

Nova Law Review

Volume 43, Issue 3

2019

Article 4

Telehealth, Children, and Pediatrics: Should the Doctor Make House Calls Again, Digitally?

Laura C. Hoffman*

*Seton Hall University School of Law, Laura.Hoffman@shu.edu

Copyright ©2019 by the authors. *Nova Law Review* is produced by The Berkeley Electronic Press (bepress). <https://nsuworks.nova.edu/nlr>

TELEHEALTH, CHILDREN, AND PEDIATRICS: SHOULD THE DOCTOR MAKE HOUSE CALLS AGAIN, DIGITALLY?

DR. LAURA C. HOFFMAN*

I.	INTRODUCTION.....	322
II.	DEFINING TELEHEALTH AND ITS APPROPRIATE USE IN PEDIATRICS	323
III.	LEGAL BARRIERS TO THE USE OF TELEHEALTH	324
A.	<i>Practicing Telehealth</i>	325
1.	Physician-Patient Relationship	325
2.	Standard of Care	328
3.	Informed Consent	331
B.	<i>Telehealth Practice Crossing State Lines</i>	335
1.	Liability and Liability Insurance.....	335
2.	Licensure Limitations and State Telehealth Laws	337
C.	<i>Equipment</i>	338
1.	Standards of Practice	338
2.	Who is Liable?	339
3.	FDA Regulation and Telehealth	341
D.	<i>Security</i>	344
IV.	THE PROS AND CONS OF TELEHEALTH USE FOR PEDIATRIC CARE	346
A.	<i>Benefits of Telehealth in Pediatrics</i>	346
B.	<i>Disadvantages of Telehealth in Pediatrics</i>	347
V.	CONCLUSION.....	349

“Children represent one of our most vulnerable populations, and as such, require special considerations when participating in telehealth encounters.”¹

* Dr. Laura C. Hoffman is an Assistant Professor of Law/Faculty Researcher for Seton Hall University School of Law’s Center for Health and Pharmaceutical Law and Policy. She earned her Doctor of Juridical Science (S.J.D.) in Health Law and Policy from Loyola University Chicago School of Law in 2012. Dr. Hoffman wishes to thank her parents, Ronald and Janet Hoffman, for their unending love and support. Also, a special thank you to her former mentors, Michael Seredick and Professor Michael Zimmer, for always being her cheerleaders. Dr. Hoffman can be reached at Laura.Hoffman@shu.edu.

1. AM. TELEMEDICINE ASS’N, OPERATING PROCEDURES FOR PEDIATRIC TELEHEALTH 3 (2017).

I. INTRODUCTION

Although telehealth was initially developed primarily for those in rural areas who have difficulty accessing traditional health care services due to distance, the use of telehealth has significantly expanded in the past decade across various groups, including children and adolescents, through pediatrics.² “Pediatricians can use telemedicine for a broad range of applications. Telemedicine can be used for tele-education, teleconsultation, telepractice, and teleresearch.”³ The growth of the acceptance of telehealth in pediatrics is also evidenced by the American Academy of Pediatrics’ (“AAP”) agreement for utilization of SnapMD.⁴ Additionally, with a rising shortage of medical professionals in pediatrics unable to sustain the growing need for pediatric care, the potential benefits of telehealth cannot be overlooked.⁵ As the use of telehealth becomes more prevalent in pediatrics, the opportunities for entrepreneurs to impact this area have increased to create greater access to health care for this vulnerable population that is not only more efficient, but also cost effective.⁶

A number of recent entrepreneurial endeavors have demonstrated a growing interest in pediatrics.⁷ In 2016, Tyto Care began marketing an at-home medical kit to enable parents to obtain medical information of their children that can be delivered to their pediatricians who also have the Tyto Care technology.⁸ While reserved for non-urgent care, the kit is designed to provide efficiency by avoiding the necessity of an in-person doctor’s office

2. See John Commins, *Pediatric Telemedicine Poised for Growth Spurt*, HEALTHLEADERS (Apr. 24, 2017), <http://www.healthleadersmedia.com/innovation/pediatric-telemedicine-poised-growth-spurt>; *Telehealth Use in Rural Healthcare*, RURAL HEALTH INFO. HUB, <http://www.ruralhealthinfo.org/topics/telehealth> (last updated Mar. 26, 2019).

3. Bryan L. Burke Jr. et al., *Telemedicine: Pediatric Applications*, 136 AM. ACAD. PEDIATRICS e293, e294 (2015).

4. Cara Livernois, *American Academy of Pediatrics Selects SnapMD as Telehealth Provider*, AI IN HEALTHCARE: CONNECTED CARE, (May 24, 2018), <http://www.aiin.healthcare/topics/connected-care/american-academy-pediatrics-selects-snapmd-telehealth-provider>.

5. *Id.*

6. See *id.*; Brit Morse, *This Startup Has a Small Army of Therapists with Laptops, Ready to Help People Anywhere*, INC. (May 7, 2018), <http://www.inc.com/brit-morse/dotcom-therapy-30-under-30-2018.html>; Josh Wilson, *Majority of Parents Plan to Use Telemedicine for Pediatric Care*, NEMOURS (Apr. 23, 2017), <http://www.nemours.org/about/mediaroom/press/dv/majority-of-parents-plan-to-use-telemedicine.html>.

7. See Morse, *supra* note 6; Rina Raphael, *Can This Home Medical Kit Save You from Constant Doctor Visits?*, FAST COMPANY (May 10, 2018), <http://www.fastcompany.com/40565776/can-this-home-medical-kit-save-you-from-constant-doctor-visits>.

8. Raphael, *supra* note 7.

visit and significantly assisting parents who are employed and/or have otherwise complicated daily schedules.⁹ Started in 2015, DotCom Therapy is a telehealth therapy startup that has partnered with schools to provide children with a variety of therapy services including “speech therapy, occupational therapy, mental health, and teleaudiology services.”¹⁰ Other examples have shown a growing market for telehealth with options available at retailers.¹¹

This Article explores the different challenges that arise in incorporating telehealth into pediatrics, especially for entrepreneurs.¹² First, this Article explains how telehealth has been applied, specifically in pediatrics.¹³ Next, the Article explores the various legal barriers involving telehealth with particular attention to these issues as they relate to pediatric care, including: Physician-patient relationship, standard of care, informed consent, liability/liability insurance, equipment, and security.¹⁴ This Article then examines the benefits and disadvantages that have been raised in the use of telehealth in relation to pediatric care.¹⁵ Finally, this Article concludes by offering recommendations to those entrepreneurs who hope to have an influence on the future development of telehealth in pediatrics.¹⁶

II. DEFINING TELEHEALTH AND ITS APPROPRIATE USE IN PEDIATRICS

As the focus of this Article is the use of telehealth, specifically as it relates to pediatric care, it is imperative to have a working knowledge of how certain terms are defined within this specialty.¹⁷ In 2015, the AAP released its own technical report on the use of telemedicine in pediatrics.¹⁸ In defining telemedicine, the AAP deferred to the definition used by the American Telemedicine Association (“ATA”).¹⁹ The ATA defined telemedicine as: “[T]he use of medical information exchanged from one site to another via electronic communications to improve a patient’s clinical

9. *Id.*

10. Morse, *supra* note 6.

11. Burke Jr. et al., *supra* note 3, at e296.

12. *See* discussion *infra* Part III–IV.

