TELEHEALTH IN THE HOT SEAT: PROACTIVE COMPLIANCE IN THE FACE OF HEIGHTENED ENFORCEMENT

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AGENDA

- State Enforcement Issues
- Federal Regulation and Flexibilities
- Federal Enforcement and Oversight Issues
- Risk Mitigation Strategies

STATE ENFORCEMENT ISSUES

WHAT'S ALLOWED DURING THE PUBLIC HEALTH EMERGENCY?

Licensure

- **All** states still require the provider to be licensed in the state in which the patient is located at the time of the encounter, unless a licensure exception OR waiver per an executive order applies
  - Most states adopted an executive order to temporarily waive licensure (full or partial) or implement a streamlined registration process
  - Waivers have an expiration date – many have expired or are scheduled to expire soon

WHAT'S ALLOWED DURING THE PUBLIC HEALTH EMERGENCY?

Remote Prescribing

- **All** states still have rules that govern remote prescribing of medications
  - All states still allow remote prescribing of non-controlled substances using audio-visual modalities, but some states added waivers for other modalities (e.g., 20% of states specifically allowed for audio-only consults)
  - Some states loosened rules to allow for remote controlled substance prescribing (e.g., eliminated requirement to first conduct an in-person visit before remote prescribing controlled substances)
- State relaxations followed DEA announcement last year that the COVID-19 public health emergency qualifies as an exception to the general prohibition against issuance of prescription for a controlled substance without a previous in-person medical evaluation, provided certain conditions have been met.

WHAT'S ALLOWED DURING THE PUBLIC HEALTH EMERGENCY?

Ancillary Requirements

- **Majority** of states require one or more of the following:
  - Advance informed consent (verbal or in writing)
  - Sharing of patient records to the patient's primary care providers
  - Provider telehealth training
  - Technology requirements
  - Special state telemedicine-specific registration (e.g., Indiana, Alaska)
- 31 states have a "corporate practice of medicine prohibition" that requires providers to only deliver services through a legal entity that is owned and controlled by a licensed physician.

WHAT WILL BE ALLOWED AFTER THE PUBLIC HEALTH EMERGENCY?

