



## VIDEO DIRECTLY OBSERVED THERAPY FOR TUBERCULOSIS FACT SHEET

# Legal Considerations Relevant to Video Directly Observed Therapy (VDOT) in Minnesota

## Background


Treatment and containment of active tuberculosis (TB) remains a serious global public health concern. In 2014, an estimated 9.6 million people fell ill with TB, and an estimated 1.5 million people died from the disease.<sup>1</sup> Many people may be surprised to learn that approximately one-third of the world's population is infected with the bacteria that causes TB, though only ten percent of those infected will develop the active form of the disease during their lifetime.<sup>2</sup> The disease is still prevalent in the United States—9,421 cases of active TB were reported to the CDC in 2014.<sup>3</sup> The disease continues to take its toll in Minnesota as well—in 2014, 147 cases of TB were reported in the state.<sup>4</sup>

TB is generally treatable and curable with a course of antibiotic treatment that lasts for six to nine months, but it can be fatal if not treated properly. Patients who do not complete their drug regimen as prescribed are at risk for developing and transmitting dangerous, drug-resistant TB. To ensure people adhere to their treatment regimens, directly observed therapy (DOT) is considered the global standard of care. DOT is a method in which a health care worker watches the patient swallow each dose of the prescribed medication.

In-person DOT can be time-consuming and costly to administer, especially in rural communities where a health care worker may have to travel a significant distance for home visits. It may also be inconvenient for patients, who need to be accessible to the health care worker every time they take their medication. Declining public health resources have increased the need for local health departments to develop cost-effective and innovative strategies to monitor patient compliance with treatment regimens.

Telemedicine may provide an effective means to monitor patient adherence to TB treatment regimens. Some local health departments in the United States and elsewhere have piloted the use of video directly observed therapy (VDOT) in which health care providers observe patients taking their TB medication remotely via a webcam, tablet, videophone, or smartphone. VDOT allows for monitoring of medication via video without routine in-person visits from public health providers. Results from these pilot programs suggest that VDOT is a patient-centered, cost-effective,<sup>5</sup> and reliable method of ensuring treatment compliance. Patients as well as providers participating in these programs have reported a high level of satisfaction with use of the technology.<sup>6</sup>

There appears to be a growing interest among local health departments in Minnesota and in other jurisdictions to utilize innovative approaches in the treatment of TB. VDOT appears to be a promising alternative to traditional DOT practices and has the potential to improve TB control efforts in Minnesota and in other jurisdictions. However, there are legal,



regulatory, and practical challenges relating to the use of VDOT, and the implementation of VDOT in Minnesota will not be immediate or simple. This Fact Sheet summarizes some of the laws and regulations implicated by the use of VDOT in Minnesota, including legal permissibility, HIPAA privacy and security issues, data practices and health record issues, and reimbursement. The goal of this Fact Sheet is to provide a starting point for local health departments to discuss with their legal counsel when considering the integration of a VDOT program into their TB control program efforts.

## Legal and Regulatory Considerations

### Legal Permissibility

In Minnesota, there is neither a legal requirement nor a prohibition to deliver DOT by telemedicine. Minnesota statutes do not explicitly mention video directly observed therapy. While VDOT is not expressly addressed in Minnesota statutes, it appears that VDOT fits within the statutory definition of “directly observed therapy” under Minnesota state law. Minnesota statutes define “directly observed therapy” as “a method for ensuring compliance with medication directions in which a licensed health professional or designee observes a person ingesting prescribed medications or administers the prescribed medication to the person.”<sup>7</sup> The definition states that the health professional must observe the person ingesting the medication but does not state that the observation must take place in person. The law does not appear to preclude the health professional from observing the treatment administration via video technology. Therefore, the use of VDOT is likely permitted under current Minnesota law.