13. *See* discussion *infra* Part II.

14. *See* discussion *infra* Part III.

15. *See* discussion *infra* Part IV.

16. *See* discussion *infra* Part V.

17. *See* discussion *infra* Part III.

18. Burke Jr. et al., *supra* note 3, at e293. It should be noted that, according to this technical guidance document: “All technical reports from the [AAP] automatically expire [five] years after publication unless reaffirmed, revised, or retired at or before that time.” *Id.*

19. *Id.* at e293, e304 n.1.

health status.”²⁰ The AAP recognized that the term telehealth has a more expansive definition than telemedicine.²¹ “Telehealth has historically had a broader definition, encompassing telemedicine’s clinical care for patients and tele-education, teleresearch, and disaster response.”²² Despite this, the AAP acknowledged the interchangeability of telemedicine and telehealth, describing the common use of these terms as synonymous.²³ For purposes of this Article, the term telehealth will be used generally to describe all telemedicine services unless reference is made to a specific document’s use of a particular term.²⁴

A primary consideration for pediatric care is whether there is an appropriate age for which a child may have medical care and treatment using telehealth.²⁵ The ATA’s April 2017 Operating Procedures for Pediatric Health—approved by the AAP—specifically advises against the use of telehealth with a child under the age of two unless there has been a prior in-person relationship developed and referral is made for telehealth services based on a chronic or medically complex condition.²⁶

III. LEGAL BARRIERS TO THE USE OF TELEHEALTH

The AAP guidance summed it up quite simply when it stated, “[l]egal barriers can be substantial” with regard to the use of telehealth.²⁷ “Liability in the context of telemedicine means the exposure of a physician to a claim for damages for alleged medical malpractice or negligence while providing telemedicine services.”²⁸ The AAP identified several issues that should be examined with regard to legal liability, including: The physician-patient relationship, roles and communications responsibilities, patient abandonment, technological failures, liability insurance, site of malpractice action, standard of care, informed consent, security, and unknown legal risks associated with telemedicine.²⁹ The following sections will explore a number of these issues.³⁰

20. *Telemedicine or Telehealth – Definitions*, TELEHEALTH ALLIANCE OF OR., <http://www.ortehealth.org/content/telemedicine-or-telehealth-definitions> (last visited May 1, 2019).

21. Burke Jr. et al., *supra* note 3, at e293.

22. *Id.*

23. *Id.*

24. See discussion *infra* Part III.

25. See AM. TELEMEDICINE ASS’N, *supra* note 1, at 2–3.

26. *Id.* at 3.

27. Burke Jr. et. al., *supra* note 3, at e300.

28. *Id.*

29. *Id.*

30. See discussion *infra* Parts III.A, III.B, III.C, III.D.

A. *Practicing Telehealth*

1. Physician-Patient Relationship

Physicians who engage in the practice of telehealth will be subject to liability for medical malpractice.³¹ Drawn from the traditional elements of tort law, the prima facie case for a malpractice liability claim is relatively uniform across jurisdictions.³² Indeed, as noted in *Rolon-Alvarado v. Municipality of San Juan*,³³ the elements of medical malpractice liability are fairly comparable among varying jurisdictions.³⁴ In order to prevail, the patient-plaintiff must prove each of the following elements: (1) the physician had a duty to act according to accepted professional standards; (2) the physician breached that duty by deviating from the applicable standard of care; (3) the patient suffered injury; and (4) a causal connection exists between the breach of duty and the patient's injury.³⁵ "For telemedicine physicians, the most significant issues will be: (1) [d]oes the telemedicine physician owe the patient a duty of care, [i.e.,] has a physician-patient relationship been established? (2) [w]hat is the applicable standard of telemedical care or, more accurately, what are the applicable standards of care?"³⁶

To be successful in a claim for medical malpractice, a plaintiff-patient must, among other things, prove the existence of a physician-patient relationship as it is from this relationship that a duty is created of the physician to the patient.³⁷ "In the context of telemedicine, several factors need to be considered in determining when, or if, a physician-patient

31. See Christopher J. Caryl, *Malpractice and Other Legal Issues Preventing the Development of Telemedicine*, 12 J.L. & HEALTH 173, 192–93 (1997–1998).

32. *Id.* at 193; see also *Hollis v. United States*, 323 F.3d 330, 336 (5th Cir. 2003); *Arkin v. Gittleson*, 32 F.3d 658, 664 (2d Cir. 1994); *Rolon-Alvarado v. Municipality of San Juan*, 1 F.3d 74, 77 (1st Cir. 1993); *MacGuineas v. United States*, 738 F. Supp. 566, 569 (D.D.C. 1990).

33. 1 F.3d 74 (1st Cir. 1993).

34. *Id.* at 77 n.2; see also *Hollis*, 323 F.3d at 336 (applying Texas law); *Arkin*, 32 F.3d at 664 (applying New York law); *Fletscher v. United States*, No. C-92-20151, 1993 WL 151223, at *1 (N.D. Cal. May 5, 1993) (applying California law); *MacDonald v. United States*, 767 F. Supp. 1295, 1307 (M.D. Pa. 1991) (applying Pennsylvania law); *MacGuineas*, 738 F. Supp. at 569 (applying Maryland law); *Powers v. United States*, 589 F. Supp. 1084, 1099 (D. Conn. 1984) (applying Connecticut law).

35. *Hollis*, 323 F.3d at 336; *Rolon-Alvarado*, 1 F.3d at 77 n.2; Caryl, *supra* note 31, at 193.