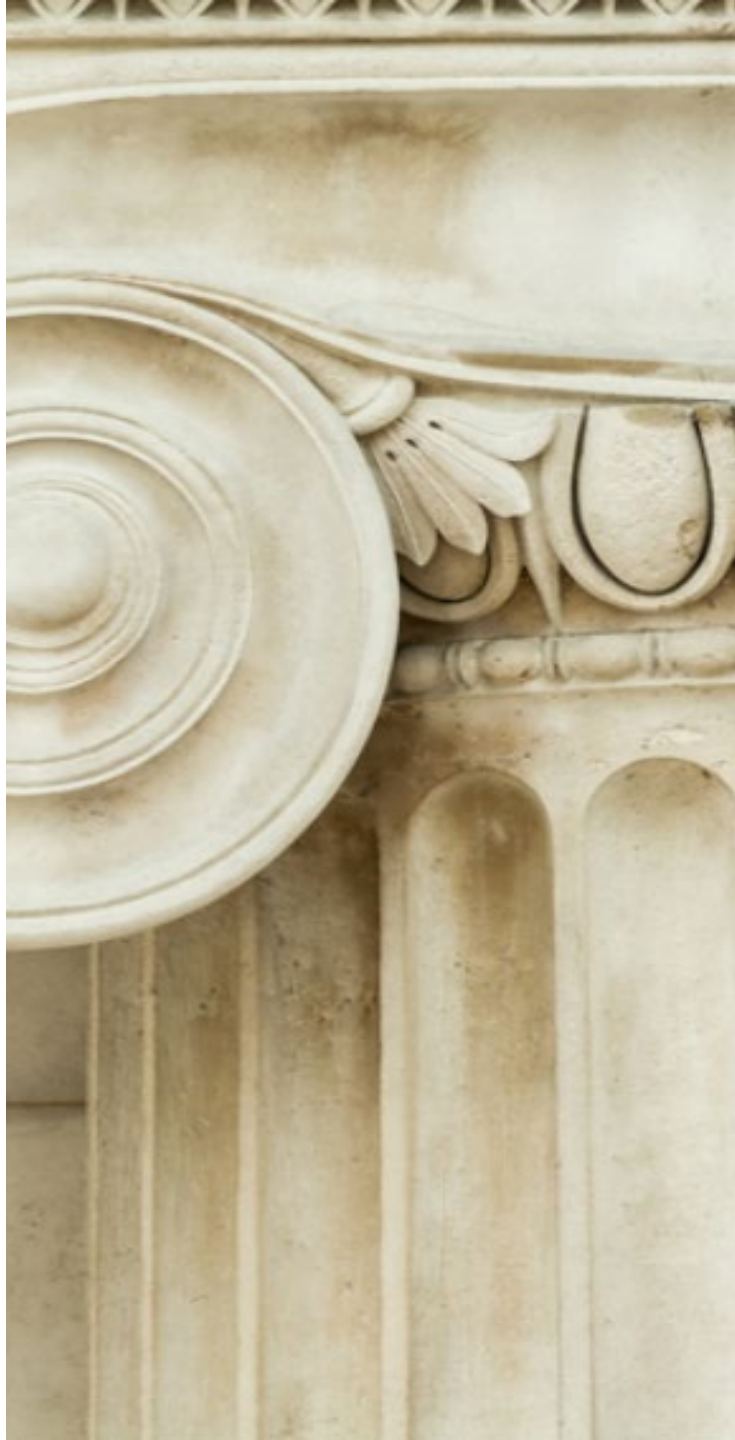
- Many states are re-evaluating their existing professional licensure rules
  - Addition of “existing patient” exception
  - Addition of “reciprocity” exceptions
  - Expansion of Interstate Medical, Physical Therapy, Psychology and other Compacts
- Uniform Law Commission focused on developing legislation that eases remote prescribing rules
- Medicaid programs are expanding coverage and easing enrollment requirements
  - Some Medicaid programs require an “in-state presence” which usually equates to a physical office location or mailing address
- States are not generally addressing “ancillary telehealth requirements” like corporate practice of medicine, informed consent and special telemedicine registration requirements

STATE ENFORCEMENT ACTIVITIES CONTINUE TO GROW

- Increase in **state licensure investigations** for unlicensed or unprofessional practice
  - Focus on “nursing” and “coaching”
  - Disciplinary action taken against physicians for failure to deliver care that meets standard of care
    - Usually a case alleging “unprofessional conduct”
    - **Example**: Medical Director prescribing antibiotics forfeited license as part of settlement
    - **Multi-state Example**: Telehealth physicians prescribing pain creams and devices by phone sanctioned and licenses revoked (multi-state suspensions)
  - Scrutiny may fall on telehealth organizations in addition to individuals
  - States are currently focused on “online questionnaires” (different from dynamic questionnaires)

CASE STUDY:
FAILURE TO MEET THE STANDARD OF CARE

- Physicians who have prescribed certain types of medications to patients using “asynchronous” (i.e., an online questionnaire) telehealth solutions to conduct consultations have been investigated and subject to enforcement action in certain states.
  - In 2018, a physician employed by an online-only healthcare provider was investigated, sanctioned and ultimately forfeited his California license after allegations that he delivered care using an asynchronous solution that did not meet the standard of care or his professional obligations.
  - Multiple physicians have since been investigated for “unprofessional conduct” related to the use of telehealth modalities.
  - State medical boards differ in their interpretation of what is and what is not the “standard of care”, which creates challenges for providers rendering care via telehealth in multiple states.



FEDERAL REGULATION AND FLEXIBILITIES

TELEHEALTH AND COVID-19 FLEXIBILITIES

- Historically, Medicare paid for telehealth on a limited basis: when the person receiving the service was in a designated rural area and at a certain type of location.
- In recent years, Medicare started paying for virtual check-ins, plus e-visits under Part B.
- Under a Section 1135 waiver, Medicare pays for office, hospital, and other visits furnished via telehealth across the country, including at patient residences. In addition, a broader range of providers may furnish the telehealth.

