

Morgan Lewis

TECHNOLOGY MAY-RATHON

Advancements in Telehealth Law

May 22, 2019

Jake Harper and Anthony Ferrara

Agenda

- Legislative Updates Involving Telehealth
 - BiBA and Medicare Advantage
 - Other Federal Laws
 - State Initiatives
- Government Enforcement Involving Telehealth
 - Federal Enforcement
 - State Enforcement
- Takeaway Considerations and Best Practices



SECTION 01

TELEHEALTH LEGISLATIVE UPDATE

Telehealth Legislative Update

- Drumbeat of laws and regulations implicating telehealth and digital health continue in 2019
 - 17 bills currently involving telehealth pending in Congress from a bipartisan group of legislators in both the House and the Senate
 - Bills focus on mental health, respiratory care, veterans issues, rural health clinics, and various changes to and innovations for Medicare program
 - Sponsors include:
 - Sen. Cory Gardner (R-CO)
 - Rep. Mike Thompson (D-CA)
 - Rep. Suzan Delbene (D-WA)
 - Sen. Jon Tester (D-MT)
 - Rep. Antonio Delgado (D-NY)
 - Sen. John Barrasso (R-WY)

Telehealth Legislative Update

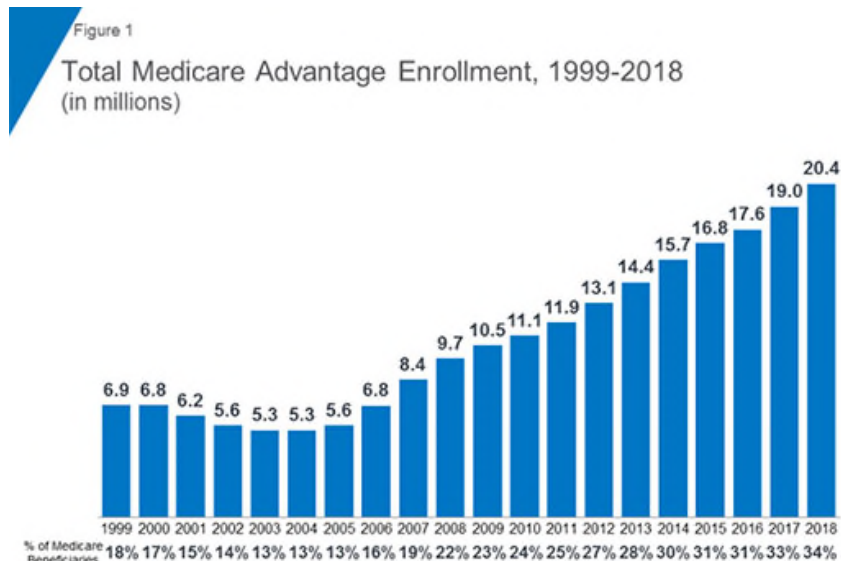
- Congressional Telehealth Caucus
 - Formed in 2017
 - Bipartisan group of House Representatives with interest in advancing telehealth policy
 - CTC has been largely responsible for the CONNECT Act (portions of which included in the Bipartisan Budget Act of 2018) as well as many other telehealth legislative efforts
- CTC continues to be active in considering and advancing legislation that will enable increased adoption of telehealth
 - Focus on implementing additional elements of CONNECT Act

BiBA and Medicare Advantage

- Bipartisan Budget Act of 2018
 - Comprehensive budget bill that includes many updated policies on Medicare coverage for telehealth services
 - Most notably, removes two main statutory barriers for telehealth from Medicare Advantage plans starting in 2020
- CMS recently finalized its Medicare Advantage rule implementing BiBA
 - This rule will permit MA Plans to offer telehealth as a standard covered service (not a supplemental benefit) to all participants irrespective of service location or geographic area

BiBA and Medicare Advantage

- Why is this so remarkable?
 - 34% of Medicare patients are now in an MA plan, so the rule should open up telehealth services (long enjoyed by private insurance or self-pay patients) to MA members