36. LYNN D. FLEISHER & JAMES C. DECHENE, TELEMEDICINE AND E-HEALTH LAW § 1.04(3), LexisNexis (last visited May 1, 2019).

37. *Id.* § 1.04(3)(a).

relationship exists.”³⁸ Among one of the chief considerations that arises is distinguishing whether a website is simply providing general information to a patient or is in an interactive format that is being utilized by licensed physicians and patients.³⁹ When a website is distinguishable as an interactive site, it will be deemed a practice location.⁴⁰

In a court’s determination of whether a physician-patient relationship exists in the context of telehealth, the following considerations will be made:

A physician-patient relationship likely will be found where: (1) the telemedicine physician and the patient see each other during the telemedicine visit; (2) where an actual exam takes place; (3) where the physician provides diagnosis, treatment or other care on which the patient relies; (4) where the physician has access to the patient’s medical records; and (5) where the physician accepts a fee for the telemedicine consultation.⁴¹

A number of cases have found that a physician-patient relationship has been established without a physician actually physically seeing a patient.⁴² The AAP guidance further indicates that as telehealth medical malpractice will likely be similarly aligned to telephone medical malpractice, the physician-patient relationship may attach to both the on-site physician as well as the remote consultant.⁴³ “Extrapolating from case law on telephone use, it is reasonable to conclude that a physician-patient relationship has been established with both the on-site treating physician and the remote consultant

38. *Id.*

39. *Id.*

40. *Id.*

41. FLEISHER & DECHENE, *supra* note 36, § 1.04(3)(a)(i); P. Greg Gulick, *E-Health and the Future of Medicine: The Economic, Legal, Regulatory, Cultural, and Organizational Obstacles Facing Telemedicine and Cybermedicine Programs*, 12 ALB. L.J. SCI. & TECH. 351, 393–94 (2002). But lack of payment may not immunize the physician from liability, except when the physician’s services fall under a state’s Good Samaritan laws. *Compare* Blanchard v. Murray, 771 N.E.2d 1122, 1131–32 (Ill. App. Ct. 2002) (finding that even though an obstetrician did not charge for services related to the performance of a caesarean section, it was still a question of fact as to whether the obstetrician was liable for negligence because she was given prior notice of the patient’s condition), *with* 745 ILL. COMP. STAT. 49/25 (2018) (Illinois Good Samaritan law conferring civil immunity to physicians under certain circumstances, including not charging the patient any fee for the service). *See also* Henslee v. Provena Hosps., 373 F. Supp. 2d 802, 809–15 (N.D. Ill. 2005) (discussing good faith requirement for *without fee* element of the Illinois statute).

42. Diggs v. Arizona Cardiologists, Ltd., 8 P.3d 386, 388–89; 391 (Ariz. Ct. App. 2000); McKinney v. Schlatter, 692 N.E.2d 1045, 1050 (Ohio Ct. App. 1997), *overruled in part by* Lownsbury v. VanBuren, 762 N.E.2d 354 (2002); Bienz v. Central Suffolk Hosp., 557 N.Y.S.2d 139, 139–40 (N.Y. App. Div. 1990); *see also* Caryl, *supra* note 31, at 195–96.

43. Burke Jr. et al., *supra* note 3, at e300.

during a telemedicine encounter if the remote consultant participates in the history, examination, diagnosis, and development of the treatment plan.”⁴⁴

Case law has developed in the area of telephone communications establishing a physician-patient relationship.⁴⁵ Several cases have been illuminating.⁴⁶ For example, the Supreme Court Appellate Division of New York held that a telephone call was sufficient to create a doctor-patient relationship.⁴⁷ Courts have even found a past relationship between a physician and patient sufficient to create the requisite physician-patient relationship and, thus, to establish a duty.⁴⁸ This has specifically occurred within the area of pediatrics.⁴⁹

Indeed, courts have found physician-patient relationships in the most casual of circumstances.⁵⁰ For example, in *Wilson v. Teng*,⁵¹ a pediatrician who had a previous relationship with a patient may have had a duty to the patient when she encountered her in the emergency room while she was seeing another patient and simply exchanged a few words with her.⁵² The Alabama Supreme Court held that there was a genuine issue of fact as to whether Dr. Teng breached the standard of care by not admitting the patient to the hospital despite the fact that, at the time Dr. Teng encountered the patient, she was neither an emergency physician nor was she even in the emergency room to see that particular patient.⁵³

“Thus, in the telemedicine context, it is unlikely that courts will allow a physician to avoid responsibility for a missed diagnosis or other negligent act on the basis of never having met or directly examined the patient.”⁵⁴

44. *Id.*

45. *Bienz*, 557 N.Y.S.2d at 139–40.

46. *See id.* at 140; *Diggs*, 8 P.3d at 389, 391; *McKinney*, 692 N.E.2d at 1050.

47. *Bienz*, 557 N.Y.S.2d at 140; *see also Diggs*, 8 P.3d at 389 (finding that the test to be applied is “whether a sufficient relationship existed between [the doctor and patient] such that, as a matter of policy, [the doctor] owed [the patient] a duty of reasonable care”). Even though the advice was communicated over a telephone wire rather than in person, the existence of a doctor-patient relationship was an issue of fact for the jury. *Bienz*, 557 N.Y.S.2d at 140.

48. *See Wilson v. Teng*, 786 So. 2d 485, 499 (Ala. 2000).

49. *Id.* at 487.

50. *See id.* at 499.

51. 786 So. 2d 485 (Ala. 2000).

52. *Id.* at 487–88.

53. *Id.* at 499.

54. FLEISHER & DECHENE, *supra* note 36, § 1.04(3)(a)(i).

2. Standard of Care

Another legal barrier that occurs in telehealth can occur with regard to the standard of care.⁵⁵ As the AAP points out, there is the potential for a variety of standards for telehealth practice, which substantially complicates this area.⁵⁶ “The standard of care for telemedicine may vary depending on technological sophistication, available options, and patient expectations.”⁵⁷ In order to succeed in a medical malpractice case, a plaintiff-patient, after establishing the physician-patient relationship, will need to substantiate the standard of care.⁵⁸ The standard of care in medical malpractice must be established as follows:

The standard of care element of a malpractice case is a two-part inquiry. First, the applicable standard of care must be established. Second, a determination must be made as to whether the physician-defendant breached that standard. Historically, the accepted standard of care for malpractice cases was defined as the degree of care exercised by clinicians, in good standing, in the same or similar locality as the defendant physician.⁵⁹

One development that has occurred with regard to standard of care has been the courts’ adoption of recognized national standards, in particular, with regard to specialties.⁶⁰ While it was believed that the traditional standard of care would be applicable to physicians, standards of care have evolved due to the technological nature of the medical care being provided to patients in these instances.⁶¹

Telehealth creates a host of additional issues in the delivery of health care.⁶² Of particular concern, in the area of standard of care for a medical malpractice claim, a plaintiff may be challenging “whether the use of telemedicine was appropriate.”⁶³ The appropriateness or suitability of a physician opting to use telehealth to deliver medical care can arise in a number of circumstances.⁶⁴

55. Burke Jr. et al., *supra* note 3, at e300.

56. *See id.*

57. *Id.*

58. FLEISHER & DECHENE, *supra* note 36, § 1.04(3)(b).

59. *Id.* at § 1.04(3)(b); Caryl, *supra* note 31, at 197.