### HIPAA Privacy and Security


A VDOT program will need to comply with a number of laws and regulations regarding protecting the privacy and security of patient health information.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) is a federal law that protects personal health information and provides patients with certain rights to their health information, among other provisions.<sup>8</sup> The Health Information Technology for Economic Clinical Health Act of 2009 (HITECH) enhanced the enforcement of HIPAA and extended provisions of HIPAA to business associates.<sup>9</sup> Among other provisions, the HIPAA Privacy Rule sets standards for when protected health information (PHI) may be used and disclosed, while the HIPAA Security Rule requires safeguards to ensure that only those who should have access to electronic PHI will have access.<sup>10</sup>

Entities covered by HIPAA Rules include: (1) health plans, (2) health care clearinghouses, and (3) health care providers who electronically transmit any health information in connection with transactions for which the U.S. Department of Health and Human Services (HHS) has adopted standards.<sup>11</sup> A health care provider or agency that furnishes, bills, or receives payment for health care, and transmits PHI electronically, is a “covered entity” under HIPAA.<sup>12</sup> Local health officers should consult legal counsel to determine whether their department performs functions that make it a covered entity subject to HIPAA requirements.<sup>13</sup> A covered entity utilizing telemedicine for the delivery of DOT must ensure that the telemedicine application has security settings that are HIPAA-compliant and that the application is used in HIPAA-compliant ways.<sup>14</sup>

The issues regarding privacy and security in a telemedicine setting are not necessarily that different from those in a conventional (in-person) setting. HIPAA does not contain any special section devoted to telemedicine.<sup>15</sup> Covered entities utilizing telemedicine for the delivery of health care services must meet the same HIPAA requirements that they would for services provided in person. As with conventional medicine, a telemedicine provider has the same duty to keep information regarding patients’ treatments confidential and to safeguard a patient’s medical records.<sup>16</sup> Electronic files, such as images or audio/video recordings, must be stored with the same level of precaution and care as paper documents.

A local health department may wish to partner with a “business associate” (such as a telemedicine software company) in administering a VDOT program. HIPAA defines a “business associate” as a person or organization, other than a member of a covered entity’s workforce, that performs certain functions or activities on behalf of, or provides certain services to, a covered entity that involve the use or disclosure of PHI.<sup>17</sup> HHS has issued guidance stating that “a software company that hosts the software containing patient information on its own server or accesses patient information when troubleshooting the software function, is a business associate of a covered entity.”<sup>18</sup> The HIPAA Privacy Rule requires that a covered entity enter into a “business associate agreement” with its business associate to ensure that the business associate will



appropriately safeguard PHI.<sup>19</sup> The written contract must detail the uses and disclosures of PHI the business associate may make and require that the business associate safeguard the PHI. Sample business associate contract language is available on the HHS Office for Civil Rights' website.<sup>20</sup>

Some video conferencing platforms such as Skype were not specifically designed for health care purposes and do not currently enter into business associate contracts. Skype has previously claimed that it is not a business associate because it is merely a "conduit" for transporting information, similar to the U.S. Postal Service or a private courier.<sup>21</sup> HHS regulations define a "conduit" as an entity that transports information but does not access it other than on a random or infrequent basis as necessary to perform the transportation service or as required by other law.<sup>22</sup> HHS makes clear that the conduit exception is a narrow one, and "such a determination will be fact specific based on the nature of the services provided and the extent to which the entity needs access to protected health information to perform the service for the covered entity."<sup>23</sup>


Even if a technology provider is not determined to be a "business associate," it is questionable whether a covered entity can meet its HIPAA requirements (i.e. such as reviewing audit logs, access reports, etc.) by utilizing such a provider. Furthermore, a recent medical board sanction illustrates the potential serious risk posed to providers by using a technology option such as Skype. An Oklahoma physician practicing telepsychiatry and pain management was recently suspended from practice by the Oklahoma Board of Medical Licensure and Supervision for a number of violations, including providing telemedicine services via Skype.<sup>24</sup> While the primary focus of this case was on the physician's prescribing practices, the Board of Medicine did state that "Skype is not an approved method of providing telemedicine."<sup>25</sup> Although this case occurred in a different jurisdiction and is not controlling in Minnesota, it illustrates the potential risk that a local health department could be exposed to by not using HIPAA-compliant technology.

