

Telemedicine Compliance: The Practice Requirements

Kyle Y. Faget

As is true with almost anything “new” in health care, the more popular that new thing becomes, the more it is scrutinized for compliance deficiencies. Scrutiny is not a bad thing, but it can catch unsuspecting novices to the field by surprise. Telemedicine is particularly complex in that the practice raises multiple compliance issues, including how telemedicine services may be delivered and to whom, what telemedicine services may be billed and under what circumstances, how telemedicine businesses can and must be structured in a given state, how telemedicine businesses can and cannot enjoy profits, and how telemedicine businesses can advertise and promote their products and services as well as layers of privacy considerations. At the most fundamental level, telemedicine raises multiple compliance issues related just to practicing this form of clinical care, which is the focus of this article.



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Before jumping into the compliance concerns associated with telemedicine, it is important to understand some basic terminology that helps to define telemedicine practice. Because the practice of medicine is largely defined by each individual state, each state has its own definition of what constitutes telemedicine. For example, in Massachusetts, “telemedicine” as it pertains to the delivery of health care services, means the use of interactive audio, video, or other electronic media for the purpose of diagnosis, consultation, or treatment. “Telemedicine” does not include the use of audio-only telephone, facsimile machine, or e-mail.¹ In Colorado, by contrast, “telemedicine” means the delivery of medical services and any diagnosis, consultation, or treatment using interactive audio, interactive video, or interactive data communication.² Regardless of the exact definition employed, telemedicine necessarily involves a health care professional providing services to a patient at a location that’s different from where the physician is located. In telemedicine, the location of the patient who is receiving telemedicine services is referred to as the “originating site,” whereas the location of the physician providing services via telemedicine is referred to as the “distant site.” These terms end

up being important when discussing coverable services.

LICENSING

As a threshold matter, physicians generally must be licensed in the state in which they provide health care services to patients. This is true because most states define the practice of medicine based on where the patient is located and consequently require that a physician be licensed within the particular state in order to practice telemedicine on a patient in that state. For example, in Georgia, a physician who is physically located in another state who performs an act that is part of a patient care service located in the state through the use of any means, including electronic, radiographic, or other means of telecommunication, is practicing medicine and must be appropriately licensed.³

There are, of course, exceptions to the general rule that a physician must be licensed in the state in which his or her patient is located when providing health care services. For example, in Ohio, a physician or surgeon in another state or territory who is a legal practitioner of medicine or surgery in that state and who provided services to a patient in that original state or territory may provide follow-up services in person or through the use of any communication, including oral, written, or electronic communication, in this state to the patient for the same condition for one year following the date of services for that condition, if that patient is now in Ohio.⁴ In Florida, licensure is not required for a physician located and licensed in another state or foreign country who is in actual consultation with a Florida-licensed doctor.⁵

There are also states that specifically offer a limited license for physicians who are located outside the state whereby a physician may obtain a telemedicine license to provide telemedicine services to patients located in, for example, the state of Georgia. (See Ga. Code Ann. §

43-34-31.1.) Similarly, in Alabama, a physician located outside the state may not engage in the practice of medicine or hold himself or herself as qualified to practice without first obtaining a special purpose license from the state.⁶

Because so many physicians hoping to practice medicine across state lines are overwhelmed with the time and expense associated with getting licensed in multiple states, pressure on medical boards and state legislatures to devise a more efficient mechanism for licensure has been growing. The solution may reside in The Interstate Medical Licensure Compact (IMLC or “Compact”), which is an agreement between participating states and the Medical and Osteopathic Boards in those states. Currently, the IMLC is an agreement between 29 states, the District of Columbia, and the Territory of Guam, where physicians are licensed by 43 different Medical and Osteopathic Boards.⁷ (See Figure 1.)