60. *See* Caryl, *supra* note 31, at 197–98. “In recent years, however, national standards of care, particularly specialty care, have been recognized and accepted by most courts.” FLEISHER & DECHENE, *supra* note 36, § 1.04(3)(b).

61. FLEISHER & DECHENE, *supra* note 36, § 1.04(3)(b).

62. Caryl, *supra* note 31, at 192–93.

63. FLEISHER & DECHENE, *supra* note 36, § 1.04(3)(b)(i).

64. *See id.*

Among the myriad *tele*-specific issues that may arise in a telemedicine malpractice suit are questions relating to: (1) whether the use of telemedicine was appropriate in the specific circumstances of the patient's care; (2) whether the best available technology, e.g., store and forward vs. dynamic imaging, was used; and (3) whether it was sufficient, for example, to have a pathology assistant rather than a physician select and transmit patient images. Few standards currently exist to address these issues.⁶⁵

As new technologies emerge, physicians may be hesitant to use such technologies for fear of creating a greater potential to face liability.⁶⁶ At the other end, there may be a legal argument by a plaintiff-patient that telehealth should have been used in the course of care in the case of misdiagnosis—i.e., a test should have been read by a remote expert/specialist that would have made a different diagnosis.⁶⁷

Another issue that arises as to standard of care is whether or not a difference exists in the clinical standards required of a physician with the introduction of the use of telehealth in the delivery of medical care.⁶⁸ “With respect to some medical procedures and services, there will be little distinction between the way a physically-present physician and a telemedicine physician should perform. In such circumstances, the standard of care in both cases should be similar.”⁶⁹ However, this does not mean it will always be the case that standards will be the same when a patient's care involves a technological component.⁷⁰ In some specialties, the nature of the specialty has already incorporated telehealth's use to such a degree that it has become virtually a regular part of that specialty.⁷¹ However, there are instances of medical care in which the use of telehealth presents a new dynamic that demands an adjustment in the standard of care.⁷² “In many other cases, however, the customary standard of care for a particular

65. *Id.*

66. *Id.*

67. *Id.*

68. *See* FLEISHER & DECHENE, *supra* note 36, § 1.04(3)(b)(ii).

69. *Id.*

70. *See id.*

71. *Id.*

In other instances, certain uses of telemedicine, such as the transmission of digitized pathology images, already have become part of the customary practice of care for that specialty. In these cases, standard practice is fairly well-established and both physicians and patients are comfortable with the use of telemedicine in the provision of care.

Id.

72. FLEISHER & DECHENE, *supra* note 36, § 1.04(3)(b)(ii).

procedure may have to be modified significantly to accommodate, *inter alia*, the fact that the physician will not be able to touch the patient.”⁷³ Several states have regulated the standard of care for the use of telehealth that, unsurprisingly, differ by state.⁷⁴ Despite these attempts to provide consistency for telehealth practice in terms of a standard of care, the establishment of standards in this area have been described as a *moving target*.⁷⁵ A pertinent example of how a state’s standard of care can impact a telehealth startup business is demonstrated by an Illinois order which prohibited a company from treating and prescribing for online patients due to the lack of previous physician-patient relationship and physical exam.⁷⁶ More will be discussed in a later section regarding the licensure barriers that have already existed for physicians to practice medicine across state lines but presents an even greater challenge to the various startup businesses that want to pursue a purely telehealth medical practice.⁷⁷ States still have an enormous ability to regulate and essentially dictate the boundaries of the

73. *Id.*; Caryl, *supra* note 31, at 199.

74. FLEISHER & DECHENE, *supra* note 36, § 1.04(3)(b)(ii).

Some states already have promulgated regulations that attempt to specify applicable standards of care for telemedicine practice. And, as expected, they vary from state to state. Colorado’s regulation requires the standard of care for telemedicine treatment to be the same as the standard of care for in-person treatment. Florida’s regulation states that prescribing medicine based solely on an electronic medical questionnaire fails to meet the required standard of care. Texas has a rule similar to Florida’s, which states that the standard of care is not met merely by an online or telephonic evaluation of the patient. The regulations state that “[t]reatment and consultation recommendations made in an online setting, including issuing a prescription via electronic means, will be held to the same standards of appropriate practice as those in traditional in person settings.” The Texas regulation requires the physician to diagnose the patient using acceptable medical practices, discuss treatment options with the patient, and be available for follow up care, if necessary. At least two states require that a physician treating a patient via telemedicine keep that patient’s records confidential.

Id.; see also TEX. OCC. CODE ANN. § 111.003 (West 2017); ALA. ADMIN. CODE r. 540-x-9-.11 (2018); ALA. ADMIN. CODE r. 540-x-15-.01 (repealed 2015); 10 COLO. CODE REGS. § 2505-10, 8.200.3.B (LexisNexis 2018); FLA. ADMIN. CODE ANN. r 64B8-9.0141 (2018); FLA. ADMIN. CODE ANN. r 64B15-14.0081 (2018); FLA. ADMIN. CODE ANN. r 64B8-9.014 (repealed and reenacted as 64B8.9.0141 (2018)); GA. COMP. R. & REGS. 360-3-.07 (2018); MONT. ADMIN. R. 24.156.810 (repealed 2018); 22 TEX. ADMIN. CODE § 174.4 (2018); 22 TEX. ADMIN. CODE § 174.8 (2018).

75. FLEISHER & DECHENE, *supra* note 36, § 1.04(3)(b)(ii).

76. *Id.*

In November 2002, the Illinois Department of Professional Regulation ordered MyDoc.com, an Indiana-based medical consultation company, to stop treating and prescribing to online patients ‘without the benefit of prior physician-patient relationship or physical exam.’ The order also alleges that the company violated the Illinois Medical Practice Act by practicing medicine without a license.

Id. (citation omitted) (quoting Tyler Chin, *Firm Treating Strangers by Web Shut Out by Illinois Directive*, AM. MED. NEWS, Nov. 4, 2002, at 21).

77. See discussion *infra* Part III.B.2.

practice of medicine within its borders.⁷⁸ It should also be noted that a number of voluntary telehealth standards have been developed by various associations.⁷⁹

3. Informed Consent

“Informed consent refers to a process of communication between a patient and physician that results in the patient’s authorization or agreement to undergo a specific medical intervention.”⁸⁰ The AAP has identified the importance of informed consent in the use of telehealth; “[s]pecial consent may be necessary regarding the risks associated with the use of telemedicine, including involvement of nonmedical staff, recording of the interaction, and the vulnerability of the equipment to failure.”⁸¹ The failure of a physician to obtain proper consent can result in legal consequences.⁸² “In most states, a physician who fails to obtain informed consent from a patient may face liability for assault, battery, fraud, and/or negligence.”⁸³ The first case credited for the doctrine of informed consent is *Schloendorff v. Society of New York Hospital*.⁸⁴ States have developed different standards for evaluating the doctrine of informed consent, including the professional standard and the reasonable patient standard.⁸⁵ “Additionally, some states require the disclosure of specific factors including diagnosis, nature and purpose of treatment, potential risks and outcomes, skill or status risks, alternatives, prognosis without intervention, prognosis with intervention, and potential conflicts of interest as part of the informed consent process.”⁸⁶ While much more can be said, generally, about informed consent, the importance here is that the duty of a physician to obtain informed consent still applies in the telehealth context.⁸⁷ Several states have laws mandating

78. See FLEISHER & DECHENE, *supra* note 36, § 1.04(3)(b)(iii).

79. *Id.*

80. *Id.* § 1.04(3)(c)(i).