Certain technological features may help a covered entity meet its compliance obligations under the HIPAA Security Rule. Examples of such features may include encryption or the use of required passwords.<sup>26</sup> However, no specific technological features can ensure that an entity is HIPAA-compliant. There must also be an organized system of security practices and procedures in place to ensure that PHI is accessed appropriately.

There is a growing number of videoconference platforms that can support a HIPAA-compliant telemedicine encounter. Although telemedicine products may be marketed as HIPAA-compliant, the most that can be said is that these products may be used in HIPAA-compliant ways, while some are impossible to use in HIPAA-compliant ways. As a starting point for assessing whether a telemedicine product is appropriate for a VDOT program, a local health department will want to ask the potential business associate what administrative, physical, and technical safeguards it has in place to protect patient information. A local health department should seek legal counsel when assessing whether a telemedicine product can be used in HIPAA-compliant ways.

## Consent, Data Practices, and Health Record Issues

Although there are no telemedicine-specific statutory requirements relating to consent for telemedicine services in Minnesota, local health departments will want to consider what informed consent procedures are necessary to comply with their legal obligations and medical standards of care. Patients have a right to be informed about their health care, regardless of whether it is delivered via telemedicine or in-person. An informal survey of telehealth programs conducted by the Great Plains Telehealth Resource and Assistance Center revealed that the process for obtaining "proper patient consent differs by healthcare organization more so than by state borders."<sup>27</sup> Each organization must determine the process that fits best with their established traditional processes and legal structure and makes the most sense for their patients. Some organizations have determined that a separate telemedicine-specific patient consent form is needed, while other entities have simply included a telemedicine section on the entity's general patient consent form.<sup>28</sup> Other organizations have determined that telemedicine services are already assumed within the patient consent process and do not delineate telemedicine services specifically.<sup>29</sup> The process for consent will be influenced by local standards, facility policies, and payer requirements, in addition to applicable federal and state requirements. Given the variety of health department and program structures, determining what consent process is appropriate will likely require a case-by-case assessment of each program.



There are also various privacy-related federal and state requirements that local health departments will want to discuss with their legal counsel in developing appropriate consent and notice procedures for their VDOT programs. A few relevant statutes to consider as a starting point are noted below.

Local health departments that are HIPAA-covered entities must comply with the notice requirements of the HIPAA Privacy Rule. The Privacy Rule provides that an individual has a right to “adequate notice of how a covered entity may use and disclose protected health information about the individual, as well as his or her rights and the covered entity’s obligations with respect to that information.”<sup>30</sup> The Privacy Rule also provides many specific requirements relating to the content of the notice and how the notice is provided to patients.<sup>31</sup> Covered entities should consult their legal counsel and their privacy officer to ensure compliance with all applicable laws.

Under Minnesota law, health data are private data on individuals and must not be disclosed unless particular requirements are met.<sup>32</sup> The Minnesota Government Data Practices Act requires the government to give individuals notice when collecting private or confidential information from them.<sup>33</sup> This is referred to as a “Tennessee warning notice.”<sup>34</sup> With limited exceptions, a government entity may not collect, store, use, or disseminate private or confidential data for any purpose other than those specified in the Tennessee warning notice.<sup>35</sup> A Tennessee warning must include the following: “(a) the purpose and intended use of the requested data within the collecting government entity; (b) whether the individual may refuse or is legally required to supply the requested data; (c) any known consequence arising from supplying or refusing to supply private or confidential data; and (d) the identity of other persons or entities authorized by state or federal law to receive the data.”<sup>36</sup>

Local health departments will want to consider the requirements of the Minnesota Health Records Act as well. Minnesota law defines a “health record” to include “any information, whether oral or recorded in any form or medium, that relates to the past, present, or future physical or mental health or condition of a patient; the provision of health care to a patient; or the past, present, or future payment for the provision of health care to a patient.”<sup>37</sup> Any retained video recordings or provider notes from the VDOT interaction would likely become part of the patient’s health record. Pursuant to Minn. Stat. § 144.292, subd. 4, a provider must also “provide to patients, in a clear and conspicuous manner, a written notice concerning practices and rights with respect to access to health records.” The Minnesota Health Records Act also provides that a health care provider<sup>38</sup> may not release a patient’s health records to a person without: (1) a signed and dated consent from the patient or the patient’s legally authorized representative authorizing the release; (2) specific authorization in law; or (3) a representation from a provider that holds a signed and dated consent from the patient authorizing the release.<sup>39</sup> Local health departments that implement VDOT should adopt appropriate health record policies from the outset.