ENFORCEMENT DISCRETION AND PREP ACT

- To the extent the waiver requires a prior established relationship with a practitioner, HHS is not auditing compliance with that requirement.
- OIG is exercising enforcement discretion with providers that reduce or waive beneficiary cost-sharing for telehealth visits.
- OCR is exercising enforcement discretion and will not impose penalties for noncompliance with the regulatory requirements under the HIPAA Rules “in connection with the good faith provision of telehealth” during the public health emergency.
- HHS has announced a fourth amendment to the Secretary’s Public Readiness and Emergency Preparedness Act (PREP Act) declaration that addresses the cross-border practice of medicine via telehealth.

PERMANENT REFORMS?

- Annual CMS Physician Fee Schedule Final Rule added more than 60 services to the Medicare telehealth list.
    - Final Rule recognizes that Medicare does not have the statutory authority to pay for telehealth outside of rural areas or, with certain exceptions, allow beneficiaries to receive telehealth in their homes.
- Numerous bills pending in the U.S. House, including the Telehealth Modernization Act (S. 368, H.R. 1332), which would remove the originating and geographic site restrictions for telehealth.

FEDERAL ENFORCEMENT AND OVERSIGHT ISSUES

PRE-COVID ENFORCEMENT ACTIONS INVOLVING TELEHEALTH WERE INCREASING

- **Focus Areas:**
  - Compounded medications / compounding pharmacy relationships
  - Durable medical equipment (DME) / DME company relationships
  - Genetic testing / laboratory relationships
- **Common Themes:** Allegations of medically unnecessary items or services and lack of legitimate doctor / patient relationship; kickbacks

OPERATION RUBBER STAMP

- DOJ announced the largest national healthcare fraud “takedown” in the DOJ’s history on September 30, 2020
- DOJ charged more than 345 defendants with participating in healthcare fraud schemes involving more than $6 billion in alleged losses to federal health care programs, including $4.5 billion stemming from telehealth arrangements

JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE — Wednesday, September 30, 2020

National Health Care Fraud and Opioid Takedown Results in Charges Against 345 Defendants Responsible for More than $6 Billion in Alleged Fraud Losses

Largest Health Care Fraud and Opioid Enforcement Action in Department of Justice History

OPERATION RUBBER STAMP (CONT.)

- Alleged fraudulent schemes involving telehealth included the following:
  - A marketing company that recruited Medicare beneficiaries to obtain medically unnecessary genetic testing ordered by telehealth physicians who received illegal kickbacks and bribes from telehealth companies
  - An owner and operator of a telehealth company who paid kickbacks and bribes to call centers and healthcare professionals in exchange for referrals and orders for medically unnecessary genetic cancer screening tests for Medicare beneficiaries
  - A laboratory owner who conspired to pay kickbacks for genetic testing orders and specimens to run medically unnecessary diagnostic testing
  - Laboratory owners who were charged with paying kickbacks to a network of marketers to procure DNA samples for genetic testing that they knew to be medically unnecessary and not reimbursable by the patients' health care benefit programs; beneficiaries were solicited through methods such as telemarketing, door-to-door sales and appearances at senior health fairs, and the tests were approved by a range of medical professionals, including doctors operating on telehealth platforms, who had not previously treated the patients and had little or no contact with the patients in connection with prescribing the testing
- **Enforcement Tools**: Health Care Fraud Statute (18 U.S.C. § 1347), False Statements Relating to Health Care Matters (18 U.S.C. § 1035), Federal Anti-Kickback Statute (42 U.S.C § 1320a-7b(b)), etc.

RECENT ENFORCEMENT EXAMPLES
(CONTINUING PRE-COVID FOCUS)

- In the first few months of 2021, there has been significant activity in resolving federal cases involving telehealth
  - Florida businessman pleaded guilty in connection with an alleged $174 million health care fraud scheme involving the submission of fraudulent prescriptions purchased from a telemarketing company
  - New Jersey physician received 33 months prison sentence for his role in an alleged telemedicine scheme to prescribe expensive compounded medications to patients who did not need them
  - Florida telemarketing call center owner convicted and sentenced to 10 years in prison for an alleged $3.3 million cancer genetic testing fraud scheme involving paying unlawful kickbacks to telemedicine companies and receiving unlawful kickbacks from laboratories
  - Florida operator of DME companies pleaded guilty to conspiracy to commit healthcare fraud, and settled FCA claims, based on an alleged scheme where telemedicine doctors were paid to approve DME without any underlying doctor-patient relationship