81. Burke Jr. et al., *supra* note 3, at e300.

82. FLEISHER & DECHENE, *supra* note 36, § 1.04(3)(c)(i).

83. *Id.*

84. 105 N.E. 92, 93 (N.Y. 1914), *overruled by* Bing v. Thunig, 143 N.E.2d 3 (N.Y. 1957).

In the case at hand, the wrong complained of is not merely negligence. It is trespass. Every human being of adult years and sound mind has a right to determine what shall be done with his own body, and a surgeon who performs an operation without his patient’s consent commits an assault, for which he is liable in damages.

Id. at 93.

85. FLEISHER & DECHENE, *supra* note 36, § 1.04 (3)(c)(i).

86. *Id.*

87. See *id.* § 1.04(3)(c)(ii)(A).

physicians practicing telehealth obtain informed consent.⁸⁸ While physicians may traditionally obtain informed consent orally, much more emphasis is made on getting written consent when medical care is delivered by means of telehealth, even to the extent that some states require consent to medical care be in written format when delivery involves telehealth.⁸⁹ Additionally, telehealth necessitates the possibility of having to obtain informed consent in more than one instance.⁹⁰ The introduction of technology into traditional health care delivery amplifies the significance of acquiring multiple informed consents.⁹¹

Moreover, the practice of telemedicine raises novel informed consent issues and more than one type of consent may be necessary. A practitioner should consider documenting consent for the general risks of a treatment or procedure, as well as special consent for the specific risks associated with the use of telemedicine for that treatment or procedure. Additionally, in the context of the interstate practice of telemedicine, both the teleconsulting physician's home state and the patient's home state may impose other specific informed consent duties on the physician.⁹²

It has also been stressed that as the use of technology in medical care is likely to be novel for a patient, it is critical that a physician is careful in explaining a number of things to the patient for consent.⁹³

Because the use of telemedicine will be a new experience for most patients, the treating physician is well advised to . . . explain to the patient the risks and benefits associated with receiving medical care from a telemedicine physician and/or through the use of telemedical technology. At a minimum, the patient should know that a telemedicine consult: (1) necessitates that the treating physician and the telemedicine physician discuss the patient's health information via telecommunication technology; (2) may require that non-medical staff be involved in the consult for the purposes of operating the technology, both at the treatment site and at the teleconsult physician's site; and (3) may be recorded by audio, video, or some other medium. . . . The patient also should be informed that, as with any technology,

88. *Id.*

89. *Id.*

90. FLEISHER & DECHENE, *supra* note 36, § 1.04(3)(c)(ii)(A).

91. *Id.*

92. *Id.*

93. *Id.*

telemedicine systems are vulnerable to failure and unauthorized access. . . . In addition, the patient should be advised of his or her rights to privacy and informed consent. Finally, the patient should be informed regarding the state(s) in which the telemedicine physician is licensed and should be advised of the procedure for follow-up. . . . Patients should be told up front which physician—the referring physician or the teleconsult physician—should be contacted if the patient has any follow-up questions.⁹⁴

The AAP also emphasized the importance of informed consent regarding possible technology failure in its 2015 technical assistance: “When any electronic device is used, plans should be in place to deal with problems such as system failure, loss of power, or loss of connectivity. Telemedical informed consent should include this potential problem.”⁹⁵ It is critical to know that, similar to licensure, informed consent will vary by state in terms of requirements and will often require an obtained oral consent to be captured in writing.⁹⁶

A number of special considerations come up in the area of informed consent involving pediatrics that were addressed by the ATA in its April 2017 Operating Procedures for Pediatric Health.⁹⁷ The ATA gives general guidance regarding informed consent as follows:

Prior to the initiation of a telemedicine encounter, except in the case of emergency, the provider or designee shall inform and educate the patient and/or legal representative about the nature of telemedicine service compared with in-person care, billing arrangements, and the relevant credentials of the distant site provider. The provider or designee should also include information about the timing of service, record keeping, scheduling, privacy and security, potential risks, mandatory reporting, and billing arrangements. Providers should consider whether consent for care is based on a specific condition, episode of care or a period of time. The information shall be provided in simple language that can be easily understood by the patient and/or legal representative. The provider shall follow state-specific requirements for the use of translation services for consent, and the provider may utilize translation services as necessary for consent in the absence of such state-specific requirements. These considerations are particularly important when discussing technical issues like encryption or the potential for technical

94. *Id.* (citations omitted).

95. Burke Jr. et al., *supra* note 3, at e299.

96. FLEISHER & DECHENE, *supra* note 36, at § 1.04(3)(c)(i).

97. AM. TELEMEDICINE ASS’N, *supra* note 1, at 3.

failure. As with in-person care, providers should also make an effort to obtain the assent of pediatric patients participating in telehealth services in a manner appropriate to their understanding.⁹⁸

Additionally, the ATA provides guidance on the age of consent for telehealth practice involving pediatric care.⁹⁹ While this becomes more of an issue concerning adolescence, it is something important to be mindful of with regard to informed consent in the context of telehealth as well as the applicable state laws.¹⁰⁰ Finally, the ATA provided guidance regarding emergency scenarios that may arise.¹⁰¹ The ATA articulated the following guidance for informed consent in emergency care in pediatrics using telehealth:

In certain limited emergency situations, as with in person care, the informed consent requirement may be waived. A health care professional's decision to treat combined with parental consent and patient assent, when appropriate, is the preferred scenario for the provider working in a medical emergency. When any one of those factors is absent or unclear, the health care provider shall be (1) knowledgeable of state and federal laws related to a minor's right, or lack thereof, to consent for testing and treatment and (2) prepared to confront the ethical challenges surrounding those same issues.¹⁰²

98. *Id.* at 4–5.

99. *Id.* at 5.

100. *See id.* at 4–5.