This section is not an exhaustive summary of all the possible data practices issues that may arise, but it may provide a starting point for local health departments to consider. Given the variety of health department and program structures, determining what consent forms and additional notices are appropriate will likely require a case-by-case review of each VDOT program. Local health departments should consult their legal counsel when developing consents and other notices to ensure compliance with all applicable laws.

## **Telemedicine Reimbursement Law and Policy**

### **Local Health Department Billing Capacity**

Whether local health departments can bill third party payers for DOT delivered via telehealth may be an important consideration for local health departments contemplating an investment in VDOT technology. This section discusses new Minnesota legislation and policies relating to telemedicine reimbursement that may be relevant to local health departments.

As a threshold matter, it should be noted that different local health departments may be at different stages in terms of their capacity to bill third party payers for clinical services in general. As local health departments across the country have increasingly faced budget cuts, many local health departments have found that billing public and private insurance providers for reimbursable services is a way to ensure sustainability and continue to provide essential public health services.<sup>40</sup> The growing move toward billing for public health services represents a paradigm shift to some extent as many



public health services have “traditionally been viewed as free,”<sup>41</sup> and local health departments may face challenges in trying to implement a billing system.

Some local health departments may already have the infrastructure in place to bill public payers, such as medical assistance, but may not have experience billing private payers for clinical services. Other local health departments may not have the staff capacity or infrastructure for billing and may not yet be billing any third party payers. When deciding whether to implement a billing system, local health departments will want to carefully assess the communities they serve and the services they provide to determine whether billing makes sense for their department. For example, a local health department that serves predominantly uninsured communities or does not offer many reimbursable services may not find revenue generation feasible. Local health departments will want to weigh the expected revenue against the costs of developing and sustaining a billing infrastructure.<sup>42</sup> For local health departments that are considering billing for clinical services for the first time, the National Association of County and City Health Officials (NACCHO) and the Centers for Disease Control and Prevention (CDC) have published various toolkits and resources which may be helpful.<sup>43</sup>

### **Minnesota Telemedicine Act**

The absence of consistent, comprehensive reimbursement policies is often cited as one of the most serious obstacles to the wider adoption of telemedicine practices.<sup>44</sup> However, a growing number of states, including Minnesota, have recently enacted laws expanding opportunities for reimbursement of telemedicine services. While new legislation in Minnesota creates additional opportunities for telemedicine reimbursement, reimbursement for VDOT in Minnesota still remains uncharted territory. Clarifications and possible administrative action may still be needed to implement new legislation and to allow for reimbursement of VDOT as discussed in further detail below.


During the 2015 legislative session, the Minnesota legislature enacted the Minnesota Telemedicine Act, which requires health insurance carriers and Minnesota’s Medicaid program (medical assistance) to provide coverage for telemedicine. The Minnesota Telemedicine Act took effect on January 1, 2016, with some provisions fully operational on January 1, 2017. The Minnesota Telemedicine Act is codified in two separate chapters of Minnesota Statutes. The Act added new statutory sections relating to telemedicine coverage for health insurance carriers, which are codified in Chapter 62A (Accident and Health Insurance) under the Individual Market Regulation section (see Minn. Stat. § 62A.67 *et seq.*) The Act also amended the section on the services covered by medical assistance, which is codified in section Chapter 256B (Medical Assistance for Needy Persons). Although the new law is codified in these separate chapters, this Fact Sheet refers to the law generally as the “Minnesota Telemedicine Act” and explains the different provisions below.

