POST-PANDEMIC COMPLIANCE AND ENFORCEMENT TRENDS

NEW ENGLAND HEALTHCARE INTERNAL AUDITORS (NEHIA)
HEALTHCARE FINANCIAL MANAGEMENT ASSOCIATION (HFMA)
ANNUAL COMPLIANCE AND AUDIT CONFERENCE

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Of Note

We note that in this presentation we are only providing general information; the information contained in this presentation does not constitute legal advice. No attorney-client relationship has been created. If legal advice or other assistance is required, please contact us directly.

Overview

- COVID-19 PHE: Ended May 11, 2023
- What has been extended?
- What has not?
- What are regulators focused on?

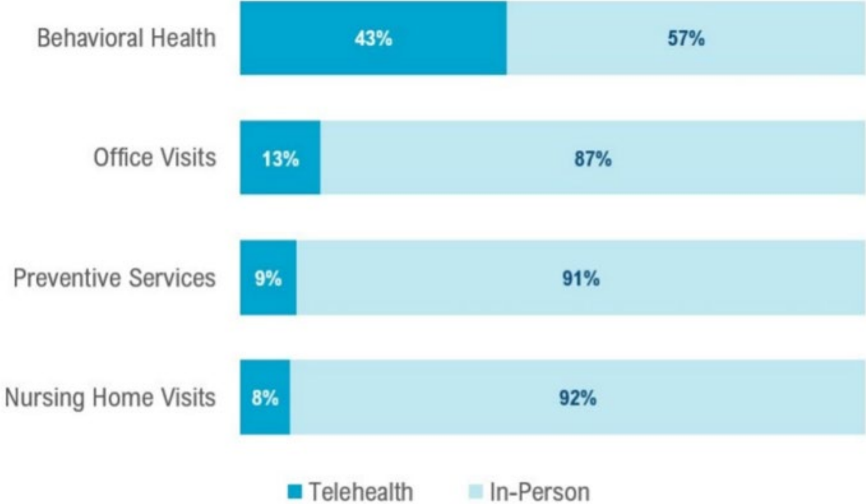
Telehealth

- COVID-19 telehealth flexibilities extended through **December 31, 2024**, including:
  - Expansion of allowable 'originating sites' for telehealth services (including patient's home/residence)
  - Expansion of eligible telehealth providers, including OT/PT/SLP and audiologists
  - Payment parity for in-person / telehealth services
  - Audio-only telehealth
  - Expanded list of telehealth services
  - Delay of in-person visit within 6 months prior to initiating tele-mental health services
- Goal: Retain payment stability, reduce confusion and burden, and avoid unnecessary access restrictions

Telehealth

More than **2 in 5 Medicare beneficiaries used telehealth** during the first year of the pandemic

Medicare beneficiaries used telehealth for a much larger share of their behavioral health services.



Tele-Prescribing of Controlled Substances

- DEA has extended pandemic-era telehealth flexibilities tied to tele-prescribing of controlled substances through December 31, 2024
  - Initial extension in two parties (through 11/9/23 and grace period through 11/9/24) superseded

- Practitioners allowed to form new patient relationships involving tele-prescribing of CS through 12/31/24
  - Subject to state laws and DEA-imposed standards for prescribing (legitimate purpose, acting in usual course, etc.)

Virtual Supervision

- Pandemic-era waiver allowing "direct supervision" (of diagnostic tests, incident to services, etc.) to be provided via real-time, audio-video technology.
  - I.e., tele-supervision.
  - Still must be immediately available
- Extended through **12/31/24** by the 2024 MPFS Final Rule – intent to align with extension of other telehealth policies.
- State scope of practice requirements may impose heightened supervision requirements.

Remote Physiologic/Patient Monitoring

- RPM services can continue to be provided to patients with both acute and chronic conditions
- Post-PHE, RPM services can only be provided to "established" patients
  - CMS: Receipt of RPM services during PHE qualifies patient as "established" – otherwise, expectation of E/M visit or similar encounter to establish plan of care
- Similarly, post-pandemic e-visits / virtual check-ins limited to established patients

Virtual Supervision *of Residents*

- Policy allowing teaching physicians to participate virtually when residents are furnishing telehealth services extended through December 31, 2024
  - Applicable in all residency training locations
  - Requires use of audio-video technology (not audio-only)
  - Requires *real-time observation* (not just availability) to have virtual presence during key portions of virtual service

- CMS declined to extend the policy to include in-person services by residents.