Age of Consent: The age at which a person may lawfully consent to care can vary with the health condition at issue, the person's state of residence, or the state where the patient is at the time of the telemedical visit. Minors in all states have the right to consent to testing and treatment for a sexually transmitted disease ("STD"). In many states, minors also have the right to consent to: (1) outpatient treatment for mental health issues; (2) prenatal care; (3) contraceptive services; and/or (4) alcohol and substance abuse. The age of consent for these various conditions can vary not only among states, but also within a given state. For example, in one state the age of consent is [twelve] years for treatment for an STD and [fourteen] years for substance abuse. The provider shall be aware of each state's rules in which the patient is physically located for that visit. In certain environments additional elements of consent may need to be considered.

Id. at 5.

101. AM. TELEMEDICINE ASS'N, *supra* note 1, at 5.

102. *Id.*

B. *Telehealth Practice Crossing State Lines*

1. Liability and Liability Insurance

Another issue that comes up in medical malpractice cases involves the issue of liability.¹⁰³ In the telehealth context, multiple providers have the potential to be involved, which leads to the question of who will ultimately be liable in the event that something goes wrong.¹⁰⁴ Although it is not groundbreaking for there to be multiple providers of medical care involved in a patient's treatment, the introduction of telehealth practice does create another wrinkle in the liability determination and one that apparently has not been addressed.¹⁰⁵

Although relevant cases have not yet arisen in the telemedicine context, general principles of joint and several liability should apply when apportioning liability between, for example, the local treating physician and the remote telemedicine specialist. However, as with many legal issues arising from telemedicine practice, apportionment of liability will be a matter of state law, and thus will vary from state to state.¹⁰⁶

Additionally, the AAP recognized the potential legal barrier—in terms of the insurance coverage—that someone practicing telehealth has when the telehealth physician's practice of medicine crosses state lines: "If a physician crosses a state line to practice telemedicine, he or she must determine whether malpractice insurance covers out-of-state telemedicine encounters and whether the coverage is sufficient for the distant state."¹⁰⁷ The issue of liability insurance will be important to companies that have developed specifically to be able to provide telehealth coverage across state lines.¹⁰⁸ Regardless, the issue of liability insurance may be even more complex generally for physicians practicing telehealth.¹⁰⁹

"Exacerbating concerns over potential telemedicine malpractice liability is the fact that medical malpractice liability insurance policies may not cover allegations of *telemedicine malpractice*. Yet, physicians who are

103. FLEISHER & DECHENE, *supra* note 36, § 1.04(2).

104. *See id.* at § 1.04(3)(d).

105. *See id.*

106. *Id.* § 1.04(3)(d).

107. Burke Jr. et al., *supra* note 3, at e300.

108. FLEISHER & DECHENE, *supra* note 36, § 1.04(3)(d)–(e).

109. *See id.* § 1.04(3)(e); Alicia Gallegos, *Telemedicine Poses Novel Legal Risks for Doctors*, *CARDIOLOGY NEWS* (Oct. 6, 2015), <http://www.mdedge.com/chestphysician/article/103362/health-policy/telemedicine-poses-novel-legal-risks-doctors>.

involved in the practice of telemedicine may be in particular need of such coverage.”¹¹⁰

Liability insurance may not cover telehealth practitioners in a number of other ways.¹¹¹ “For one thing, malpractice liability insurance policies may not cover telemedicine activities that cross state lines, or where the physician is found to be practicing telemedicine *without a license*.”¹¹² Another distinction that may be made in liability insurance coverage with regards to telehealth is whether the coverage pertains to actual medical care and/or technical error that may occur as a result of the use of technology.¹¹³ It is important that a physician consider this in ensuring proper liability coverage for telehealth practice.¹¹⁴

“A liability insurer also may not provide telemedicine coverage where the alleged malpractice arises from actions or omissions relating to the telecommunications rather than the medical aspects of the service. Accordingly, physicians should ensure that their malpractice liability insurance policy covers such telemedicine-related telecommunications errors.”¹¹⁵

It has been recommended that the physician practicing telehealth should be mindful of the extent of liability coverage and have the following items included in liability coverage.¹¹⁶

Specifically, a telemedicine physician’s medical malpractice liability insurance policy should contain an endorsement specifying that the policy covers medical malpractice and related claims arising from medical diagnosis, treatment, consultation and/or referral, including claims arising in connection with the use of telecommunications technology, and that such coverage is provided for every state the telemedicine physician *enters*.¹¹⁷

It is also likely that the telehealth practitioner will face increased costs associated with liability coverage.¹¹⁸ Another issue that is of significance in consideration of liability insurance for telehealth is technology failures.¹¹⁹ It is advised that the telehealth physician pursue

110. FLEISHER & DECHENE, *supra* note 36, § 1.04(3)(e).

111. *Id.*

112. *Id.*

113. *Id.*

114. Gallegos, *supra* note 109.

115. FLEISHER & DECHENE, *supra* note 36, § 1.04(3)(e).

116. *Id.*

117. *Id.*

118. *Id.*

119. *Id.*

coverage for equipment failure, if at all possible, and consider other options for coverage if that is unavailable.¹²⁰

Further, telemedicine adds the additional risk of equipment failures and transmission errors. Because of these unresolved issues, telemedicine practitioners are likely to find that, if in fact they can obtain comprehensive telemedicine coverage, it is likely to come at a significantly higher price. If a malpractice insurer is unwilling to cover failures of telecommunications problems, telemedicine equipment failure or similar *non-medical* claims, a telemedicine practitioner may wish to seek a general negligence insurance policy to cover such failures.¹²¹

Thus, issues of liability and liability coverage are extremely important for the physician practicing telehealth—in particular, due to the fact that practitioners may practice across state lines and that the introduction of technology into medical care requires extra layers of protection to account for the possibilities of technological, as well as equipment, malfunctions.¹²²

2. Licensure Limitations and State Telehealth Laws

One of the biggest issues for startup businesses that endeavor to provide telehealth services is that state laws will often limit the ability to cross state lines due to licensure.¹²³ Because of differing telehealth laws, a telehealth startup may need to have physicians licensed in multiple states.¹²⁴ The complexity that exists due to the lack of a national telehealth law is explained by the AAP as follows:

However, the use of interstate telemedicine often requires participants to be licensed in both states, which can be a formidable barrier, particularly for telemedicine providers who work in multiple states. Many states have recognized the value of allowing out-of-state physicians to share their knowledge and expertise and have therefore granted specific exceptions to their licensing rules. Nevertheless, all states still have the authority to license and regulate the practice of medicine within their borders, and physicians who practice telemedicine must carefully follow

120. FLEISHER & DECHENE, *supra* note 36, § 1.04(3)(e).

121. *Id.*

122. *Id.*

123. Burke Jr. et. al., *supra* note 3, at e300–01.

124. *Id.*

the rules in each state that they *enter* electronically to provide medical care.¹²⁵

The AAP has pointed to several cases that have been litigated that emphasize the significance of state control and regulation over the ability to practice medicine within its state's borders, although it is done by a physician remotely.¹²⁶

