Providers, Investors Need Clear Post-COVID Telehealth Picture

September 22, 2020

At the outset of the Covid-19 pandemic, the Centers for Medicare and Medicaid Services ("CMS") and state governments waived many restrictions on the provision of telehealth services—but only for the duration of the public health emergency. Since that time, the demand for such services has increased exponentially. According to a recent analysis by CMS of Medicare Fee for Service beneficiaries, the percentage of primary care visits conducted via telehealth rose from .1% in February 2020 to 43.5% in April 2020 and was 23% as of early June 2020. Similarly, an analysis by FairHealth shows that the percentage of insurance claims for telehealth services rose from .15% in May 2019 to 8.69% a year later—a 5679% increase. As a result, there are new opportunities for physician groups who are able to provide telehealth services successfully and cost-effectively, telehealth technology providers that facilitate virtual visits, and investors in these entities.

For providers and investors, a key unanswered question is the extent to which recent regulatory changes will outlive the pandemic. Many of the barriers to the provision of telehealth are statutory and were waived by the federal and state governments only for the duration of the public health emergency. Below, we provide an overview of the legal framework governing telehealth before and during the pandemic. Providers and potential investors evaluating future telehealth opportunities should be aware of some critical legal and regulatory issues.

Regulatory Frameworks Governing Telehealth

CMS – Medicare

Under federal law, CMS is allowed to provide reimbursement for telehealth services for Medicare beneficiaries only if (among other things) the beneficiary is located within a Healthcare Professional Shortage Area (*i.e.*, an underserved community); the patient's "originating site" (*i.e.*, where the patient was located when receiving telehealth services) was a qualifying healthcare facility at the time that telehealth services were provided; and the beneficiary has a preexisting relationship with the provider. These limitations

ordinarily preclude one of the most significant benefits of telehealth: the ability of a patient to receive care from home.

Acting pursuant to a statute enacted in March 2020, CMS waived many of the statutory limitations on telehealth for the duration of the public health emergency. Currently, the emergency declaration lasts through October 2020, but is likely to be extended. As a result of these waivers, Medicare currently reimburses many telehealth services provided to beneficiaries at their homes (regardless of whether they live in underserved areas), including standard "office" visits, preventative health screenings, and mental health services. Providers must utilize technology that allows for real-time communications between the patient and the provider. Medicare currently reimburses eligible telehealth services at the same rate as in-person services under the Physician Fee Schedule.

Additionally, the Department of Health and Human Services ("HHS") Office for Civil Rights ("OCR") has used its enforcement discretion to permit healthcare providers serving patients in good faith to use technology platforms during the public health emergency that might not otherwise be permissible due to Health Insurance Portability and Accountability Act ("HIPAA") privacy and security rules. OCR is currently permitting providers to use any nonpublic-facing remote communication product to communicate remotely with patients, potentially including applications such as FaceTime or Skype, which are generally not considered to be HIPAA-compliant technology platforms.

The Trump administration is now considering extending telehealth services beyond the pandemic. On August 3, 2020, President Trump issued an Executive Order ("EO") directing CMS to review temporary measures put into effect during the pandemic, including the "additional telehealth services offered to Medicare beneficiaries," and to "propose a regulation to extend these measures, as appropriate" beyond the current emergency. The same day the EO was issued, CMS issued the proposed Physician Fee Schedule for 2021, which included (among other things) two sets of telehealth services to be covered by Medicare:

- Adding nine new billing codes to the Medicare telehealth services list, which is a list of telehealth services permanently covered by Medicare (assuming applicable conditions are met). These codes encompass group psychotherapy, neurobehavioral exams, and various evaluations related to home healthcare.

- Adding 13 new billing codes to the Medicare telehealth services list through the calendar year in which the public health emergency ends. As the emergency is likely to continue into 2021, these services should be covered through at least the end of

that year (if not longer). These codes relate to various forms of detailed patient evaluations and psychological testing.

While CMS may be able to make certain telehealth services permanently available, it cannot eliminate by rule the statutorily imposed telehealth limitations addressed above. As CMS Administrator Seema Verma recently explained, "[w]ithout a change to the statute, telehealth will revert to a rural benefit that can only be utilized from a healthcare facility rather than from one's home." Various members of Congress—from both parties—have proposed statutory changes that would facilitate additional telehealth services after the end of the public health emergency.

State Telehealth Laws

Providers can offer telehealth services only if authorized by state laws governing the provider and those governing the beneficiary. Where the provider and beneficiary are in different states, the patchwork of laws governing telehealth can create barriers to the provision of telehealth. Some states, for example, may allow out-of-state providers to provide care to in-state beneficiaries only in limited circumstances, *e.g.*, the out-of-state provider may be required to register with a state agency or may be allowed to provide telehealth only when there is an existing physician/patient relationship. Some states also have rules that prohibit audio-only telehealth, which is a significant barrier to older or less affluent patients who may not have access to or ability to use video technology. To date, 47 states have issued waivers of these types of requirements with the aim of facilitating telehealth during the course of the public health emergency.

Although some state licensing laws may impose barriers to telehealth, state telehealth parity laws have the opposite effect. Many states require commercial insurers to cover certain services provided via telehealth to the same extent they cover the services in person. A few states—notably California starting in 2021—go a step further and require reimbursement for telehealth services at the same level as in-person services. California's new law also prohibits insurers from restricting telehealth coverage to selected corporate telehealth providers.

