OF DIGITAL INTEREST QUARTERLY ROUNDUP

Q1 2023 SUMMARY

McDermott Will & Emery

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SPECIAL REPORT

INTRODUCTION

McDermott's digital health team continually monitors legal developments affecting all aspects of the remote delivery of care. This inaugural issue of our Of Digital Interest Quarterly Roundup highlights key issues and trends in the first quarter of 2023.

Remote care is an important development in care delivery, but the regulatory patchwork is complicated. Our digital health team works alongside the industry's leading providers, payors and technology innovators to help them enter new markets, break down barriers to delivering accessible care and mitigate enforcement risk through proactive compliance. Are you working to make healthcare more accessible through telehealth?

Let us help you transform care delivery.

IN THIS ISSUE

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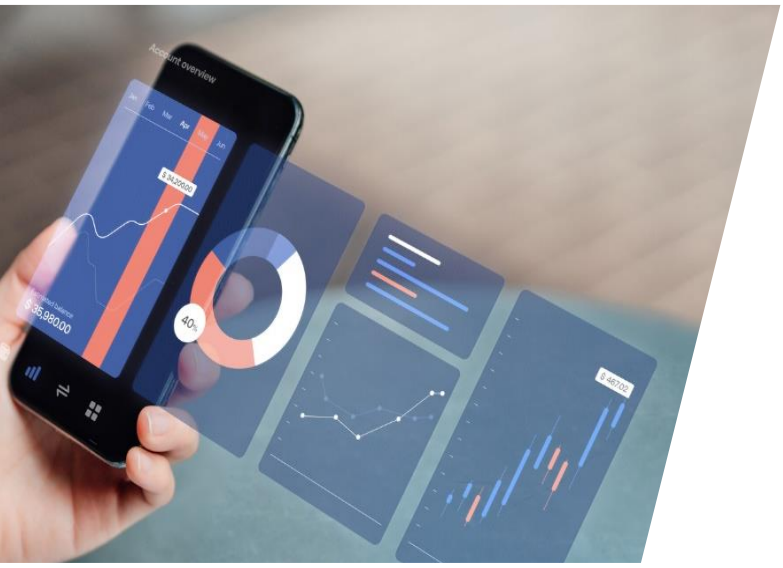
SPECIAL REPORT

SILICON VALLEY BANK COLLAPSE

On March 10, 2023, Silicon Valley Bank (SVB), the trusted partner to almost half of venture-backed healthcare and technology companies in the US, collapsed. This collapse shocked many in the digital health industry and beyond, because it was the largest bank failure since the 2008 financial crisis according to many news reports. California regulators and the Federal Deposit Insurance Corp. intervened to shut down the bank after its failure to secure adequate capital. Shortly thereafter, Signature Bank, a New-York-based regional bank, faced a similar fate. Three days after SVB's collapse, the US Department of the Treasury, the Federal Reserve and the Federal Deposit Insurance Corp. stepped in to provide depositors with assurances that their money would be returned.

Digital health companies and other stakeholders are still digesting the short- and long-term ramifications of the SVB collapse, but most agree that the loss of SVB places additional stress on digital health companies looking for funding opportunities.



DEA PROPOSED RULES' POTENTIAL IMPACT ON TELEMEDICINE PRESCRIPTION OF CONTROLLED SUBSTANCES

On February 24, 2023, the US Drug Enforcement Administration (DEA) issued two proposed rules (the Telemedicine Controlled Substance Proposed Rule and the Telemedicine Buprenorphine Proposed Rule) that would establish additional potential pathways for the prescription of certain controlled substances in limited quantities via telehealth without an initial in-person medical examination. Currently, this practice is allowed during the COVID-19 public health emergency (PHE) under a telemedicine exception to the Ryan Haight Online Pharmacy Consumer Protection Act of 2008. The COVID-19 PHE is slated to end on May 11, 2023, and subject to certain exceptions, the Ryan Haight Act generally prohibits the prescription of a controlled substance to a patient for whom the prescriber has not performed an in-person medical evaluation. DEA accepted public comments until March 31, 2023.

As we reported in our previous analysis, the proposed rules would expand the use of telemedicine for prescribing controlled substances compared with pre-PHE requirements. However, by requiring at least one in-person visit, the proposed rules would also re-establish certain barriers that many patients face in accessing care, as well as the barriers that telehealth providers without physical practice locations face in providing care.

Providers and other industry stakeholders have long anticipated that DEA would release a proposed rule laying out the "special registration" process for telemedicine, which the DEA has indicated that it would do since 2009. Despite several congressional

requirements to move forward, however, the DEA has not specified any requirements around a special registration process. In the Telemedicine Controlled Substance Proposed Rule, the DEA declined to incorporate a special registration, stating that it would "be too burdensome for both prospective telemedicine providers and patients." Many hoped that the special registration process would relieve providers of the requirement to obtain DEA registrations in multiple jurisdictions, which has been burdensome.