C. *Equipment*

1. Standards of Practice

In addition to the state laws regulating telehealth practice as described above and case law that has developed on these issues, a number of standards or guidelines have been developed with regard to the oversight of equipment and technologies being used in the practice of telehealth—"in an effort to assure the clarity, reliability, interoperability, and interconnectivity of telemedicine equipment."¹²⁷ An example of such standards are those used for digital imaging and the equipment that stores this information.¹²⁸ The ATA's 2017 Operating Practices for Pediatric Health has a number of provisions for guidance specific to equipment.¹²⁹ An important first provision acknowledges that the equipment used for telehealth in pediatrics has to be such that it is appropriate for the child based on a number of factors: "Equipment used for provision of pediatric telehealth services should be appropriate to the age, size, and developmental stage of the child, including size, comfort, accuracy, and validity of measurements."¹³⁰ Another notable provision by the ATA is the need for someone to be present who can properly operate the equipment and that the telehealth practitioner appropriately evaluates whether the images provided by the technology are adequate for diagnosis purposes.¹³¹

For any telehealth encounter, there shall be at least one party to the encounter who is capable of operating all involved equipment in accordance with the specifications for the use of that equipment. Providers should be aware that the use of some equipment in children may pose unique challenges relating to

125. *Id.*

126. *Id.* at 301.

127. FLEISHER & DECHENE, *supra* note 36, § 1.04(4)(a).

128. *Id.*

129. AM. TELEMEDICINE ASS'N, *supra* note 1, at 10.

130. *Id.*

131. *Id.*

patient cooperation, size, comfort, and technique, and should be comfortable with the use of all involved equipment in children. Providers shall determine whether the quality of the device output and displayed images are sufficient for the diagnosis and/or management of the patient's condition.¹³²

Further, the ATA advises planning due to any technological or equipment failure: "Telehealth providers shall have a technical support plan and contingency plan in place in the event of technology or equipment failure during an encounter."¹³³

Of particular interest regarding equipment are the latest technological developments for telehealth involving children, such as the Tyto Care home kit described at the beginning of this Article; however, the ATA has refrained from providing any direct guidance on these technologies, finding them too novel to adequately assess them.¹³⁴ This is according to the ATA's 2017 Operating Procedures for Pediatric Health.¹³⁵

"Peripheral examination devices designed for home use by parents or other nonclinical caregivers are an emerging technology. However, further study of the accuracy and effectiveness of these devices is required before any recommendations can be made regarding their use."¹³⁶ With the growing use of such technologies, the ATA will likely develop guidelines regarding these items, as well.¹³⁷

2. Who is Liable?

Besides the standards for use of equipment, it has already been mentioned that a physician practicing telehealth may be subject to liability for malfunctioning equipment as it has been advised that telehealth physicians get liability insurance to cover the possibility of equipment failure.¹³⁸ The AAP pointed out in its guidance regarding pediatrics: "The liability for technology failures may be shared by all involved parties. A supervising physician may be at risk for equipment failure, although the [ATA] has no record of any such lawsuit."¹³⁹ A physician using telehealth to deliver medical care may be subject to liability in a number of instances

132. *Id.*

133. *Id.*

134. *See* AM. TELEMEDICINE ASS'N, *supra* note 1, at 3; Raphael, *supra* note 7.

135. AM. TELEMEDICINE ASS'N, *supra* note 1, at 3.

136. *Id.*

137. *See id.*

138. FLEISHER & DECHENE, *supra* note 36, § 1.04(4)(b); Burke Jr. et al., *supra* note 3, at e300.

139. Burke Jr. et al., *supra* note 3, at e300.

including: “[A] physician’s negligent selection of telemedicine equipment, misuse of the equipment, or misdiagnosis or mistreatment based on faulty data received from the equipment.”¹⁴⁰ However, if the particular defect of the equipment is latent, the telehealth physician will not be liable.¹⁴¹

While physicians and health care entities may be held liable for negligence in the care, maintenance, or use of telemedicine equipment, providers will not likely be liable for latent defects. However, plaintiffs who are injured by telemedicine equipment that is defective and unreasonably dangerous may sue the manufacturers and distributors of the equipment under a theory of strict liability.¹⁴²

The rationale behind this is that the manufacturer or seller is in the best position to bear financial responsibility based on its relationship to the public.¹⁴³ A strict liability claim involving a latent defect may take the following forms:

A strict liability claim against a manufacturer could arise from a misdiagnosis based upon defective machinery that produced, for example, defective image resolution, sound quality, speed of encoding, or delivery of data. Under a theory of strict liability, manufacturers and distributors of defective and unreasonably dangerous telemedicine products may be jointly and severally liable for injuries to the patient caused by such products unless one defendant party can prove that its co-defendant was solely at fault. One hundred and sixty [h]ospitals and practitioners, in general, are not subject to strict liability claims, since they are not engaged in the business of selling or supplying products but instead provide professional services.¹⁴⁴

Understanding the potential liability that a telehealth practitioner may be subjected to by the use of equipment is an important consideration in entering into this area of practice.¹⁴⁵

140. FLEISHER & DECHENE, *supra* note 36, § 1.04(4)(b).

141. *Id.*

142. *Id.* at § 1.04(4)(c).

143. *Id.*

144. *Id.*

145. *See* FLEISHER & DECHENE, *supra* note 36, § 1.04(4)(c).

3. FDA Regulation and Telehealth

In addition to the issues already discussed regarding equipment, a substantial portion of regulation may occur involving the Food and Drug Administration (“FDA”), which can be implicated in the area of telehealth due to the use of both equipment and technology.¹⁴⁶ Specifically, the FDA is implicated in the oversight of medical devices which are those “intended for use in the diagnosis . . . treatment, or prevention of disease.”¹⁴⁷ Device is defined under the Federal Food, Drug, and Cosmetic Act as:

[A]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is: (1) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them; (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.¹⁴⁸

Overall, there have been specific barriers to approval of medical devices in pediatrics.¹⁴⁹ The FDA has specified regulatory authority over telehealth services in a number of categories.¹⁵⁰ The following is the guidance provided with regard to technologies as they relate to telehealth for FDA regulation.¹⁵¹

Given the breadth of that definition, it is not surprising that telemedicine systems—and many of their components—fall within the regulatory purview of the FDA. The FDA Working Group on Telemedicine has defined *clinical telemedicine* as the “delivery and provision of health care and consultative services to individual

146. *Id.* at § 1.04(4)(c)–(d).

147. *Medical Device Overview*, FDA, <http://www.fda.gov/forindustry/importprogram/importbasics/regulatedproducts/ucm510630.htm> (last updated Sept. 14, 2018).

148. 21 U.S.C. § 321(h)(1)–(3) (2012).

