar J, Coye MJ, Everett W. 2014. Connected Health: A Review Of Technologies And Strategies To Improve Patient Care With Telemedicine And Telemedicine. *Health Aff.* 33(2), 194-99. PubMed dx.doi.org/10.1377/hlthaff.2013.0992
9. *E.g.*, ALA. CODE §§ 34-24-51, 34-24-501(a)(1), 34-24-502(a); MINN. STAT. §§ 147.032, 147.081; MONT. CODE §§ 37-3-102(8), 37-3-342, 37-3-343; NEV. REV. STAT. §§ 630.020(3), 630.049, 630.160(1), 630.261(e); N.M. STAT. §§ 61-6-6(K), 61-6-11.1(A), 61-6-20; N.M. ADMIN. CODE §§ 16.10.2.7(E), 16.10.2.11; OHIO REV. CODE §§ 4731.296, 4731.34(A)(3), 4731.41; OR. REV. STAT. §§ 677.135, 677.137, 677.139; TENN. CODE §§

- 63-6-201, 63-6-231(b)(21), 63-6-209(b); TENN. COMP. R. & REG. § 0880-2-.16.
10. The Center for Connected Health Policy (CCHP) ([www.cchpca.org](http://www.cchpca.org)) and the American Telemedicine Association (ATA) ([www.americantelemed.org/home](http://www.americantelemed.org/home)) provide overviews of current state telemedicine informed consent requirements.
  11. *E.g.*, ARIZ. REV. STAT. § 36-3602(C); CAL. HEALTH & SAFETY CODE § 123149.5(a); COLO. REV. STAT. §§ 25-1-801, 25-1-802; MONT. CODE § 37-3-348(2)(b); OKLA. STAT. § 36-6804; 22 TEX. ADMIN. CODE § 174.1 *et seq.*
  12. Tara Kepler, Telemedicine Chapter, 2015 Physician Law Evolving Trends and Hot Topics.
  13. CMS, Telemedicine, [www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Delivery-Systems/Telemedicine.html](http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Delivery-Systems/Telemedicine.html)
  14. CMS, Telemedicine.
  15. Center for Connected Health Policy, Telehealth Medicaid & State Policy, accessed January 2019, [cchpca.org/state-telehealth-laws-and-reimbursement-policies-report](http://cchpca.org/state-telehealth-laws-and-reimbursement-policies-report)
  16. *Id.*
  17. Section 1834(m) of the Social Security Act; See also, CMS, Medicare Learning Network, Telehealth Services, [www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/telehealthsrvcfsctshst.pdf](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/telehealthsrvcfsctshst.pdf)
  18. Centers for Medicare & Medicaid Services. Your Medicare Coverage: Telehealth. Medicare.gov. [www.medicare.gov/coverage/telehealth.html](http://www.medicare.gov/coverage/telehealth.html)
  19. The Social Security Act (SSA) Section 1834(m) (42 U.S.C. § 1395m) authorizes the Secretary, by regulation, to establish Medicare payment for telehealth service under Part B.
  20. Telemedicine in Medicare Advantage Fact Sheet November 2017, Better Medicare Alliance. [www.bettermedicarealliance.org/sites/default/files/2018-02/BMA\\_OnePager\\_Telemedicine%20in%20Medicare%20Advantage\\_2018\\_01\\_26\\_v2a.pdf](http://www.bettermedicarealliance.org/sites/default/files/2018-02/BMA_OnePager_Telemedicine%20in%20Medicare%20Advantage_2018_01_26_v2a.pdf)
  21. MedPac Report to Congress, March 2018
  22. The CPT/HCPCS code for the service must be included on list of covered Medicare telemedicine services.
  23. Balanced Budget Act of 2018.
  24. CMS, "Announcement of Calendar Year (CY) 2016 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter," April 6, 2015, at [www.cms.gov/medicare/health-plans/medicareadvtspecraterates/downloads/announcement2016.pdf](http://www.cms.gov/medicare/health-plans/medicareadvtspecraterates/downloads/announcement2016.pdf).
  25. These may be a telephone system run by registered nurses administering protocol-driven, medically appropriate advice and scheduling office visits when necessary. Nursing hotlines are not explicitly defined in the Medicare Managed Care Manual.
  26. OIG Advisory Opinion 98-18 (December 3, 1998).
  27. OIG Advisory Opinion 11-12 (August 29, 2011).
  28. OIG Advisory Opinion 99-14 (December 28, 1999).
  29. *Id.*
  30. OIG Advisory Opinion 04-07 (June 17, 2004).
  31. *Id.*
  32. FQHC look-alikes are community health center providers that meet the requirements for the FQHC program but do not receive Section 330 Grant funding. FQHC look-alikes are eligible to apply for reimbursement under FQHC Medicare and Medicaid payment methodologies and to purchase discounted drugs through the 340B Federal Drug Pricing Program. In addition, they receive automatic Health Professional Shortage Area designation and may access National Health Service Corps providers.
  33. OIG Advisory Opinion 18-03 (May 24, 2018).
  34. *Id.*
  35. *Id.*
  36. *Id.*
  37. OIG Advisory Opinion 19-02 (January 24, 2019).
  38. *Id.*
  39. *Id.*
  40. Social Security Act Section 1128A(i)(6)(F) and 42 C.F.R. Section 1003.110 (Incentives given to individuals to promote the delivery of preventive care services where the delivery of such services is not tied (directly or indirectly) to the provision of other services reimbursed in whole or in part by Medicare or an applicable state health care program).
  41. Note 35, *Supra*.
  42. CMS PAID PRACTITIONERS FOR TELEHEALTH SERVICES THAT DID NOT MEET MEDICARE REQUIREMENTS, Department of Health and Human Services OFFICE OF INSPECTOR GENERAL Report April 2018, A-05-16-00058. [oig.hhs.gov/oas/reports/region5/51600058.pdf](http://oig.hhs.gov/oas/reports/region5/51600058.pdf)
  43. Medicaid Services Delivered Using Telecommunication Systems, Centers for Medicare & Medicaid Services, November 2017, Report Numbers W-00-18-31527; A-06-18-00000, [oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000259.asp](http://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000259.asp)
  44. AHIMA Practice Brief. "Telemedicine Services and the Health Record (2013 update)." Updated May 2013. [bok.ahima.org/doc?oid=300269](http://bok.ahima.org/doc?oid=300269).
  45. Note 5, *Supra* at pp. 26.
  46. *Id.* at pp. 22.

---

Reprinted from Journal of Health Care Compliance, Volume 21, Number 2, March–April 2019, pages 5–18, with permission from CCH and Wolters Kluwer.  
For permission to reprint, e-mail [permissions@cch.com](mailto:permissions@cch.com).

---