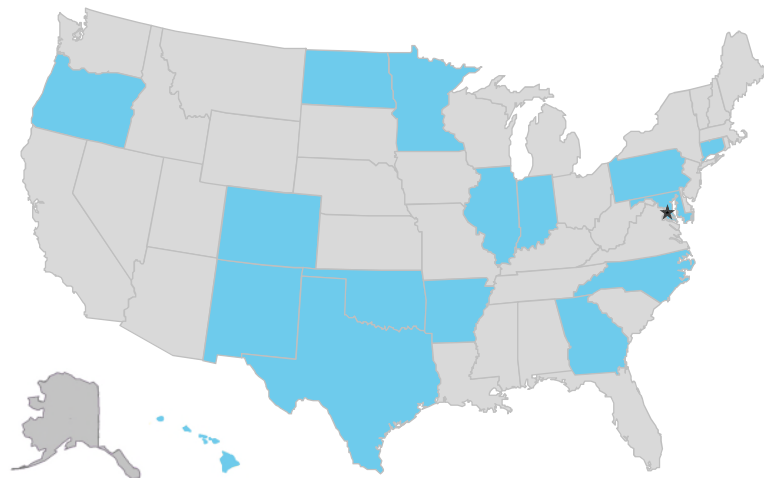
NOTE: Includes cost plans as well as Medicare Advantage plans. About 61 million people are enrolled in Medicare in 2018.
SOURCE: Kaiser Family Foundation analysis of CMS Medicare Advantage enrollment files, 2008-2018, and MPR, 1999-2007; enrollment numbers from March of the respective year, with the exception of 2006, which is from April.

Other Federal Laws

- Medicare Exchange Health Plan
 - Requires the Secretary to create new health plans that will require significant delivery system reform to include telehealth and RPM
- Telehealth Innovation and Improvements Act
 - Requires the Secretary to test various telehealth models over the next several years to include “expanded telehealth services,” such as RPM, two-way A/V, physiologic and behavioral monitoring, store and forward, point-of-care testing, and engagement prompt technologies.
- There’s even bill pending that would require Border Patrol Agents to get training in EMT and have access to a physician or other practitioner to provide telehealth services to individuals stopped at the US border

State Initiatives

- Pending legislation or regulations involving telehealth in 17 states currently
 - Hawai'i just established a Strategic Telehealth Advisory Council and a State Telehealth Coordinator to direct the state's telehealth policies
 - Arizona and New Mexico have recently passed laws to expand telehealth access and require greater insurance coverage of telehealth services
- Telehealth not just being used for the provision of primary health
 - In Texas, a bipartisan bill would establish a telehealth center to conduct forensic medical exams for rape victims, enabling underserved populations to more quickly access a sexual assault nurse examiner



SECTION 02

TELEHEALTH & GOVERNMENT ENFORCEMENT

Basis for Action

- False Claims Act
- Anti-Kickback Statute
- Physician Self-Referral (Stark) Law
- Health Care Fraud
- Mail and Wire Fraud
- Practicing Medicine without a License



Medicare Fraud

- US Department of Health & Human Services Report, April 2018
 - Originating site fraud
 - Unallowable means of communication
 - Cross-state licensing
 - Non-covered services
 - Non-US doctor
 - Relatively small Medicare spending, room for compliance development with technology growth

Recent Federal Actions

- *United States v. Roix* (E.D. Tenn. 2018): telehealth company and its CEO pleaded guilty to several counts of fraudulently soliciting prescriptions resulting in \$1B in fraudulent claims
- *United States v. Cesario* (N.D. Tex. 2016): twelve-defendant conspiracy to commit health care fraud and wire fraud for kickback scheme with prescribing physicians, telemarketers, and TRICARE beneficiaries
- *United States v. Grow* (S.D. Fla. 2016): conviction for paying kickbacks to telehealth companies in exchange for recruiting and referring TRICARE beneficiaries without legitimate doctor-patient relationships

Recent Federal Actions

- *United States v. Powers* (C.D. Cal. 2017): physicians allegedly recruited other physicians to review patient files on a telehealth portal, falsely claiming the files were prepared by other physicians, and used the reviewing physicians credentials to authorize compound medication prescriptions
- DOJ, USAOs, FBI, HHS-OIG, IRS-CI investigation (spanning 17 federal districts) April 2019: executives at five telemedicine companies, DME company owners, and medical professionals allegedly involved in kickback and bribe schemes totaling \$1.2B involving referral of Medicare patients who were prescribed unnecessary braces through telehealth technology without legitimate doctor-patient relationships



Recent State Actions

- *Hageseth v. Superior Court* (Cal. Ct. App. 2007): physician sentenced to nine months in prison for contracting with a web-based prescription service to review patient responses to questionnaires and prescribing medications
- *Golob v. Arizona Medical Board* (Ariz. Ct. App. 2008): state medical board's sanctions upheld for physician's issuing of prescriptions based almost entirely on online questionnaires