State Medicaid Laws

State Medicaid programs have significant flexibility in deciding which types of telehealth services may be offered to beneficiaries. Under the laws in effect before the start of the pandemic, Medicaid plans in all 50 states provided reimbursement for at least some telehealth services for beneficiaries through real-time video connection between provider and beneficiary. However, there is significant variation between states regarding the scope of services covered. For example, Alabama and Idaho cover only specific listed services, whereas California covers a much broader array of telehealth services. Some states have limitations analogous to the Medicare rules that do not allow

a beneficiary’s home to be an originating site for telehealth services. Conversely, in addition to real-time video telehealth, 16 states reimburse for “store and forward” technology (where a patient takes a picture and electronically transmits it to the provider for analysis) and 23 states reimburse for remote patient monitoring (where a patient is outfitted with a device that takes measurements and transmits data to a provider).

Nearly all states’ Medicaid programs have expanded coverage for telehealth services for the duration of the public health emergency. Some states have waived the requirement that a beneficiary must have a preexisting relationship with a provider before receiving telehealth benefits and have expanded the services that may be provided through telehealth. For example, more states now allow beneficiaries to receive telehealth services from home and via audio only.

Issues to Consider When Investing in Telehealth

Any healthcare company or investors that are considering investing in telehealth providers or technology should carefully consider the following questions:

Government Programs

Does the provider organization offer—or plan to offer—telehealth services to a large volume of patients who are beneficiaries of government healthcare programs, including Medicare and Medicaid?

If so, the size of the available market may depend in significant part on whether there are permanent changes made to the governing laws. Absent congressional action, after the pandemic ends, CMS will no longer reimburse telehealth services for the vast majority of Medicare beneficiaries because reimbursement is ordinarily limited by statute to rural beneficiaries receiving services from a remote facility. Many states similarly have limitations on the provision of care to Medicaid beneficiaries that will return after the pandemic.

Additionally, organizations that provide services to beneficiaries of government healthcare programs are always subject to federal and state fraud and abuse laws. These laws prohibit practices that might be lawful in other industries, *e.g.*, organizations cannot incentivize the use of telehealth by reimbursing telehealth physicians based on the volume of patients they treat or offering to waive co-payments. Noncompliance with these laws can result in criminal investigations and costly civil litigation.

Covered Services

Is the provider organization offering services likely to be covered by Medicare or commercial payors?

CMS telehealth coverage decisions have significance beyond Medicare beneficiaries because commercial insurers often follow the lead of CMS. Ms. Verma recently identified three issues that should be evaluated when assessing whether telehealth services should be continued after the pandemic:

- whether delivering the service via telehealth is safe and delivers outcomes that are equivalent to in-patient visits;
- the appropriate reimbursement level for telehealth services, *i.e.*, whether adjustments should be made because costs incurred for patient hygiene are not incurred when a patient is treated remotely; and
- whether expanding telehealth results in additional fraud and abuse, *e.g.*, by providers taking advantage of the telehealth medium to provide shorter visits or bill for more patients than can be seen in a day.

CMS, as well as commercial insurers, is likely to be receptive to reimbursing telehealth services for which proponents can present empirical data showing that telehealth yields clinically similar—or better—results at comparable costs.

Licensing Laws

Is the provider organization compliant with physician licensing laws both in the jurisdictions where the organization operates and where patients are located?

Organizations should have surveys of the licensing laws in the state(s) in which they operate and the state(s) in which their patients reside; these surveys should be periodically updated to stay current, as requirements change frequently.

Further, they should have protocols to ensure that telehealth services are provided to patients only in jurisdictions in which physicians are authorized to provide telehealth services, and to ensure any additional requirements are met (*e.g.*, that the physician must have met the provider in person before providing telehealth services).

Privacy, Data Security

Does the organization comply with applicable laws governing patient privacy and data security?

Although privacy and data security laws are applicable to all provider organizations, these issues are of particular concern where all physician-patient interactions are digital. In particular, organizations should be compliant with HIPAA privacy and security rules.

Of note, although the federal government is currently permitting providers to use any nonpublic-facing remote communication product to communicate remotely with patients, potentially including applications such as FaceTime or Skype, which are generally not considered to be HIPAA-compliant technology platforms, the use of HIPAA-compliant platforms will be required again after the emergency.

Organizations should also consider applicable state privacy and data security laws in the jurisdictions where the organization and its patients are located as some state laws are more stringent than HIPAA rules. In addition, organizations that promote privacy practices should be prepared to substantiate their claims.

Prescription Drugs

Do providers working for the organization prescribe prescription drugs?

Some telehealth organizations have financial interests in the sale of certain pharmaceutical products. It is important to ensure that providers have appropriate prescribing practices, *e.g.*, any prescribed drugs are authorized by the Food and Drug Administration (whether as prescription or over-the-counter drugs) and are prescribed in medically appropriate circumstances pursuant to a valid patient-provider relationship.

Additionally, controlled substances should be prescribed by telehealth prescribers only under circumstances permitted by applicable federal and state regulation.

Remote Monitoring

Does the organization offer telehealth services that involve remote monitoring?

If the organization that engages in remote patient monitoring utilizing hardware (*e.g.*, a networked blood pressure monitor) or software (*e.g.*, a mobile app), it is important to assess whether the hardware or software will be regulated by the FDA as a medical device and, if so, ensure that the product is compliant with applicable regulatory requirements.

Attentiveness to these issues will allow provider organizations and investors to make well-informed decisions about marketplace opportunities and to avoid unlawful conduct.

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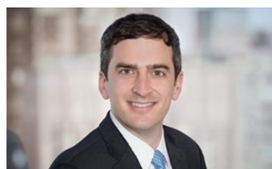

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