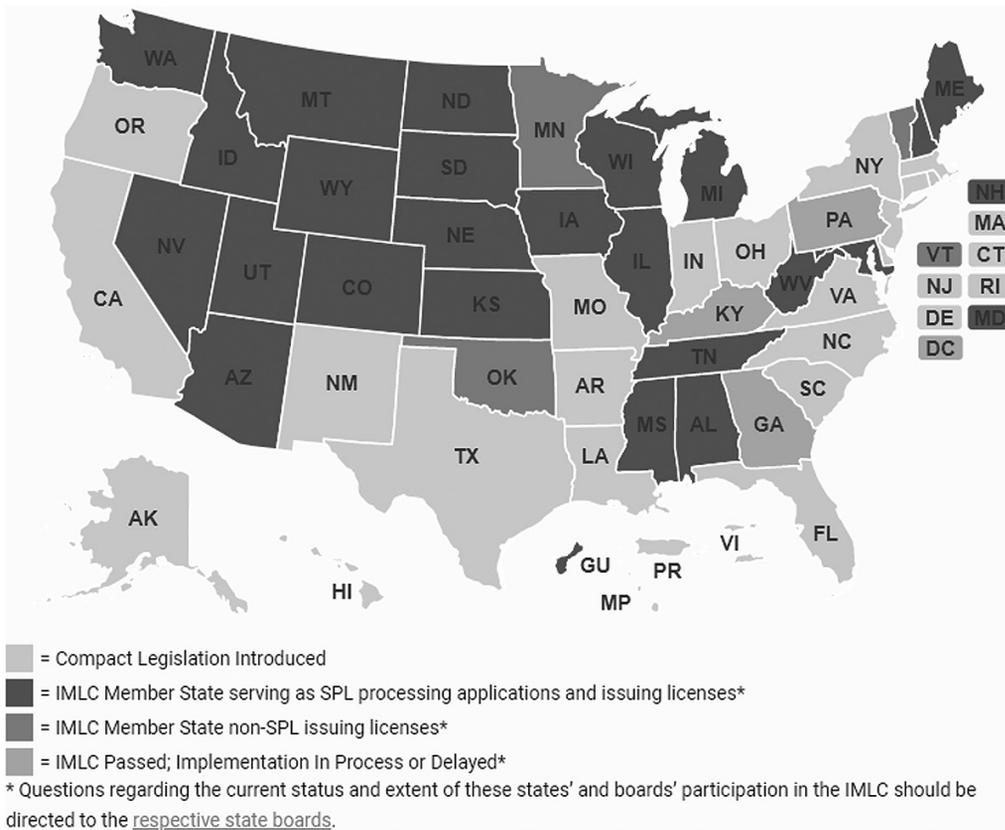
The IMLC offers an expedited pathway to licensure for qualified physicians who wish to practice in multiple states. Licensed physicians can qualify to practice medicine across state lines within the Compact if they meet the agreed upon eligibility requirements. For example, Montana-licensed physicians can apply to the Interstate Medical Licensure Compact Commission and select Montana as the State of Principal License, which means Montana can issue a Letter of Qualification for licensure in other states within the Compact.⁸

Because licensure is fundamental to the practice of telemedicine and is also a barrier to entry into the practice, it is truly the first compliance hurdle for physicians. The unlicensed practice of medicine can lead to unwanted altercations with state medical boards.

VALID PHYSICIAN–PATIENT RELATIONSHIP AND ACCEPTED MODALITIES

After securing the appropriate license to practice telemedicine in a given state,

Figure 1:



physicians must establish a doctor–patient relationship before prescribing or rendering treatment. The way in which a physician delivers care remotely—*e.g.*, using real-time audio–video, interactive audio, or using asynchronous store-and-forward technologies, meaning the acquisition and storing of clinical information (*e.g.*, data, image, sound, video) that is then forwarded to (or retrieved by) another site for clinical evaluation—known as the modality, through which the physician can establish a valid doctor–patient relationship depends on the language of the state law as well as the specific clinical situation.

Overall, the current gold standard in telemedicine (clinically and under the majority of state laws) is to use real-time audio–video wherein the physician has a meaningful clinical interaction with the patient and incorporates diagnostic peripherals such as blood draws when

needed. As noted earlier, in Massachusetts, “telemedicine” as it pertains to the delivery of health care services, means the use of interactive audio, video, or other electronic media for the purpose of diagnosis, consultation, or treatment. “Telemedicine” does not include the use of audio-only telephone, facsimile machine, or email.⁹ Massachusetts, like many states, prohibits the use of audio-only telemedicine and asynchronous store-and-forward technologies.