TELEHEALTH OVERSIGHT ACTIVITIES

- **Pre/Early-COVID OIG completed and planned additional telehealth audits and evaluation**
  - In April 2018, the OIG issued a report containing findings from its audit of Medicare payments for telehealth services
    - OIG had previously announced its plan to review telehealth service claims where there was no corresponding claim submitted by the originating site, indicating that the originating site might not have met Medicare's telehealth coverage requirements
    - OIG found that **31% of claims did not meet Medicare requirements**
  - In April 2020, OIG issued a report on South Carolina's Medicaid Fee-for-Service telemedicine payments
    - OIG found that **96% of the payments were unallowable**, in nearly all cases because providers did not document the start and stop times or the consulting site location of the medical services
- **Ongoing OIG Work:**
  - Announced/Revised 2021
    - Use of Telehealth to Provide Behavioral Health Services in Medicaid Managed Care (Evaluation)
    - Audits of Medicare Part B Telehealth Services During the COVID-19 Public Health Emergency (Audit)
    - Home Health Agencies' Challenges and Strategies in Responding to the COVID-19 Pandemic (Evaluation)
  - Announced/Revised 2020
    - Medicare Telehealth Services During the COVID-19 Pandemic: Program Integrity Risks (Evaluation)
    - Use of Medicare Telehealth Services During the COVID-19 Pandemic (Evaluation)
    - Medicaid—Telehealth Expansion During COVID-19 Emergency June 2020 (Audit)

WHAT MIGHT WE EXPECT IN A POST-COVID ENFORCEMENT AND OVERSIGHT ENVIRONMENT?

- Continuing DOJ Focus/Effort:

  In February, Acting Assistant Attorney General Brian Boynton noted DOJ's "continued focus on telehealth schemes, particularly given the expansion of telehealth during the pandemic."

- OIG issued a statement in late February to respond to concerns:

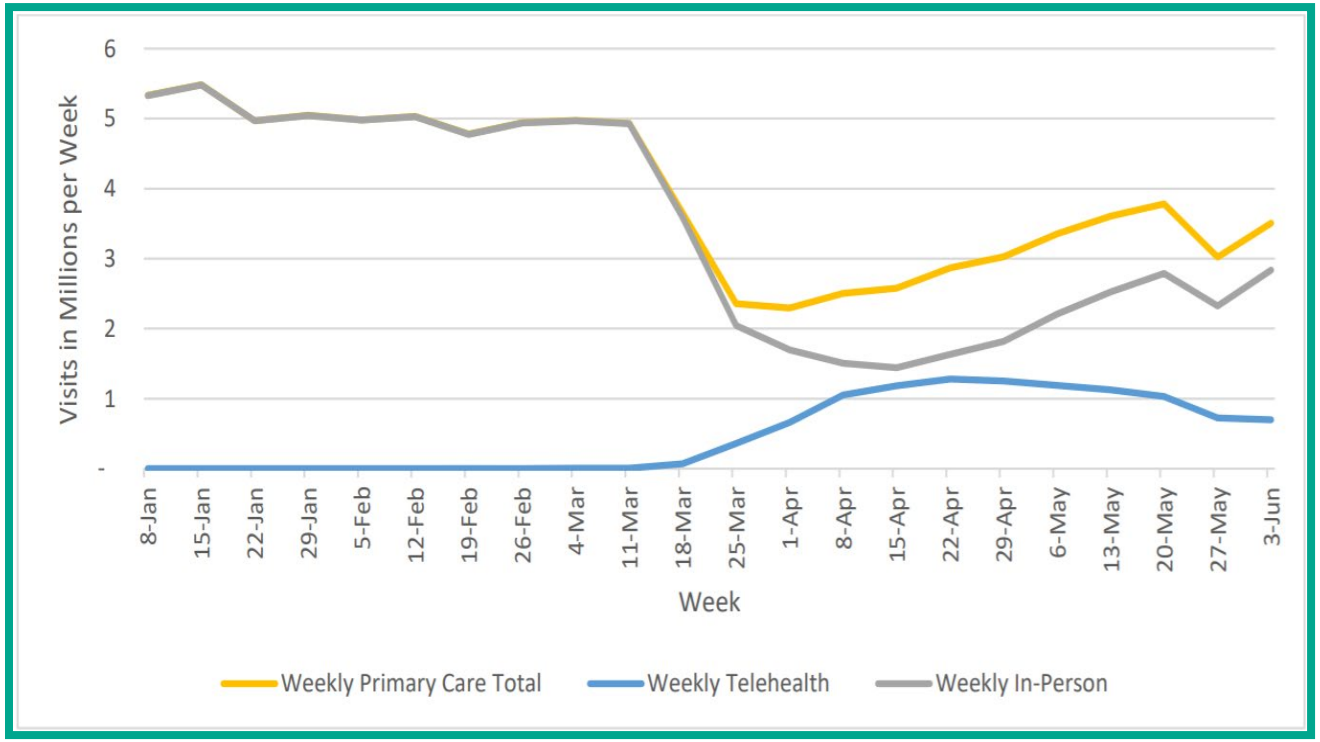
  "….We are aware of concerns raised regarding enforcement actions related to 'telefraud' schemes, and it is important to distinguish those schemes from telehealth fraud. In the last few years, OIG has conducted several large investigations of fraud schemes that inappropriately leveraged the reach of telemarketing schemes in combination with unscrupulous doctors conducting sham remote visits to increase the size and scale of the perpetrator's criminal operations. In many cases, the criminals did not bill for the sham telehealth visit. Instead, the perpetrators billed fraudulently for other items or services, like durable medical equipment or genetic tests. ***We will continue to vigilantly pursue these 'telefraud' schemes and monitor the evolution of scams that may relate to telehealth****."*

