The Healthcare Law Section Presents

18th Annual Healthcare Law Compliance Symposium: Part I

Thursday, October 7, 2021
3:30 - 5:45 P.M.
Via Zoom
2.0 hours Gen. CLE Credit

Provider #36
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18th Annual Healthcare Law Compliance Symposium, Part I

Program Title
Healthcare Law

Section/Committee

Program Date and Time
Thursday, October 7, 2021 3:30 PM

Event Location
Zoom Webinar

Participant Name
Brett D. Moodie

State Bar Number

Profession, if not a lawyer

- Please rate by circling the appropriate number (5 = highest rating; 1 = lowest rating)

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<th>Speakers</th>
<th>Usefulness of Information</th>
<th>Speaking ability</th>
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<td>Andrea L. Frey</td>
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<td>Brett D. Moodie</td>
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<td>Carol K. Lucas</td>
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- Overall program rating

- Contribution of written materials to the learning experience (Consider whether the material contained significant, current intellectual or practical content)

- Contribution of the location/environment to the learning experience

- Did the program meet your expectations? [ ] Yes [ ] No

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- Please rank the factors that influenced your attendance at this program.

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Number of years in practice __________________
Number of lawyers in firm __________________

List of your area(s) of practice/interest ____________________________________________

Who recommends/authorizes CLE attendance in your firm?

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What program length do you prefer?

☐ 1 Hour ☐ 2 Hours ☐ 3 Hours ☐ All-day

What time of day do you prefer to attend program?

☐ Weekday before 10 a.m. ☐ Weekday lunch ☐ Weekday evening
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Session 1: Telehealth in a Pandemic and Post-Pandemic World

• Andrea L. Frey, Hooper, Lundy and Bookman
• Brett D. Moodie, Corporate Legal Counsel, Cedars-Sinai Medical Center

Andrea Frey is an Associate with Hooper, Lundy & Bookman, PC, San Francisco, and the co-chair of the firm’s Digital Health Task Force. Her practice focuses on transactional and health care regulatory matters, with an emphasis on health privacy, digital health, licensure and certification, scope of practice, and medical staff issues.

Brett Moodie is corporate counsel for legal affairs at Cedars-Sinai Medical Center. His practice is primarily focused on transactional, compliance, and privacy matters. Prior to joining Cedars-Sinai in 2020, Brett worked as a Certified Fraud Examiner for the CMS Zone Program Integrity Contractor (ZPIC) and as an associate at Hooper, Lundy & Bookman.
Telehealth in a Pandemic and Post-Pandemic World

Andrea L. Frey, Hooper, Lundy and Bookman
Brett D. Moodie, Cedars-Sinai Medical Center

OCTOBER 7, 2021
AGENDA

• National and State Regulatory Trends and Developments
  • Year in Review and What Lies Ahead

• Sustainably Seizing the Moment
  • Opportunities, Risks and Compliance Considerations with Telehealth Programs

• Lessons from the Inside with In-house Counsel

• Q&A
National & State Regulatory Trends & Developments

*Year in Review, and What Lies Ahead*
National Regulatory Trends during the Pandemic

A TELEHEALTH EXPLOSION

The COVID-19 pandemic catapulted telehealth forward.

Medicare flexibilities

Originating Site Restriction Abandoned (including rural HPSA requirement)

Eligible Services and Providers Expanded

Modality Restrictions Lifted

DEA Flexibility around Prescribing Controlled Substances

Breathing room on HIPAA, Beneficiary Inducement Law, Stark
State Regulatory Trends during the Pandemic

- During PHE, every state medical board adopted regulatory flexibility around provider licensure requirements
- Flexibilities around patient consent and state privacy law requirements
- State Medicaid programs largely followed Medicare’s lead
- Push for coverage and payment parity in commercial markets
More Than 1 in 4 Medicare Beneficiaries Had a Telehealth Visit Between the Summer and Fall of 2020

Provider offers telehealth, and beneficiary had a telehealth visit  

Provider offers telehealth, but beneficiary did not have a telehealth visit  

Provider does not offer telehealth, or offering unknown*

27%  33%  40%

Total Number of Medicare Beneficiaries, 2020: 55.3 million


Growth in telehealth usage peaked during April 2020 but has since stabilized.

Telehealth claims volumes, compared to pre-Covid-19 levels (February 2020 = 1)\(^1\)

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\(^1\) Includes cardiology, dental/oral, dermatology, endocrinology, ENT medicine, gastroenterology, general medicine, general surgery, gynecology, hematology, infectious diseases, neonatal, nephrology, neurological medicine, neurosurgery, oncology, ophthalmology, orthopedic surgery, poisoning/drug tox./comp. of TX, psychiatry, pulmonary medicine, rheumatology, substance use disorder treatment, urology. Also includes only evaluation and management visits; excludes emergency department, hospital inpatient, and physiatry inpatient claims; excludes certain low-volume specialties.