Some state statutes, rules, and/or board guidance, however, expressly permit the use of asynchronous store-and-forward technologies. For example, in Colorado, provider–patient relationships may be established using *telehealth technologies*, so long as the relationship is established in conformance with generally accepted standards of practice.¹⁰ The Board defines “telehealth technologies” as “technologies and devices enabling secure

electronic communications and information exchange between a licensee in one location and a patient in another location with or without an intervening healthcare provider.”¹¹

“Telehealth” means a mode of delivery of health care services through telecommunication systems, including information, electronic, and communication technologies, to facilitate the assessment, diagnosis, consultation, treatment, education, care management, or self-management of a person’s health care while the person is located at an originating site and the provider is located at a distant site. The term includes synchronous interactions and store-and-forward transfers.¹² Under the Board Policy, “telehealth” includes “telemedicine” as defined by Medical Practice Act—which defines “telemedicine” as “the delivery of medical services and any diagnosis, consultation, or treatment using interactive audio, interactive video, or interactive data communication.”¹³ Note that “any act or omission in the practice of telemedicine that fails to meet generally accepted standards of medical practice” is considered unprofessional conduct.¹⁴

There are still some states that are silent as to what the accepted modality is for telemedicine practice. For example, Florida is silent with respect to the modality required to establish a doctor–patient relationship. In these cases, the most risk-averse way to ensure compliance is to use real-time audio–video modality when providing health care services via telemedicine. What is clear is that each state has its own idea of what modality is acceptable in the telemedicine clinical context. Failure to comply with a given state’s modality requirement can lead to unwanted attention from state medical boards.

PRESCRIBING

After creating a valid doctor–patient relationship, the telemedicine physician also must conduct an appropriate exam and assessment prior to issuing a prescription,

if medically necessary. Here, an appropriate exam and assessment via telemedicine means complying with the applicable standard of care similar to in-person services. Regardless of what modality is used, if a physician does not have sufficient information available to render a diagnosis, treatment recommendation, or prescription, the physician should not continue with the telemedicine examination.

Failure to have sufficient information to appropriately prescribe is the underpinning for the prohibition against Internet prescribing. The definition of “Internet prescribing” varies state by state but is commonly defined as prescribing drugs to an individual the physician has never met based *solely* on a patient’s responses to a set of questions offered via the Internet. The majority of states have medical and/or pharmacy board laws, rules, and/or policies prohibiting this practice. States that have Internet prescribing prohibitions represent a higher-risk for store-and-forward prescribing, particularly if the telemedicine physician does not have access to, and does not review, the patient’s full medical record or any extrinsic clinical information outside of the patient-completed questionnaire.

A patient-facing questionnaire can be *part* of the overall medical information in the clinical intake process, but the physician’s diagnosis, treatment recommendations, and prescribing should not rely solely on the patient’s self-generated responses to an online questionnaire. In addition, the questionnaire itself should be dynamic, not static; it should have different follow-up questions for the patient based on the patient’s prior answers, and it must be rooted entirely in clinically valid care protocols and decision tree questions, just as if the physician were to interview and examine the patient in-person.

In addition to what has already been stated, some states place a wholesale ban on the prescription of controlled substances and other “lifestyle” treatments

(muscle relaxants, weight-loss, erectile dysfunction) via a telemedicine encounter, limiting prescribing of such drugs to in-person circumstances. Similarly, some states also prohibit the use of telemedicine to prescribe abortion-inducing medications, opioids, or medications used for the treatment of chronic pain.

Physicians who prescribe controlled substances should be aware of The Ryan Haight Act and its implementing regulations (the “Act”),¹⁵ which prohibit the distributing, dispensing, or delivery of controlled substances by means of the “Internet” (a broadly defined term) without a valid prescription.¹⁶ A prescription for a controlled substance is not valid or effective unless it is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.¹⁷ The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner.¹⁸

With respect to telemedicine practices and remote prescribing, no controlled substance may be delivered, distributed, or dispensed by means of the Internet without a valid prescription.¹⁹ The term “valid prescription” means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by: 1) a practitioner who has conducted at least one in-person medical evaluation of the patient; or 2) a covering practitioner.²⁰ The term “in-person medical evaluation” means a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals.²¹ Once the prescribing practitioner has conducted an in-person medical evaluation, the regulation does not set an expiration period or a requirement for subsequent annual examinations.