Christi A. Grimm, OIG Principal Deputy Inspector General (https://oig.hhs.gov/coronavirus/letter-grimm-02262021.asp?utm_source=oig-home&utm_medium=oig-home-news&utm_campaign=oig-grimm-letter-02262021)

RISK MITIGATION STRATEGIES

INCREASED UTILIZATION, INCREASED REIMBURSEMENT = INCREASED RISK

- Medicare fee-for-service in-person visits for primary care dramatically fell in mid-March at the beginning of the pandemic
- 43.5% of Medicare primary care visits were provided via telehealth in April, compared with less than 0.1% prior to the PHE in February
- As in-person visits began to resume in May, telehealth visit rates stabilized above pre-pandemic rates
- Primary care visits for FFS Medicare Beneficiaries (visits in millions per week)

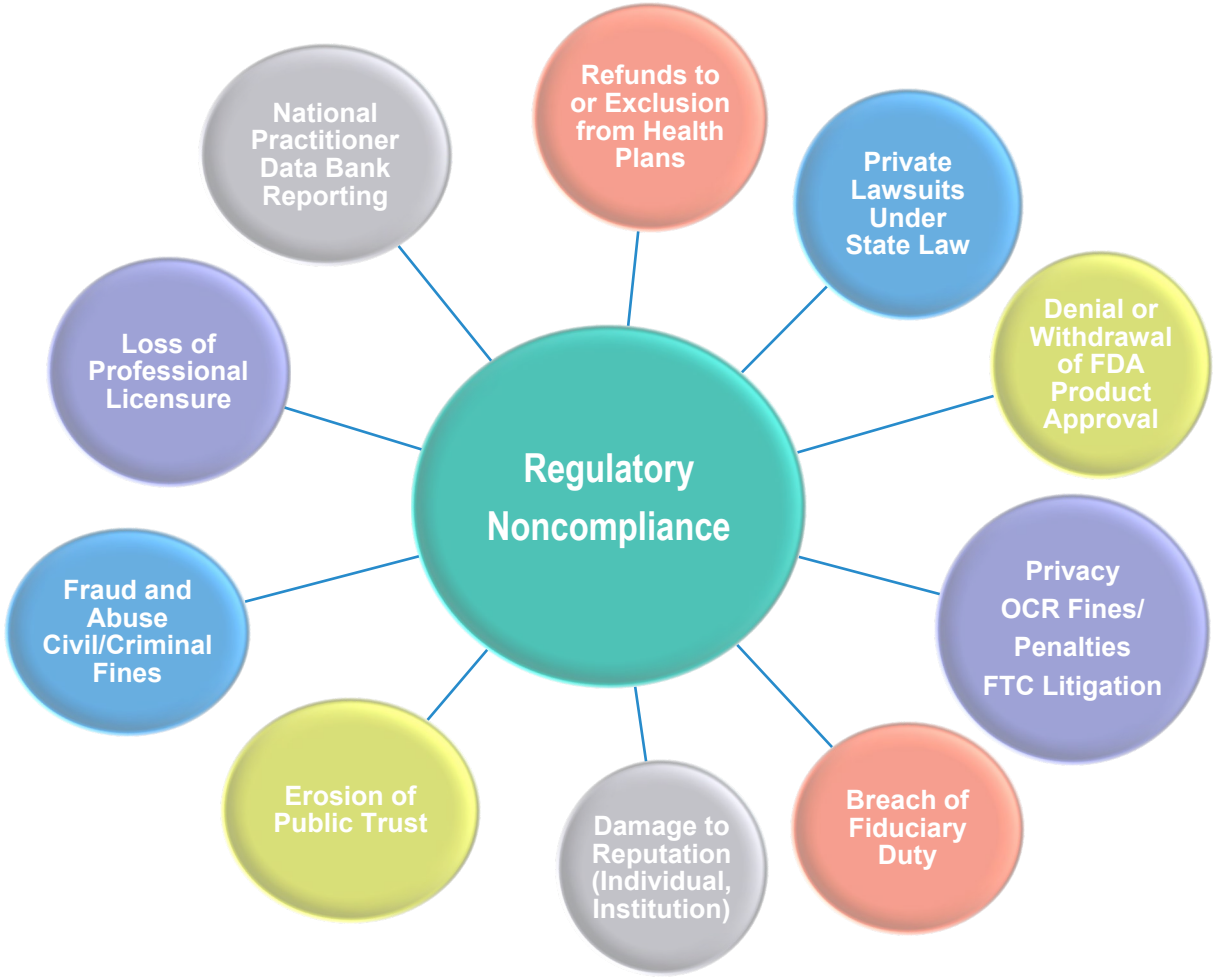


Source: "Medicare Beneficiary Use of Telehealth Visits: Early Data from the Start of the COVID-19 Pandemic," ASPE Issue Brief, July 28, 2020. https://aspe.hhs.gov/system/files/pdf/263866/hp-issue-brief-medicare-telehealth.pdf

SCRUTINY ENHANCED BY PUBLIC HEALTH EMERGENCY

- Telehealth now subject to heightened scrutiny because of:
  - Inappropriate reliance on compliance waivers or expiration of compliance waivers that “fly under the radar”
  - Increased remote controlled substance prescribing
  - Rush of new entrants to take advantage of Covid-19 related testing, app-based testing, app-based vaccines, etc., some of which create compliance issues that raise scrutiny on all companies
  - Scrutiny about tax payer dollars going to these programs
  - “Telefraud” schemes involving genetic testing, DME and compounded medications

ASSESS RISK TOLERANCE THROUGH AN INFORMED LENS



DESIGN AND FOLLOW THOUGHTFUL RISK MITIGATION STRATEGIES

- Ensure that state-level requirements to establish a legitimate physician-patient relationship are satisfied.
  - This involves evaluating the proposed arrangement under applicable state laws and regulations, some of which have changed in light of COVID-19 and may continue to evolve.
- Be particularly diligent in the design and compliance oversight of marketing strategies to confirm that patients are reached through appropriate channels, which may not include “cold calls.”
- Confirm that each partner to any collaboration has a robust compliance program that appropriately addresses, among the other elements, review of marketing materials and practices, as well as requirements related to permissible compensation arrangements.
- Carefully evaluate billing and coding practices to ensure practices are consistent with both government and commercial payor requirements; again, a number of these requirements have changed considerably because of COVID-19 and likely will continue to evolve.
- Consider compliance comprehensively—for example, develop a data strategies compliance program. Compliance concerns in one area create scrutiny for other areas.

QUESTIONS?

THANK YOU

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