Expired Waivers/Flexibilities

- Stark Law Blanket Waivers
  - Government issued guidance in February 2023 indicating expectation of "immediate compliance" with Stark Law upon expiration of PHE
  - Stark Law = Strict Liability Statute
  - Modified arrangements protected by waivers needed to be fixed by 5/11/23 (limited allowance under current Stark regulations for temporary non-compliance)

Expired Waivers/Flexibilities

- OIG Policy Statements and COVID-19 Guidance
  - No more reduction/waiver of cost-sharing for telehealth services
  - No further enforcement discretion of administrative sanctions aligned with activities protected by Stark Law blanket waivers
  - Rescission of non-binding guidance on applicability of AKS, CMPs and OIG enforcement authorities to PHE-connected arrangements
    - Includes OIG COVID-19 FAQs

Expired Waivers/Flexibilities

- HIPAA Enforcement Discretion Notices
  - Expired 11:59 p.m. on May 11, 2023
  - 4 Notices Expired:
    - COVID-19 Community Testing Sites
    - Telehealth Communications (note transition period below)
    - Public Health Activities related to COVID-19
    - Online/Web-Based COVID-19 Appointment Scheduling
  - OCR providing 90-day post-PHE transition period to come into compliance on the provision of telehealth (through 8/9/23)

Expired Waivers/Flexibilities

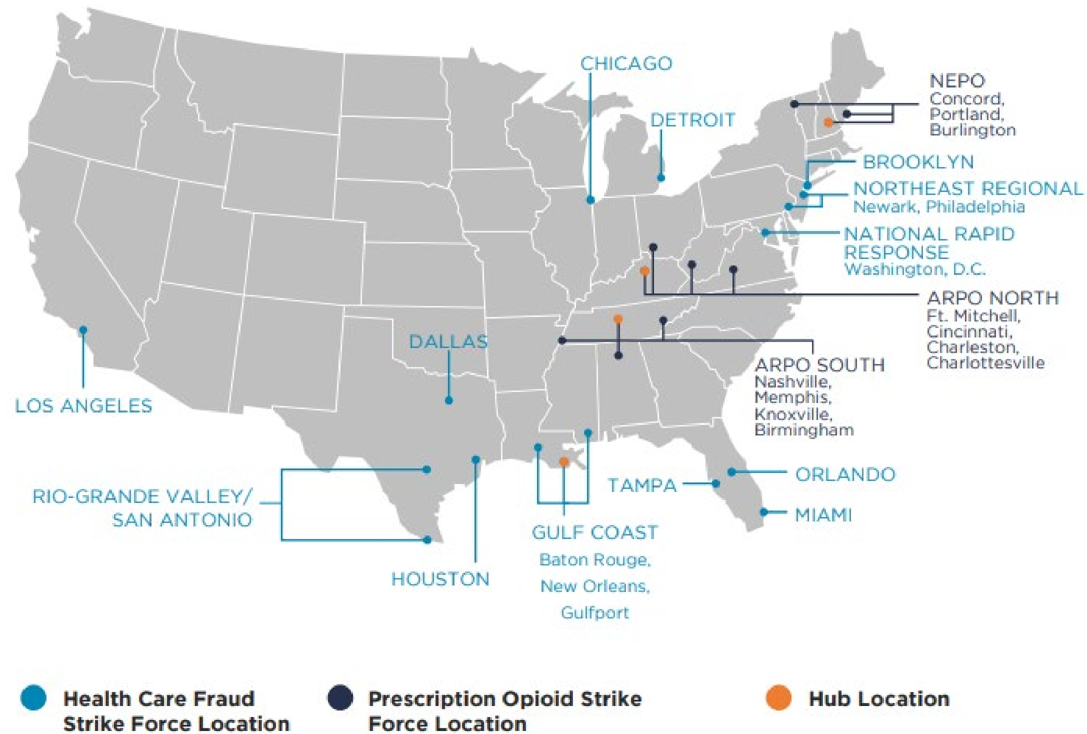
- Hospital Services
  - Post-pandemic hospital services must be under care of a physician (condition of participation)
  - No longer allowed to have APPs ultimately responsible