Source: Compile database; McKinsey analysis

Substantial variation exists in share of telehealth claims across specialties.

Share of telehealth of outpatient and office visit claims by specialty (February 2021), %

1 Includes only evaluation and management claims; excludes emergency department, hospital inpatient, and physiatry inpatient claims; excludes certain low-volume specialties.
2 Also includes addiction medicine and addiction treatment.

Are any of these federal or state regulatory flexibilities going to be permanent?
Lessons from the Inside with In-house Counsel

BE FLEXIBLE

• Solutions may be neither one-size-fits-all nor consistent month to month
• Check your assumptions
• Note of caution: progress is frequently two steps forward, one step back
Federal Developments

• **CY 2022 Physician Fee Schedule proposed rule (look out for final rule in November)**
  - Eliminates geographic restrictions on telemental health coverage as long as patient and telemental health provider meet in-person within six months of beginning telehealth services and at least once every six months after
  - Permanent coverage of audio-only telemedicine for mental health services
  - Keeps in place more than 130 newly created Category 3 codes for temporary telehealth services through the end of 2023 “so that there is a glide path” to evaluate which services should be permanent

• **Proposed federal legislation**
  - CONNECT for Health Act of 2021
Federal Developments

INCREASED ATTENTION AND $$ → INCREASED ENFORCEMENT SCRUTINY

NATIONAL TELEFRAUD TAKEDOWN

Scammers are targeting Medicare and Medicaid beneficiaries in schemes which involve the use of illegal kickbacks and bribes by durable medical equipment companies, laboratories, and pharmacies to telemedicine corporate executives in exchange for orthotic braces, diagnostic testing, and prescription drugs that are medically unnecessary.

The ALLEGED SCHEME and KEY PLAYERS

Telemedicine Executives
They own telemedicine companies and call centers. They use international marketing networks to lure unsuspecting individuals into a criminal scheme through telemarketing calls, direct mail, television ads, and internet pop-up ads. A call center confirms that an individual is on Medicare or Medicaid and transfers the individual to a telemedicine company for a medical practitioner’s consultation.

Telemedicine executives are the masterminds of this scheme. They pay practitioners for prescriptions.

Medical Practitioner & Telemedicine Company
The telemedicine company obtains prescriptions from medical practitioners and sells them to pharmacies, laboratories, or medical equipment companies.

Medical practitioners are being paid by telemedicine executives to order unnecessary prescriptions, either without any patient interaction or with only a brief telephonic conversation with patients they have never met or seen.

Pharmacy, Lab, Medical Equipment Company
After the pharmacy, lab, or medical equipment company purchases the prescription, it sends the prescription to the beneficiary. Medicare or Medicaid is then billed and the telemedicine executives receive a kickback from the scam.

This telemedicine fraud scheme has caused more than $43.3 billion in loss and the wrecking of Medicare and Medicaid billing privileges of over 220 medical professionals.

It is important that new policies and technologies with potential to improve care and enhance convenience achieve these goals and are not compromised by fraud, abuse or misuse.

-HHS Principal Deputy Inspector General Christi A. Grimm

Learn More: oig.hhs.gov/2020takedown
Report Fraud: 1-800-HHS-TIPS or oig.hhs.gov/fraud/hotline

U.S. Department of Health and Human Services
Office of Inspector General
Data Brief
September 2021, OEI-02-19-00401

Opportunities Exist To Strengthen Evaluation and Oversight of Telehealth for Behavioral Health in Medicaid
The Federal Trade Commission (FTC) recently issued a policy statement reaffirming that health apps and connected devices that collect or use consumer health information must comply with the Health Breach Notification Rule.
State Developments

• Rapidly evolving state legislative and regulatory activity in telehealth space
  • Coverage and payment parity laws
    ▪ E.g. Nevada and Oregon
  • Easing of professional licensure requirements and/or ability to provide services remotely
    ▪ E.g. Arizona
  • Requiring registration of telehealth organizations with regulatory agencies
    ▪ E.g. New Jersey and Mississippi

• Enforcement actions
  • Privacy
    ▪ The CA AG recently issued a bulletin reminding health care providers of their duty to notify the Attorney General in the event of a “data breach” affecting 500 or more CA residents
  • Disciplinary actions by state Professional Licensing Boards
  • Fraud and abuse?
California Updates