### **Telemedicine Reimbursement for Insurance Carriers**

Under the Minnesota Telemedicine Act, a health plan sold, issued, or renewed by a health carrier “for which coverage of benefits begins on or after January 1, 2017” is required to include coverage for telemedicine benefits in the same manner as any other benefits covered under the plan.<sup>45</sup> The Act requires that a health carrier reimburse a health care provider for covered services delivered via telemedicine on the same basis and at the same rate as the health carrier would apply to those services if the services had been delivered in person.<sup>46</sup> The law defines telemedicine as follows:

“Telemedicine” means the delivery of health care services or consultations while the patient is at an originating site and the licensed health care provider is at a distant site. A communication between licensed health care providers that consists solely of a telephone conversation, e-mail, or facsimile transmission does not constitute telemedicine consultations or services. A communication between a licensed health care provider and a patient that consists solely of an e-mail or facsimile transmission does not constitute telemedicine consultations or services. Telemedicine may be provided by means of real-time two-way, interactive audio and visual communications, including the application of secure video conferencing or store-and-forward technology to provide or support health care delivery, which facilitate the assessment, diagnosis, consultation, treatment, education, and care management of a patient’s health care.<sup>47</sup>

The statute specifies that a “distant site” is the “site at which a licensed health care provider is located while providing health care services or consultations by means of telemedicine.”<sup>48</sup> The statute defines “originating site” broadly as “a site including, but not limited to, a health care facility at which a patient is located at the time health care services are provided



to the patient by means of telemedicine.”<sup>49</sup> This definition leaves open the possibility of coverage for home visits because it is not limited to health care facilities. The statute further provides that telemedicine may be provided via live video (synchronous) or store-and-forward technology (asynchronous). The statute defines “store-and-forward technology” as “the transmission of a patient’s medical information from an originating site to a health care provider at a distant site without the patient being present, or the delivery of telemedicine that does not occur in real time via synchronous transmissions.”<sup>50</sup>

The Minnesota Telemedicine Act provides that health insurance carriers are not required to provide coverage for services that are not medically necessary.<sup>51</sup> Further, the Act permits health insurance carriers to establish criteria that a health care provider must meet to demonstrate “the safety or efficacy of delivering a particular service via telemedicine for which the health carrier does not already reimburse other health care providers for delivering via telemedicine, so long as the criteria are not unduly burdensome or unreasonable for the particular service.”<sup>52</sup> The Act also permits health insurance carriers to require that providers agree to certain documentation or billing practices to prevent fraudulent claims so long as the practices are not unduly burdensome or unreasonable for the particular service.<sup>53</sup>

Under the Minnesota Telemedicine Act, if a health plan (with coverage beginning on or after January 1, 2017) covers in-person DOT, then the health plan would be required to reimburse telehealth-delivered DOT in the same manner and at the same rate as in-person DOT. Since reimbursement details are generally governed by the individual health plan contracts, health plan enrollees will want to check with their individual health plans to determine the extent to which DOT services (and VDOT through application of the new law) are covered. Health care providers, including local health departments, will also want to check whether the health carrier requires certain criteria or billing practices for telemedicine claims. The Minnesota Telemedicine Act opens the door for potential private payer reimbursement of VDOT and warrants further exploration.<sup>54</sup>


### **Medical Assistance Telemedicine Reimbursement Policy**

The Minnesota Telemedicine Act also expands coverage of telemedicine services by medical assistance, effective January 1, 2016. The Act states that medical assistance will cover “medically necessary services and consultations delivered by a licensed health care provider via telemedicine in the same manner as if the service or consultation was delivered in person. Coverage is limited to three telemedicine services per enrollee per calendar week. Telemedicine services shall be paid at the full allowable rate.”<sup>55</sup> The medical assistance statute adopts the same definition of an “originating site” that is used for health carriers as noted above.<sup>56</sup>

Directly observed therapy is already listed as a service covered by medical assistance. Minn. Stat. § 256B.0625, subd. 40, outlines the relevant covered services as follows:

- (a) For persons infected with tuberculosis, medical assistance covers case management services and direct observation of the intake of drugs prescribed to treat tuberculosis.
- (b) “Case management services” means services furnished to assist persons infected with tuberculosis in gaining access to needed medical services. Case management services include at a minimum:
  - (1) assessing a person’s need for medical services to treat tuberculosis;
  - (2) developing a care plan that addresses the needs identified in clause (1);
  - (3) assisting the person in accessing medical services identified in the care plan; and
  - (4) monitoring the person’s compliance with the care plan to ensure completion of tuberculosis therapy. Medical assistance covers case management services under this subdivision only if the services are provided by a certified public health nurse who is employed by a community health board as defined in section 145A.02, subdivision 5.
- (c) To be covered by medical assistance, direct observation of the intake of drugs prescribed to treat tuberculosis must be provided by a community outreach worker, licensed practical nurse, registered nurse who is trained and supervised by a public health nurse employed by a community health board as defined in section 145A.02, subdivision 5, or a public health nurse employed by a community health board.<sup>57</sup>

Given that in-person DOT is already a covered service, local health departments may anticipate that the Minnesota Telemedicine Act could be applied to expand medical assistance coverage to VDOT. However, additional clarification from the Minnesota Department of Human Services (DHS) is likely needed as discussed further below.



DHS administers the medical assistance program and also publishes the Minnesota Health Care Program (MHCP) Provider Manual. The MHCP Provider Manual is a reference for providers participating in MHCPs and contains information regarding coverage policies, rates, and billing procedures.<sup>58</sup> Following the passage of the Minnesota Telemedicine Act, DHS updated the telemedicine section of the MHCP Provider Manual in December 2015.<sup>59</sup> The Manual specifies that MHCPs allow payment for both interactive audio and video telecommunications that permit real-time communication between the distant site physician or practitioner and the recipient, and for the asynchronous transmission of medical information to be reviewed at a later time by a physician or practitioner at the distant site (also known as “store and forward” telemedicine).<sup>60</sup>


The updated MHCP Provider Manual also lists acceptable telemedicine originating sites and eligible providers, among other requirements. The Manual states that a patient’s home is an authorized originating site but further states that “a licensed or certified health care provider may need to be present to facilitate the delivery of telemedicine services provided in a private home.”<sup>61</sup> Given the self-administered nature of the medications ingested during DOT, telehealth-delivered DOT does not contemplate having a health care provider physically with the patient. Providers, including local health departments, who wish to deliver VDOT services to patients located at home may wish to seek clarification from DHS regarding whether MHCPs would reimburse for VDOT when a provider is not physically with the patient.

The updated MHCP Provider Manual further states that the following provider types are eligible to provide telemedicine services:

- Physician
- Nurse practitioner
- Physician assistant
- Nurse midwife
- Clinical nurse specialist
- Registered dietitian or nutrition professional
- Clinical psychologist
- Clinical social worker
- Dentist
- Pharmacist
- Certified genetic counselor
- Podiatrist
- Speech therapist
- Physical therapist
- Occupational therapist
- Audiologist<sup>62</sup>

This eligible provider list may impact reimbursement for VDOT if a provider not included on this list wanted to provide telehealth-delivered DOT. Local public health departments will want to check with DHS to see whether DHS intended other specific provider types, such as other nurse specialties, to qualify as eligible providers for MHCP reimbursement. Given that the Minnesota Telemedicine Act requires that medically necessary telemedicine services be covered by medical assistance “in the same manner as if the service or consultation was delivered in person,”<sup>63</sup> it would appear that the provider types authorized to bill medical assistance for in-person DOT would also need to be included on this telemedicine eligible provider list. Minn. Stat. § 256B.0625, subd. 40(c) states that medical assistance covers DOT provided by a community outreach worker, licensed practical nurse, registered nurse who is trained and supervised by a public health nurse employed by a community health board, or a public health nurse employed by a community health board. Given that the Minnesota Telemedicine Act and MHCP guidelines just went into effect a few weeks ago, it is possible that this apparent omission was an inadvertent oversight and that DHS may update the eligible provider list to harmonize it with other statutory requirements. However, local health departments will want to confirm with DHS that their VDOT providers are eligible for reimbursement.