- Telehealth & State Medicare Enrollment
  - CMS now deferring entirely to state licensure laws
  - Increases importance of state-by-state licensure compliance

Expired Waivers/Flexibilities

- CLIA Regulatory Flexibilities
  - Remote review of physical slides (secondary reading site must have its own CLIA certification)
  - Expedited review of CLIA certificate applications
  - COVID-19 testing on asymptomatic individuals
  - Use of expired reagents
  - Surveillance testing by non-CLIA laboratories (certification now required, even if no reporting of patient-specific results)

Post-Pandemic Enforcement Priorities



Post-Pandemic Enforcement Priorities

- Opioids / Controlled Substances
  - Federal and state support for renewed scrutiny of prescribing practices and diversion in connection with ongoing opioid crisis
  - Reported rises in non-opioid abuse also drawing scrutiny
  - Ongoing tension between enforcement priority targeting opioids and industry support from DEA for tele-prescribing (including of Schedule II substances)
- OIG: "CMS should take steps to increase access to treatments for opioid use disorder" (top unimplemented recommendation to reduce fraud/waste/abuse)

Post-Pandemic Enforcement Priorities

- DOJ Fraud Priorities:
  - Telemedicine
  - Clinical Laboratories
  - DME

- DOJ scrutiny of ‘multidisciplinary’ schemes involving alleged medically unnecessary referrals (often via telehealth, involving call center-generated patients) to DME and Lab companies
  - E.g., genetic testing referrals, DME referrals
- Overlap with DOJ scrutiny of fraud schemes targeting sober homes
  - Patients in recovery subject to medically unnecessary testing/treatmetns

Post-Pandemic Enforcement Priorities

TELEFRAUD SCHEME

1

Telemarketers contact beneficiaries and request health care information and health insurance numbers.

2

The purported telehealth company pays a medical provider to electronically sign orders/prescriptions in an online portal for unnecessary durable medical equipment, genetic testing, or prescription medications.

The medical provider typically does not interact with or treat the beneficiary.

3

A durable medical equipment company, laboratory, or pharmacy purchases the complete package that includes the beneficiary's information and medical provider's order/prescription, and uses the information to submit false claims for payment to Medicare, Medicaid, and other Federal health care programs.