The regulations offer seven “telemedicine” exceptions to the in-person exam requirement, but they are very narrow

and do not reflect contemporary accepted clinical telemedicine remote prescribing practices.²² The DEA is currently in the process of drafting regulations that will create a special registration process allowing physicians and nurse practitioners to prescribe controlled substances via telemedicine without an in-person exam. Nonetheless, physicians will still be required to comply with state laws on controlled substance prescribing. If a state law is more restrictive than the federal rules, the more restrictive provisions will apply.

Failure to comply with telemedicine prescribing limitations can be costly. For example, in New Jersey, a practitioner prescribed controlled substances to Internet customers throughout the United States despite never establishing a genuine doctor–patient relationship with the Internet customer. The practitioner did not see customers, had no prior doctor–patient relationships with the Internet customers, did not conduct physical exams, did not create or maintain patient records, and the only information usually reviewed prior to issuing drug orders was the customer’s online questionnaire, all of which resulted in suspension of the practitioner’s DEA Certificate of Registration.²³

BILLING AND REIMBURSEMENT

As is true across the health care industry, the largest compliance risk associated with billing in reimbursement emerges in the context of federal health care programs. Medicare, for example, has strict requirements applicable to reimbursable telemedicine services.²⁴ Although Medicare does cover certain telehealth services, the current opportunities are limited by the coverage restrictions established via statute under the Social Security Act.²⁵

Subject to certain exceptions promulgated by the Centers for Medicare & Medicaid Services (CMS), there exist five conditions of coverage for telehealth services under Medicare:

1. the beneficiary is located in a qualifying rural area;
2. the beneficiary is located at one of 11 qualifying “originating sites;”
3. the services are provided by one of 10 “distant site practitioners” eligible to furnish and receive Medicare payment for telehealth services;
4. the beneficiary and distant site practitioner communicate via an interactive audio and video telecommunications system that permits real-time communication between them; and
5. the Current Procedural Terminology (CPT®)/Healthcare Common Procedure Coding System (HCPCS) code for the service itself is named on the CY2017 (or current year) list of covered Medicare telehealth services.

QUALIFYING RURAL AREA

Medicare only covers services for specific types of health care facilities that are located in either a county outside a Metropolitan Statistical Area (MSA) or a Rural Health Professional Shortage Area (HPSA) in a rural census tract.²⁶ The Health Resources and Services Administration (HRSA) decides HPSAs, and the Census Bureau decides MSAs. Confirming whether a specific address is eligible for Medicare telehealth originating site payment is made relatively easy by the existence of the Medicare Telehealth Payment Eligibility Analyzer, which can be accessed at data.hrsa.gov/tools/medicare/telehealth.

QUALIFYING ORIGINATING SITE

The second requirement for Medicare coverage is that the patient beneficiary be located at one of 11 qualifying originating sites at the time the telemedicine service is furnished. Patient beneficiaries are eligible for telemedicine services and physician may bill for certain covered telemedicine services if the patient beneficiary receives telemedicine services at the following authorized originating sites:

1. Physician and practitioner offices;

2. Hospitals;
3. Critical Access Hospitals (CAHs);
4. Rural Health Clinics;
5. Federally Qualified Health Centers;
6. Hospital-based or CAH-based Renal Dialysis Centers (including satellites);
7. Skilled Nursing Facilities (SNFs);
8. Community Mental Health Centers (CMHCs);
9. Renal Dialysis Facilities;
10. Homes of beneficiaries with End-Stage Renal Disease (ESRD) getting home dialysis; and
11. Mobile Stroke Units.

Note that the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act removed the originating site *geographic* conditions and added an individual’s home as a permissible originating telehealth services site for treatment of a substance use disorder or a co-occurring mental health disorder. Additionally, the Bipartisan Budget Act of 2018 removed the originating site geographic conditions and added eligible originating sites to diagnose, evaluate, or treat symptoms of an acute stroke.