As noted in the statute, the MHCP Provider Manual also states that payment is limited to three telemedicine services per week per recipient.<sup>64</sup> This reimbursement limit could pose a barrier to TB patients requiring daily DOT. The medical assistance statutory section regarding in-person DOT does not appear to contain a similar restriction regarding the



number of services per week. (See Minn. Stat. § 256B.0625, subd. 40). Given that the Minnesota Telemedicine Act requires reimbursement parity between telemedicine and in-person services,<sup>65</sup> one could argue that parity would require reimbursement for more than three VDOT visits per week if they were medically necessary. It may be possible to harmonize the Act and the Manual, if multiple instances of VDOT are deemed to constitute one service. Local health departments will want to seek clarification from DHS on this point.

The medical assistance section of the Minnesota Telemedicine Act also provides that the “commissioner shall establish criteria that a health care provider must attest to in order to demonstrate the safety or efficacy of delivering a particular service via telemedicine.”<sup>66</sup> DHS published these new attestation criteria for providers in the December 2015 update to the MHCP Provider Manual.<sup>67</sup> These criteria require that providers attest that they have: (1) written policies and procedures specific to telemedicine services that are reviewed and updated regularly; (2) policies and procedures that adequately address patient safety before, during and after the telemedicine service is rendered; (3) established protocols addressing how and when to discontinue telemedicine services; and (4) an established quality assurance process related to telemedicine services which includes all applicable HIPAA requirements.<sup>68</sup> The MHCP Provider Manual further states that MHCPs do not reimburse for “electronic connections that are not conducted over a secure encrypted website as specified by the Health Insurance Portability & Accountability Act of 1996 Privacy & Security rules (e.g., Skype).”<sup>69</sup> To be eligible for MHCP reimbursement, providers must self-attest that they meet all of the conditions of the MHCP telemedicine policy by completing a “Provider Assurance Statement for Telemedicine.”<sup>70</sup>

The “Provider Assurance Statement for Telemedicine” also requires that providers attest that their agencies maintain appropriate documentation of each occurrence of a health care service provided by telemedicine consistent with the billing requirements of the new law. With respect to billing, the new law states that as a condition of payment, a licensed health care provider must document each occurrence of a health service provided by telemedicine to a medical assistance enrollee, and must document, among other requirements: the type of service; the time the service began and the time it ended; the basis for determining that telemedicine is an appropriate means for delivering the service to the enrollee; the mode of transmission; and the location of the originating site and the distant site.<sup>71</sup> Local health departments treating patients who have medical assistance coverage will want to keep abreast of conditions for payment and stay current with the attestation criteria.

Additional issues and questions are likely to arise as this new law is implemented. Those interested in pursuing reimbursement for VDOT should watch for updated guidance and contact the Minnesota Department of Human Services to ensure that all reimbursement requirements are met.

### **Medicare Telemedicine Reimbursement Policy**


Finally, Medicare covers a limited number of telemedicine services, subject to certain requirements related to geography, practice setting, type of service, and eligible technology. For example, Medicare will reimburse for telemedicine services when the originating site is in a Health Professional Shortage Area, although the originating site must be a medical facility and the telemedicine consultation must occur via live video, among other requirements.<sup>72</sup> At this time, Medicare requires the beneficiary to be at an acceptable “originating site,” which does not include the patient’s home (in contrast to Minnesota’s medical assistance definition of that term). The more stringent requirements for Medicare than for medical assistance may present a barrier to use of VDOT for some Medicare patients and providers, but VDOT may still prove a comparatively convenient and cost-effective alternative to in-person DOT for others.

As the above sections suggest, there are many issues to consider regarding potential reimbursement for VDOT and many questions to be resolved. The Center for Connected Health Policy is currently examining policies regarding the reimbursement landscape for VDOT in California, among other issues.<sup>73</sup> The results of their project should be helpful for local health departments in Minnesota and in other states considering implementation of VDOT as well.

### **Grant Funding Opportunities**

Local health departments contemplating an investment in VDOT technology may be interested in pursuing federal telemedicine grants or other grants to assist with the capital costs of starting a VDOT program. For example, the United States Department of Agriculture Distance Learning and Telemedicine grant program helps rural communities acquire technologies to connect medical providers and teachers serving rural residents.<sup>74</sup> Grant funds may be used for the





acquisition of capital assets (such as video equipment and computer hardware), instructional programming, or technical assistance. Applications for this program are currently being accepted through March 2016. This is just one example of telemedicine grant funding available to local health departments. Local health departments may consider applying for such opportunities to assist with the start-up costs of implementing a VDOT program.