SECTION 03

TAKEAWAYS AND BEST PRACTICES FOR TELEHEALTH

Telehealth Providers and Companies

- The closer you get to Federal health care program dollars, the stronger your compliance must be
- As coverage expands in Medicare and Medicaid, more attention to Anti-Kickback Statute, Stark Law, and billing fraud issues are necessary
- Perspective is important
 - Telehealth still viewed with suspicion
 - Pill Mills and the influence of the current Opioid Crisis
 - Lax examination and prescribing without effective consultation – standard of care issue
 - Telehealth providers need to appreciate that perspective when advocating for enhanced access
 - Safeguards need to be considered and built out

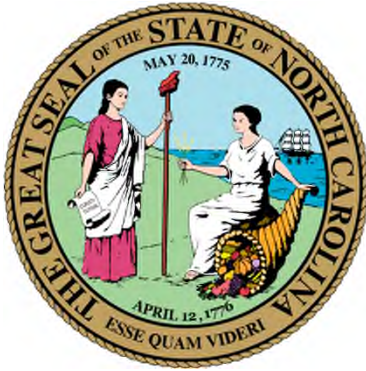
Telehealth Providers and Companies

- Although traditional Medicare coverage is still far off, providers should establish their relationships and billing mechanisms as if the laws that apply to Medicare are applicable
 - Potential issues include:
 - Fair Market Value
 - Payment for referrals/lead generator
 - Online marketing in concert with referral sources
 - Exclusive arrangements
- 



Pharmacy Considerations

- Pharmacists may have some responsibility not to turn a blind eye to illegitimate/fraudulent telehealth prescriptions
- Many state Pharmacy Practice Acts require level of diligence by pharmacist
 - North Carolina: exercise of professional judgment
 - Texas: exercise reasonable effort



Q&A

Thank you for participating in the 2019 Technology May-rathon with us.

We would be pleased to answer your questions.

The Q&A tab is located near the bottom right hand side of your screen; choose “All Panelists” before clicking “Send.”

Morgan Lewis Technology May-rathon 2019

A full listing of our Technology May-rathon programs can be found at:

<https://www.morganlewis.com/topics/technology-may-rathon>

Please be sure to tweet **#TechMayRathon**

Thank you.

Biography



Jake Harper
Associate

Washington, DC

+1.202.739.5260

jacob.harper@morganlewis.com

[Click Here for full bio](#)

Twitter: [@jacobjharper](#)

LinkedIn: [Jacob Harper](#)

Jake is a nationally-recognized speaker and thought leader on issues related to telehealth, including reimbursement and licensure. As part of his practice, Jake advises health systems, telehealth platform providers, and other companies in developing and implementing effective and compliant telehealth provider networks. Jake is experienced in advising clients on licensure and modality requirements, state parity laws, and other aspects of reimbursement, including Medicare telehealth coverage. Jake is a member of the Board of Directors for the Center for Telehealth and E-Health Law for 2019-2020.

Biography



Anthony P. Ferrara

New York

+1.212.223.6706

anthony.ferrara@morganlewis.com

[Click Here for full bio](#)

LinkedIn: [Anthony Ferrara](#)