AB 133 – HEALTH TRAILER BILL (SIGNED BY GOVERNOR NEWSOM 8/27)

• Medi-Cal Telehealth Provisions (Section 380)
  • Extends temporary Medi-Cal telehealth policies until December 31, 2022
    • Payment parity for all modalities, including audio-only, and for providers including FQHCs/RHCs
  • DHCS to convene an advisory group to inform the department in establishing and adopting billing and utilization management protocols
    • Supposed to be completed in time to incorporate into 2022-23 budget
• Protects pre-COVID-19 policies, including store-and-forward
• Allows Department to authorize RPM with separate fee schedule
California Updates

SB 156 – HEALTH TRAILER BILL (SIGNED BY GOVERNOR NEWSOM 8/20)

Implements the first year of a three-year $6 billion investment in broadband for:

- **Middle Mile Broadband Infrastructure**: $3.25 billion federal American Rescue Plan Act (ARPA) funds for the construction of a state-owned open-access broadband middle mile, appropriated in 2021-22.

- **Broadband Last Mile Support**: $2 billion ($928 million General Fund and $1.072 billion federal ARPA) for last mile funding, of which $1.072 billion is available in 2021-22, $125 million is available in 2022-23, and $803 million is available in 2022-24.

- **Loan Loss Reserve**: $750 million General Fund for the loan-loss reserve, of which $50 million in appropriated in 2021-22, $125 million is appropriated in 2022-23 and the balance of $575 million is included in 2023-24.

- Allows counties to acquire funding for the acquisition, construction and improvement of broadband infrastructure and operate a broadband service
Lessons from the Inside with In-house Counsel

...DON’T PANIC

• Look to the ultimate goals
• When in doubt: Stick to organizational values and known practices
• Phone a friend
Sustainably Seizing the Moment

Opportunities, Risks, and Compliance Considerations with Telehealth Programs
Sustainably Seizing the Moment
THE NEXT CHAPTER OF TELEHEALTH

Current landscape

• Strong continued uptake
• Favorable consumer and provider perception
• Overall, and increasingly, a more flexible regulatory environment
• Increased investment in this space
• But also increased enforcement scrutiny
Sustainably Seizing the Moment

THE NEXT CHAPTER OF TELEHEALTH

• Achieving Health Equity Goals
  • When thoughtfully structured, telehealth programs can offer convenience and improved access for more vulnerable patient populations
  • Digital literacy and access to technology essential to promoting equitable access to telehealth

• Alleviating Provider Shortages and Burn-out
  • Can help improve clinician workflows by reducing administrative tasks, giving them access to clinical decision support, and providing more flexibility in caring for patients
  • Can foster improved collaboration with patient care team and specialists
  • Eases supervision requirements
  • Mental health care programs can be offered to care for clinicians too
Building a Compliance Plan

- Policies and Procedures specific to telehealth
- Checklists, Charts, Workflows
  - Privacy and Security
  - Documentation and patient consent requirements
  - Telehealth billing protocols by payer (e.g., Medicare, commercial, Medicaid)
  - Practitioner issues (such as licensure/scope of practice requirements, credentialing, how a practitioner/patient relationship established, and assess when telehealth clinically appropriate)
- Prepare agreement templates specific to telehealth (e.g. amend professional services agreements to incorporate provision of telehealth) and ensure review process in place for vendor agreements
- Workforce training on telehealth work-flow and operations
- Monitor timeline of PHE waivers and applicability and have a waiver off-ramp
Lessons from the Inside with In-house Counsel

FIND THE OPPORTUNITIES

- New solutions to fit your organization
- Adoption of new technology
- Reevaluation of existing resources
Presenters

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Any Questions?
Session 2: Navigating Surgery Center Compliance Issues
• Carol K. Lucas, Buchalter
• Craig B. Garner, Garner Health Law Corporation

Carol K. Lucas is a Shareholder in Buchalter’s Los Angeles office and Chair of the firm’s Health Care Practice Group. Her primary practice focus is health care transactions and the state and federal regulatory environment governing participants in the industry, including corporate practice of medicine, interstate provision of services and self-referral and kickback issues. She has extensive experience in mergers and acquisitions, joint ventures, private placements, state and federal regulations, entity formation and corporate representation of both public and private companies in the healthcare industry. Ms. Lucas specializes in the representation of ambulatory surgery centers, telehealth providers, med spas, imaging centers, and other ancillary providers in a variety of medical specialties, and in the legal and business issues that confront independent practice associations and other physician organizations. She is also an expert on the establishment and representation of Federally Qualified Health Centers and related issues such as governance requirements, issues raised by hospital sponsorship of FQHCs, application issues, and the impact of health care reform on these entities.