## Other Legal and Regulatory Issues

As this Fact Sheet focuses on the use of VDOT within Minnesota, it does not address legal issues that may arise if telemedicine is practiced across state lines. If telemedicine is practiced across state lines, additional issues such as interstate licensing, credentialing, and privileging must be considered.<sup>75</sup> In addition, providers engaged in telemedicine must also ensure that their malpractice liability insurance policy extends coverage to telemedicine encounters.<sup>76</sup>

There are additional federal laws and regulations that may be relevant to VDOT. If a mobile application meets the definition of a “medical device” under the Federal Food, Drug and Cosmetic Act, the mobile application could be subject to FDA regulations.<sup>77</sup> However, the FDA has issued guidance stating that it intends to apply its regulatory oversight only to those mobile applications that are medical devices and whose functionality could pose a risk to the patient’s safety if the application failed to function as intended.<sup>78</sup> Whether the FDA would exercise enforcement discretion in the VDOT context is beyond the scope of this Fact Sheet. Health care providers incorporating telemedicine into their business models must also take care in ensuring that the model does not violate federal fraud and abuse laws, such as the Anti-Kickback Statute, the Stark Law, and the False Claims Act.<sup>79</sup> The Office of Inspector General has issued advisory opinions addressing telemedicine-related fraud issues that may be helpful to providers.<sup>80</sup>

## Conclusion

VDOT appears to be a promising, cost-effective method to provide patient-centered care which meets patients’ needs and results in increased treatment compliance and completion. However, there are legal, regulatory, and practical challenges relating to the use of VDOT, and the implementation of VDOT in Minnesota will not be immediate or simple. This Fact Sheet is not an exhaustive analysis of all the legal issues relating to VDOT, but provides a starting point for local health departments to discuss with their legal counsel when considering the integration of a VDOT program into their TB control program efforts. To ensure a successful implementation of this technology, local health departments should consult legal counsel to ensure compliance with all applicable laws and regulations implicated by VDOT. A carefully implemented VDOT program presents a promising alternative to traditional DOT practices and has the potential to improve TB control efforts in Minnesota and in other jurisdictions.

## Additional Resources

- **American Telemedicine Association:** <http://www.americantelemed.org/>
- **Center for Connected Health Policy:** <http://cchpca.org/>
- **Center for Telehealth and e-Health Law:** <http://ctel.org/>
- **Consortium of Telehealth Resource Centers:** <http://www.telehealthresourcecenter.org/>
- **Great Plains Telehealth Resource and Assistance Center:** <http://www.gptrac.org/>
- **Harris County Public Health and Environmental Services – Tuberculosis Video Directly Observed Therapy Implementation Guide:** <http://www.hcphesvdot.org/#!/videos-and-guides/c10g1>
- **Minnesota Department of Health – TB Information and Resources for Local Health Departments:** <http://www.health.state.mn.us/divs/idepc/diseases/tb/lph/index.html>
- **Minnesota Department of Human Services MHCP Manual:** [http://www.dhs.state.mn.us/main/idcplg?IdcService=GET\\_DYNAMIC\\_CONVERSION&RevisionSelectionMethod=LatestReleased&dDocName=id\\_008926#Telemedicine](http://www.dhs.state.mn.us/main/idcplg?IdcService=GET_DYNAMIC_CONVERSION&RevisionSelectionMethod=LatestReleased&dDocName=id_008926#Telemedicine)

- **National Rural Health Association:** <http://www.ruralhealthweb.org/>
- **United States Department of Agriculture, Distance Learning and Telemedicine Grants:** <http://www.rd.usda.gov/programs-services/distance-learning-telemedicine-grants>


## SUPPORTERS



Robert Wood Johnson Foundation

**The Network for Public Health Law is a national initiative of the Robert Wood Johnson Foundation with direction and technical assistance by the Public Health Law Center at Mitchell Hamline School of Law.**

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