More than 35,000 comments to the Telemedicine Controlled Substance Proposed Rule were posted on Regulations.gov. Comments originated from a variety of sources, including patients, individual prescribers, healthcare systems, health advocacy organizations and professional associations. Comments covered a wide range of concerns. For example, commenters urged DEA to revise the rules in the following ways (alone or in combination):

- Establish the special registration for telemedicine.
- Add circumstances under which schedule II and narcotic medications are eligible for telemedicine prescribing without a prior in-person exam.
- Clarify that only one member of a patient's care team must evaluate the patient in person.
- Eliminate the in-person requirement for patient-provider relationships established during the COVID-19 PHE or extend the six-month transition period provided under the proposed rules.
- Extend the current in-person visit waivers under the opioid PHE, particularly for patients prescribed buprenorphine.
- Eliminate the burdensome recordkeeping and prescription notation requirements.
- Adopt a national DEA registration for controlled substance prescribing.

The timeline between the end of the comment period and the end of the PHE allotted a mere six weeks for DEA to digest comments, issue a final rule and make providers aware of new requirements that may be effective as early as May 11, 2023. Coupled with the volume of public comments, this compressed timeline will be a challenge for the DEA, providers and patients, who are now awaiting the final rule.

TRENDS IN STATE LEGISLATION AND RULEMAKING

Q1 2023 TELEHEALTH BILL ANALYSIS BY MCDERMOTT

35 state-enacted bills

Almost 100 proposed bills that advanced past one or both chambers

More than 30 final and emergency state regulations

This activity overall points to increasing support for the implementation of remote care technologies. Details regarding our weekly findings can be found on our Of Digital Interest blog.

Telehealth Flexibilities

Much of this legislative and rulemaking activity focused on extending or making permanent temporary telehealth flexibilities that were enacted in response to the COVID-19 pandemic. These flexibilities touched on the roles and responsibilities of various healthcare professionals in telemedicine, teledentistry and other specialty areas that deliver care virtually. The legislation and regulations that passed in Q1 2023 included multiple expansions in the modalities available for establishing telehealth relationships remotely (*e.g.*, increased access to audio-only telehealth services) and changes to practitioner scope of practice rules and other standards for the provision of services via telehealth.

Licensure Compacts

Since the expiration of COVID-19-related interstate license waivers, many states have sought to increase licensure portability across state lines on a permanent basis. In Q1 2023, several states enacted legislation to join interstate compacts for various professions:

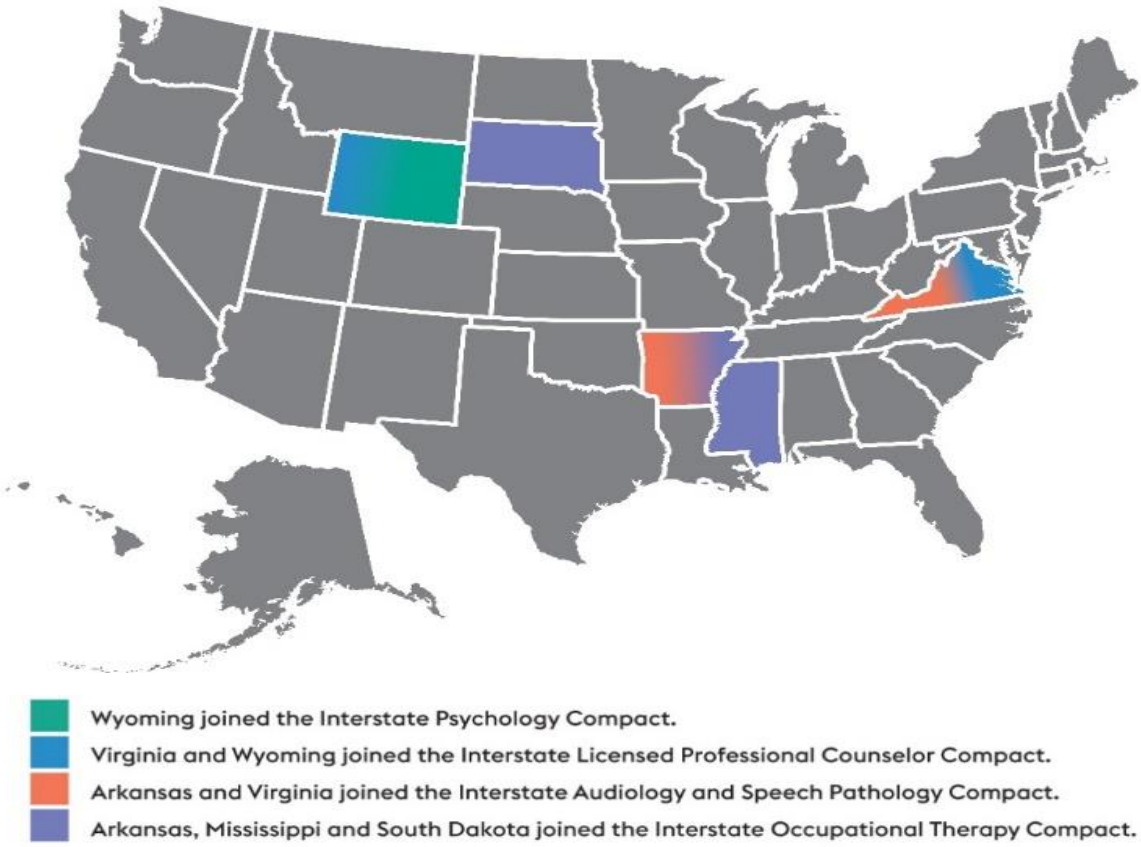
Stakeholders can expect to see continued activity in this area, as many states have introduced legislation to enter various interstate compacts.