Craig Garner is the founder of Garner Health Law Corporation as well as a health care consultant specializing in issues pertaining to modern American health care. A former hospital Chief Executive Officer, Craig is also a Fellow of the American College of Healthcare Executives and adjunct professor of law at Pepperdine University School of Law. He can be reached at craig@garnernhealth.com
NAVIGATING SURGERY CENTER COMPLIANCE ISSUES

Carol K. Lucas, Buchalter
Craig B. Garner, Garner Health Law Corp.
SELECTED ASC TOPICS

- Licensure and Accreditation
- Stark and Anti-Kickback Law
- Physician Buy-Ins
- Physician Buy-Outs
- Noncompetition Agreements
- Out-of-Network Payment Issues
- Co-Located Surgery Centers
- Equipment Leases
- Hospital Joint Ventures
Licensure and Accreditation

- License Statutes

Stark and Anti-Kickback

- Stark Laws
- Anti-Kickback Statute
  - ASC Safe Harbor
  - Other Safe Harbors
Stark Laws

- Prohibits referral by
  - a physician
  - to an entity with which the physician has a financial relationship
  - for “Designated Health Services”
  - with payment by Medicare or Medicaid
  - Unless an exception applies

- Generally does not apply to ASCs
Designated Health Services:
- Clinical laboratory
- Physical/occupational therapy
- Radiology (incl. MRI, CT, ultrasound)
- Radiation Therapy
- DME
- Parenteral and Enteral Nutrients
- Prosthetics/Orthotics
- Home health
- Outpatient prescription drugs
- Inpatient and outpatient Hospital services
Stark Laws (continued)

- The “third rail” of health care laws
  - No intent requirement-strict liability
  - Any referral that falls within its definition, if no exception applies completely, violates the Stark Laws
  - Penalties include repayment of all amounts paid to ASC, plus penalties of up to $15,000 per service, plus possible exclusion from Medicare
Anti-Kickback Statute

- Criminal Statute-Felony
- Conviction carries
  - Fine of up to $25,000
  - Imprisonment up to 5 years
Anti-Kickback Statute (continued)

☐ Prohibits
  ■ The knowing and willful
  ■ Solicitation or receipt of any remuneration
  ■ By any person
  ■ In return for a referral
  ■ For an item or service that will be paid for by any Federally funded program

☐ Applies to physician ownership in ASCs
Anti-Kickback Statute (continued)

- Anti-Kickback Safe Harbors
  - Most relevant are
    - Ambulatory Surgery Centers
    - Investment Interests
Anti-Kickback Statute (continued)

- Ambulatory Surgery Center Safe Harbors
  - 1/3 Rule (Surgeon-owned or single specialty)
  - 1/3, 1/3 Rule (Multi-Specialty)
  - “Real” investment-no loans from entity or owners
  - Terms offered unrelated to volume or value
  - No discrimination against Federal program patients
  - Return directly proportional to amount of investment
Anti-Kickback Statute (continued)

- Investment Interest Safe Harbor
  - Cap of 40% held by referral sources
  - Cap of 40% on revenue generated from investors
  - Terms for referral sources and others the same
  - Terms offered unrelated to volume or value
  - No requirement of referrals
  - Return directly proportional to amount of investment (ownership interest)
Physician Buy-Ins

- ASC Safe Harbor requirements:
  - Number of Units
  - Pricing
    - cannot be less than FMV
Buy-Backs of Physician Investors

- Redemption Rights
  - Triggering Events
  - Medical Staff Membership
  - Medical Practice Income Test
  - Procedure Test
  - Establishing Compliance
- Redemption Price
- Problems with Granting Waivers
Adjustment of Physician Ownership

- Difficult to justify
- High risk
- If done, must satisfy Anti-Kickback Statutes
Noncompetition Agreements

- Cal. Bus. & Prof. Code §§ 16600, 16601
- During the agreement vs. after termination
- What does price have to do with it?
  (Answer: *everything*)
- Definition of a competing business
- Who is covered?
- Fraud and abuse crossover
Out-of-Network Payment Issues

- Reasonable and Customary
- Balance Billing
- Waivers of Co-Payments and Deductibles
- Recognition of an Assignment of Benefits
- ERISA concerns
Co-Located Surgery Centers

- Medicare authorizes as long as it does not
  - violate state law (remember *Capen?*)
  - temporally distinct
- In and Out of Network
- Danger Areas
Equipment Leases

- Safe Harbor
- Per-Click Arrangements
Hospital/ASC Joint Ventures

- Stark Law adds Complexity
  - Price
  - Physician arrangements
- Safe Harbor requirements
- Governance
- Credentialing