ELIGIBLE DISTANT SITE PRACTITIONERS

Once the “originating site restrictions” have been satisfied, distant site practitioners who can furnish and receive payment for covered telehealth services (subject to state law) are:

- Physicians;
- Nurse practitioners (NPs);
- Physician assistants (PAs);
- Nurse-midwives;
- Clinical nurse specialists (CNSs);
- Certified registered nurse anesthetists;
- Clinical psychologists (CPs) and clinical social workers (CSWs)
- CPs and CSWs cannot bill Medicare for psychiatric diagnostic interview examinations with medical services or medical evaluation and management services. They cannot bill or get paid for CPT®

codes 90792, 90833, 90836, and 90838; and

- Registered dietitians or nutrition professionals.

ACCEPTED PRACTICE STANDARDS

According to CMS, telehealth services must be provided via an interactive audio and video telecommunications system that allows for real-time communication between the physician provider and the patient beneficiary.²⁷ Transmitting medical information to a physician or practitioner who reviews it later is permitted only in Alaska or Hawaii federal telemedicine demonstration programs.

ELIGIBLE CPT®/HCPCS CODES

Once all other requirements have been satisfied, the service itself must be listed among the eligible CPT®/HCPCS codes CMS publishes each year as covered telemedicine services. In 2019, CMS covered roughly 51 services with approximately 95 associated codes. Professional telehealth service claims must be submitted using the appropriate CPT® or HCPCS code.

If a provider performed telehealth services “through an asynchronous telecommunications system,” he or she must add the telehealth GQ modifier with the professional service CPT® or HCPCS code. Additionally, practitioners must submit telehealth services claims using Place of Service (POS) 02-Telehealth to indicate that he or she furnished the billed service as a professional telehealth service from a distant site. As of January 1, 2018, distant site practitioners billing telehealth services under the CAH Optional Payment Method II had to start submitting institutional claims using the GT modifier.

CMS instructs telemedicine practitioners to bill covered telehealth services to the applicable Medicare administrative contractor (MAC), which is typically the MAC covering the geographic location where the telemedicine provider is physically located. Medicare pays for covered

telehealth services in accordance with the Medicare Physician Fee Schedule (PFS). If a telemedicine provider is located in a critical access hospital (CAH) and has reassigned billing rights to a CAH that has elected the Optional Payment Method II for outpatients, the CAH bills the telehealth services to the MAC. The resulting payment is 80 percent of the Medicare PFS facility amount for the distant site service.

Originating sites are paid an originating site facility fee for telehealth services as described by HCPCS code Q3014. Telemedicine providers are instructed to bill the applicable MAC for the separately billable Part B originating site facility fee. Note, however, that the originating site facility fee does not count toward the number of services used to determine payment for partial hospitalization services when a CMHC serves as an originating site. As is likely abundantly clear, Medicare coverage for telemedicine services is limited. Urban areas are currently unable to benefit from Medicare reimbursement. Outside urban areas, there are still a myriad of conditions for coverage and nuanced billing practices that must be followed for compliant telemedicine billing and reimbursement. In fact, incorrect billing for telemedicine services is a trigger for federal fraud and abuse scrutiny. According to a 2018 Office of Inspector General (OIG) report, out of a sample of 100 telemedicine claims, 31 percent did not meet Medicare conditions for payment.²⁸ OIG provided the following results:

- 24 claims were unallowable because the beneficiaries received services at non-rural originating sites;
- 7 claims were billed by ineligible institutional providers;
- 3 claims were for services provided to beneficiaries at unauthorized originating sites;
- 2 claims were for services provided by an unallowable means of communication;
- 1 claim was for a non-covered service; and

- 1 claim was for services provided by a physician located outside the United States.²⁹

OIG offered and CMS concurred with the following recommendations:

- conduct periodic post-payment reviews to disallow payments for errors for which telehealth claim edits cannot be implemented;
- work with Medicare contractors to implement all telehealth claim edits listed in the Medicare Claims Processing Manual; and
- offer education and training sessions to practitioners on Medicare telehealth requirements and related resources.