20 states have introduced legislation to enter the Interstate Licensed Professional Counselor Compact

6 states have introduced legislation to enter the Interstate Psychology Compact

13 states have introduced legislation to enter the Interstate Audiology and Speech Pathology Compact

12 states have introduced legislation to enter the Occupational Therapy Compact.



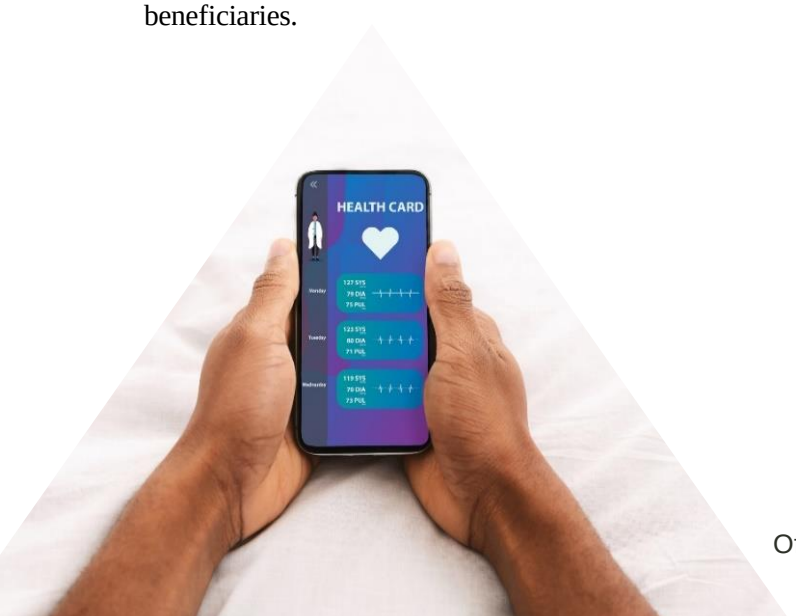
Other Focus Areas

Additional areas of state legislative and regulatory focus during Q1 included the following:

- Expansion of coverage for behavioral health via telemedicine
- Additions to the types of provider specialists authorized to provide care via telehealth (including audiologists, nutritionists and chiropractors), and related provisions corresponding to the reimbursement of those services.
- Clarification of the steps required to establish a provider-patient relationship via telehealth.

Telehealth prescribing also saw significant activity in several states, particularly around the prescribing of controlled substances, abortifacients and cannabis.

Several states passed legislation or issued regulations related to pilot programs intended to leverage telehealth technology to target underserved populations. These include Arizona's pilot program allowing hospitals to deliver acute care services to patients in the home through mobile health practitioners and Missouri's emergency dental pilot project in medically underserved populations. Many more states have pilot programs in the proposal stage. Tennessee, for example, proposed a bill in Q1 that would provide remote maternal care for eligible TennCare beneficiaries.



DEVELOPMENTS IN REMOTE MONITORING SERVICES

A variety of healthcare providers have begun furnishing remote monitoring services in recent years, following the American Medical Association's establishment of specific codes. Remote monitoring services include remote physiological monitoring (RPM) and remote therapeutic monitoring (RTM) services and generally use digital technologies (medical devices, together with software) to collect medical and other forms of health data from patients in one location and electronically transmit the information to the patient's healthcare provider in a different location for assessment and care management. In some cases, the technologies can either trigger direct patient engagement or facilitate communication with healthcare providers.

The Centers for Medicare & Medicaid Services (CMS) has gradually established payment rates and provided guidance on certain requirements and appropriate utilization for remote monitoring services. The ability to receive reimbursement for remote monitoring services under the Medicare Physician Fee Schedule and the flexibilities and waivers provided by CMS during the COVID-19 PHE greatly expanded interest in furnishing remote monitoring services.

Correspondingly, the Medicare utilization for RPM services increased significantly for many of the remote monitoring codes between 2019 and 2021. The increase in utilization and corresponding increase in payment for these services has led to increased scrutiny on the utility of remote monitoring services from a Medicare coverage perspective. There are currently no published or proposed national coverage determinations for either RPM or RTM services. However, on February 28, 2023, representatives from most Medicare Administrative Contractors (MACs) held a multijurisdictional contractor advisory committee

(CAC) meeting to obtain feedback on the strength of currently published evidence on RPM and RTM services utilizing non-implantable medical devices. See our previously published articles for background on the development of potential Medicare coverage policies for remote monitoring services and analysis of key takeaways from the CAC meeting. The CAC meeting could be a precursor to the development of a local coverage determination by one or more MACs. In addition, other commercial payors have begun publishing coverage and payment policies, which may have the practical effect of limiting payment to providers for RPM and RTM services.

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