OIG.HHS.GOV

Post-Pandemic Enforcement Priorities

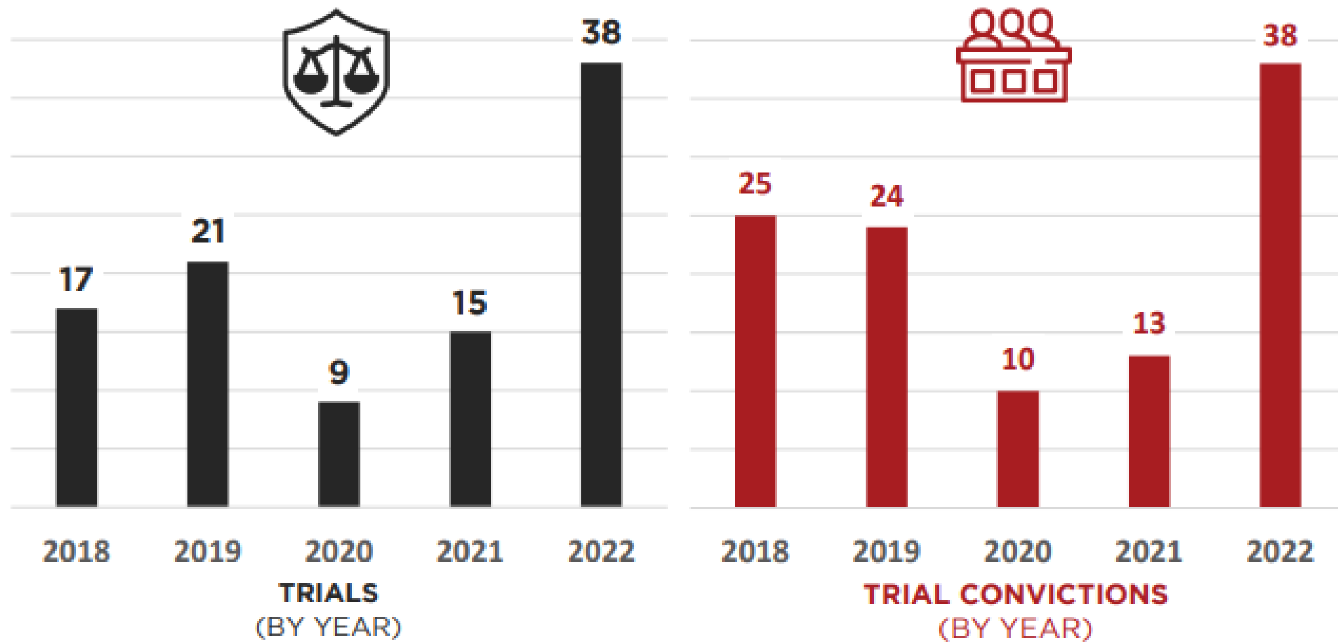
- COVID-19 Program Fraud
  - Heavy criminal and civil scrutiny of schemes targeting COVID-19 government programs, e.g.:
    - 8/23 DOJ coordinated nationwide COVID-19 fraud takedown totaling 718 criminal and civil actions and over $836M in alleged COVID-19 fraud.
    - 4/23 DOJ coordinated nationwide COVID-19 fraud takedown targeting 18 defendants and over $490M in alleged COVID-19 fraud.
    - 5 DOJ Strike Forces Targeting COVID-19 Fraud (FL, NJ, CA, CO, MD).
    - FL COVID-19 Fraud Task Force: 73 criminal prosecutions for federal fraud schemes targeting PPP, Medicare, and other govt programs.
    - CA Physician charged criminally for fraudulent submission of more than $250M in claims to HRSA under its COVID-19 Uninsured Program.

Post-Pandemic Enforcement Priorities

- COVID-19 Testing Fraud
  - Heavy criminal and civil scrutiny of COVID-19 testing fraud schemes, e.g.:
    - CA Medical Technology Company President sentenced to 8 years in connection with fraud/kickback scheme leading to submission of $77M in COVID-19 and allergy testing claims.
    - CA Clinical Lab Manager pleads guilty in $359M fraud scheme involving COVID-19 screening testing that resulted in lab running respiratory pathogen panel tests on residents/staff at nursing homes, assisted living facilities, rehab facilities, and schools.
    - Clinical Lab charged with civil FCA violations for offering COVID-19 tests to nursing homes to then bill medically unnecessary respiratory pathogen panel tests on residents.
    - Urgent Care settles FCA suit arising from upcoding of E/M services related to COVID-19 testing.

Post-Pandemic Enforcement Priorities

HCF Unit Statistics



Post-Pandemic Compliance Tools

- OIG Toolkit for Analyzing Telehealth Claims
  1. Review CMS / OIG / Payor Programs/Policies
  2. Collect Claims Data
  3. Conduct Quality Assurance Checks
  4. Analyze Data to Identify Program Integrity Risks
  5. Interpret Results

- What now? Consider OIG-identified thresholds

Post-Pandemic Compliance Tools

- OIG High-Risk Areas:
  - Billing telehealth services at highest level for high proportion of services (OIG looking at 99215s)
  - Billing high average number of hours of telehealth services per visit (look for “impossible days” of 25 hours of billing)
  - Billing telehealth services more than 300 days per year (median 26 days per year)
  - Billing telehealth for high number of patients (2k or more; median = 21)
  - Billing multiple plans/programs for same telehealth services
  - Billing telehealth then ordering DME (50+% = high risk threshold)
  - Billing telehealth and a facility fee for most visits (75%+ = high risk threshold)

Questions?

THANK YOU

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