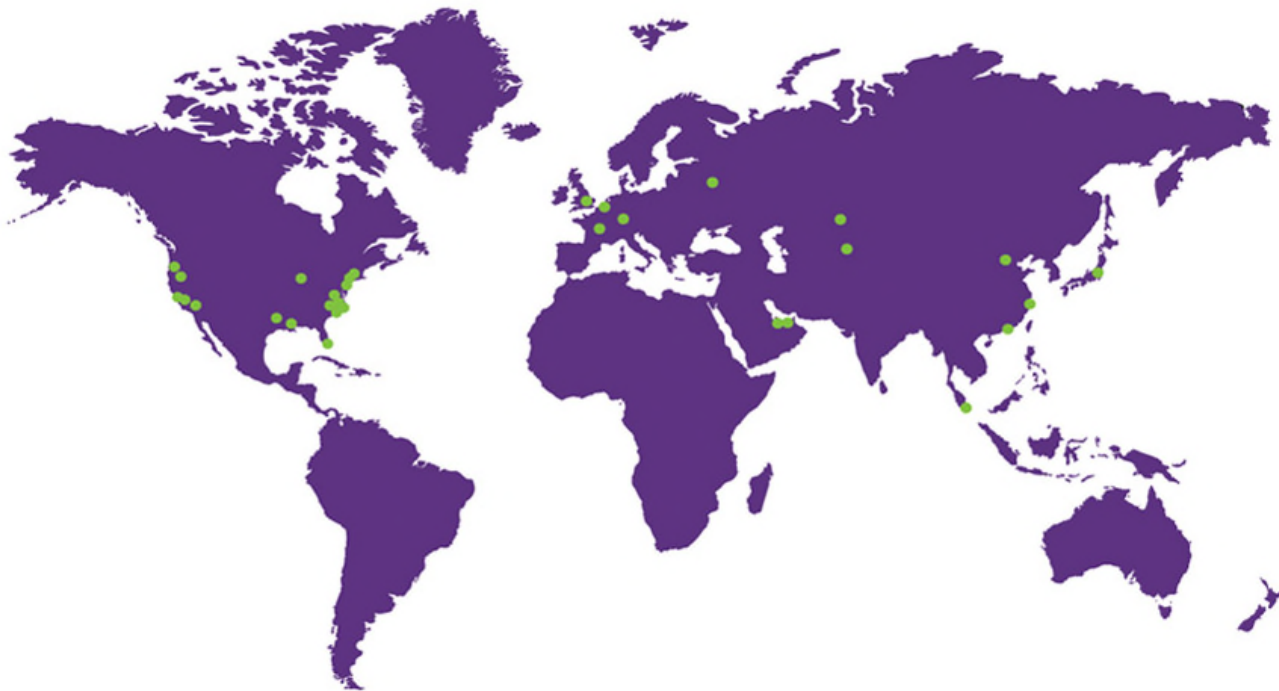
Anthony Ferrara represents large corporate clients in complex commercial disputes, internal investigations, white collar litigation, and investigation and enforcement actions. His experience includes interviewing employees at a company during an internal investigation, drafting a brief for a motion to dismiss, negotiating a small claims court settlement on behalf of a corporate client, and assisting in the writing of an amicus brief for an asylum rights case.

Our Global Reach

| | |
|--------------|---------------|
| Africa | Latin America |
| Asia Pacific | Middle East |
| Europe | North America |

Our Locations

| | |
|--------------|----------------|
| Abu Dhabi | Moscow |
| Almaty | New York |
| Beijing* | Nur-Sultan |
| Boston | Orange County |
| Brussels | Paris |
| Century City | Philadelphia |
| Chicago | Pittsburgh |
| Dallas | Princeton |
| Dubai | San Francisco |
| Frankfurt | Shanghai* |
| Hartford | Silicon Valley |
| Hong Kong* | Singapore |
| Houston | Tokyo |
| London | Washington, DC |
| Los Angeles | Wilmington |
| Miami | |



Morgan Lewis

*Our Beijing and Shanghai offices operate as representative offices of Morgan, Lewis & Bockius LLP. In Hong Kong, Morgan Lewis operates through Morgan, Lewis & Bockius, which is a separate Hong Kong general partnership registered with The Law Society of Hong Kong as a registered foreign law firm operating in Association with Luk & Partners. Morgan Lewis Stamford LLC is a Singapore law corporation affiliated with Morgan, Lewis & Bockius LLP.

THANK YOU

© 2019 Morgan, Lewis & Bockius LLP

© 2019 Morgan Lewis Stamford LLC

© 2019 Morgan, Lewis & Bockius UK LLP

Morgan, Lewis & Bockius UK LLP is a limited liability partnership registered in England and Wales under number OC378797 and is a law firm authorised and regulated by the Solicitors Regulation Authority. The SRA authorisation number is 615176.

Our Beijing and Shanghai offices operate as representative offices of Morgan, Lewis & Bockius LLP. In Hong Kong, Morgan Lewis operates through Morgan, Lewis & Bockius, which is a separate Hong Kong general partnership registered with The Law Society of Hong Kong as a registered foreign law firm operating in Association with Luk & Partners. Morgan Lewis Stamford LLC is a Singapore law corporation affiliated with Morgan, Lewis & Bockius LLP.

This material is provided for your convenience and does not constitute legal advice or create an attorney-client relationship. Prior results do not guarantee similar outcomes. Attorney Advertising.