Billing and reimbursement will only be subject to additional scrutiny as telemedicine gains a stronger foothold in the marketplace. Telemedicine providers must be vigilant about billing and institute internal controls to audit and monitor billing. Mistakes will undoubtedly be costly. For example, Operation Brace Yourself, which involved an international scheme allegedly defrauding Medicare of more than \$1.2 billion by using telemedicine doctors to prescribe unnecessary back, shoulder, wrist, and knee braces to beneficiaries resulted in the Department of Justice charging 24 people, including three medical professionals and the chief executive officers (CEOs) of five telemedicine companies.³⁰

CONCLUSION

Telemedicine, even at the level of initiating this form of clinical practice, is riddled with compliance considerations. Before a physician can treat patients across state lines, he or she must be licensed in the state in which a patient is located or qualify for an applicable exception. Even an appropriately licensed physician can find him or herself in an unwanted landmine for failure to meet the applicable standard of care if he or she does not appropriately establish a doctor–patient relationship and does not establish the relationship using an

acceptable modality in advance of prescribing medically necessary medications. At least for now, prescribers of controlled substances must be aware of the Ryan Haight Act and its impact on prescribing such substances via medicine in addition to being aware of and complying with an applicable state law that is more restrictive than the Act.

Finally, providers serving patients insured by Medicare must comply with the conditions for coverage and undertake billing meticulously and compliantly. What is particularly difficult about compliance with practice standards applicable to telemedicine is that they are constantly evolving and changing, so providers have to remain current with respect to state and federal laws and regulations or risk practicing telemedicine non-compliantly.

Endnotes

1. See M.G.L. chapter 175, § 47BB.
2. See Col. Rev. Stat. § 12-240-104(6).
3. See Ga. Code Ann. § 43-34-31.
4. See O.R.C. Ann. § 4731.36(A)(4).
5. See Fla. Admin. Code Ann. r. 64B8-2.001(5); Fla. Admin. Code Ann. r. 64B8-9.0141(9)(a),(d).
6. See Ala. Code. § 34-24-502.
7. Interstate Medical Licensure Compact, *The IMLC*, available at imlcc.org.
8. See Mon. Code Ann. § 37-3-356.
9. See M.G.L. chapter 175, § 47BB.
10. See Colorado Medical Board Policy No. 40-27, § (III)(B).
11. *Id.* at § (II)(B).
12. *Id.* at (II)(A)(1).
13. See Colo. Rev. Stat. Ann. § 12-240-104(6); Board Policy 40-27 at § (II)(A)(1)(2).
14. See Colo. Rev. Stat. Ann. § 12-240-121(1)(aa).
15. The DEA issued regulations. See 21 C.F.R. Part 1300, 1301, 1304, et al.; see also 74 FR 15596 (April 6, 2009).
16. 21 U.S.C. § 829.
17. 21 C.F.R. § 1306.04(a).
18. *Id.*
19. 21 C.F.R. § 1306.09(a).
20. 21 C.F.R. § 1300.04(l)(1); 21 U.S.C. § 829(e)(2)(A).
21. 21 C.F.R. § 1300.04(f); 21 U.S.C. § 829(e)(2)(B).
22. 21 C.F.R. § 1300.04(i).
23. 74 Fed. Reg. 10083-95 (March 9, 2009).
24. See CMS, Telehealth Services, available at www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/TelehealthSrvcsfctshst.pdf.

25. See § 1834(m)(4) of the Social Security Act.
26. Providers qualify as originating sites, regardless of location, if they were participating in a federal telemedicine demonstration project approved by (or getting funding from) the U.S. Department of Health and Human Services as of December 31, 2000. Similarly, mobile stroke units as well as hospital-based and CAH-based renal dialysis centers and renal dialysis facilities, and beneficiary homes (when such constitute an eligible originating site), are not required to be in a rural HPSA or non-MSA. CMS, *supra*, note 24 at 3.
27. CMS, *supra*, note 24 at 6.
28. OIG, *CMS Paid Practitioners for Telehealth Services That Did Not Meet Medicare Requirements* (April 2018), available at oig.hhs.gov/oas/reports/region5/51600058.pdf.
29. *Id.*
30. DOJ, *Federal Indictments & Law Enforcement Actions in One of the Largest Health Care Fraud Schemes Involving Telemedicine and Durable Medical Equipment Marketing Executives Results in Charges Against 24 Individuals Responsible for Over \$1.2 Billion in Losses* (April 9, 2019), available at www.justice.gov/opa/pr/federal-indictments-and-law-enforcement-actions-one-largest-health-care-fraud-schemes.

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