149. Melissa Jenco, *AAP Brings Need for Pediatric Medical Devices to Forefront*, AAP NEWS (Aug. 17, 2018), <http://www.aapublications.org/news/2018/08/17/fdadevices081718>.

150. FLEISHER & DECHENE, *supra* note 36, § 1.04(4)(d).

151. *Id.*

patients and the transmission of information related to care, over distance, using telecommunications technologies,” including the following activities: (1) [d]irect clinical, preventive, diagnostic, and therapeutic services and treatments impacting the clinical care of a specific patient; (2) consultative and follow-up services; (3) remote monitoring, including the remote reading and interpretation of patient’s procedures; (4) rehabilitation services; and (5) patient education delivered in the context of delivering health care to individuals. The FDA has determined that devices used in activities [one] through [four] are subject to [Center for Devices and Radiological Health] (“CDRH”) regulatory authority, and those related to activity [five] are integral to that authority when the *education* delivered is medical device labeling information.¹⁵²

The FDA’s CDRH plays a major role in the approval of medical devices that are used in the delivery of medical services using telehealth.¹⁵³

A 1996 Report of the FDA noted CDRH’s responsibility for ensuring the safety and efficacy of the medical devices used in telemedicine systems, and described its telemedicine-related activities, including pre-market review of telemedicine devices, post-market surveillance, quality systems regulations (good manufacturing practices), control, and standards development. The FDA is likely to have the greatest impact on the development and future use of telemedicine technology through its premarket review activities. Many of the telemedicine devices cleared for marketing by the FDA in recent years have been classified into Class II. Manufacturers of Class II medical devices must meet performance standards and/or comply with the requirements of [s]ection 510(k) of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360(k) and the regulations promulgated thereunder. Once a medical device has been cleared for marketing, any modification to the device made by the manufacturer that “could significantly affect the safety [and] effectiveness of a device,” such as an alteration in the device’s indications for use, may trigger further review by the FDA.¹⁵⁴

152. *Id.* (citations omitted).

153. *Id.*; *Telemedicine Related Activities*, FDA: CTR. FOR DEVICES & RADIOLOGICAL HEALTH (July 11, 1996), [<http://web.archive.org/web/19961019084/http://www.fda.gov/cdrh/telemed.html>].

154. FLEISHER & DECHENE, *supra* note 36, § 1.04(4)(d) (citation omitted) (quoting 21 C.F.R. § 807.81 (2018)); *see also* Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, § 1, 52 Stat. 1040, 1040 (1938); 21 U.S.C. § 360k (2012); *Telemedicine Related Activities*, *supra* note 153.

There are a variety of other ways the FDA is involved in regulation concerning telehealth, which in and of itself could likely be more fully explored in a complete article of its own.¹⁵⁵ Other areas of regulation include: “radiology devices related to medical image communication, storage, processing, and display,” medical devices used by patients that involve monitoring including implanted pacemakers that allow monitoring of the patient’s cardiac data by transmission of the data directly from the device to the physician’s office, robotic devices, and mobile medical applications used with smartphones and tablets.¹⁵⁶ It should be noted that medical applications can also be subjected to regulation by the Federal Trade Commission (“FTC”).¹⁵⁷

Another twist in the area of regulation by the FDA is an understanding that there are differences between regulation of the manufacturer of a medical device as opposed to regulation of a physician who chooses to use a medical device to deliver medical services using telehealth.¹⁵⁸ In fact, there has been recognition of this distinction to the extent of indicating that the physician’s actual use of a device is not at issue when it comes to FDA regulation.¹⁵⁹

While FDA’s regulatory interest in telemedicine technology has obvious implications for telemedicine equipment manufacturers, its impact on physicians, hospitals and other *users* of the equipment is less than clear. The issue of whether a manufacturer may distribute a medical device is a separate matter from the issue of whether a physician who receives the device—or manufactures it himself—may use it. More specifically, physicians’ decisions to use a particular telemedicine device within the scope of their medical practice may be implicitly exempt from regulation under the federal Food, Drug, and Cosmetic Act. Although there is no express provision in the Act, both the courts and the FDA have recognized that the Act was never intended to limit a physician’s ability to treat patients. In September 1996, FDA officials testified before Congress that “once a product is approved for marketing for a specific use, FDA generally does not regulate how, and for what uses, physicians prescribe that [product].”¹⁶⁰

155. FLEISHER & DECHENE, *supra* note 36, §1.04(4)(d).

156. *Id.*

157. *Id.*

158. *Id.*

159. *See id.*

160. FLEISHER & DECHENE, *supra* note 36, § 1.04(4)(d) (citations omitted) (quoting *Off-Label Drug Use and FDA Review of Supplemental Drug Applications: Hearing Before the Subcomm. on Human Res. & Intergovernmental Relations of the Comm. on Gov’t*

Additionally, modifications of devices by physicians have also been typically free of FDA regulation.¹⁶¹ “As a general rule, unless the physician is involved in active marketing or commercialization of the modified device, particularly in interstate commerce, the practice-of-medicine doctrine should effectively immunize the physician from regulation by the FDA.”¹⁶²

Finally, it is important to point out that there are possible consequences of using unapproved devices for telehealth.¹⁶³ Of critical consideration, “even if a physician’s use of an unapproved—or a modified—telemedicine device does not run afoul of the Food, Drug, and Cosmetic Act, it would no doubt greatly increase the risk of medical malpractice liability should a patient be injured in connection with the use of the device.”¹⁶⁴ Additionally, there are potential fraud concerns that arise when reimbursement is being sought for telehealth services and an unapproved device is used.¹⁶⁵

D. *Security*

Another potential legal issue that undoubtedly comes into play with the introduction of technology into health care is a patient’s personal information and how this information is protected.¹⁶⁶ In 2015, the AAP recognized this as one of the potential legal barriers in the practice of telehealth in pediatrics: “Security policies and procedures for telemedicine systems must be designed and operated in compliance with the final [Health Insurance Portability and Accountability Act] directive on the subject, titled ‘Standards for Privacy of Individually Identified Health Information’—published in 2002, and applicable state laws governing patient confidentiality.”¹⁶⁷ Similarly, the ATA has advised of the importance of

Reform & Oversight House of Representatives, 104th Cong. 61 (1996) (statement of Michael Friedman, Deputy Comm’r for Operations, FDA).

161. *Id.*

162. *Id.* (citing John J. Smith, *Physician Modification of Legally Marketed Medical Devices: Regulatory Implications Under the Federal Food, Drug, and Cosmetic Act*, 55 FOOD & DRUG L.J. 245, 254 (2000)).

163. *Id.*

164. *Id.*

165. FLEISHER & DECHENE, *supra* note 36, § 1.04(4)(d). “Moreover, a physician or hospital’s requests for reimbursement for telemedicine services involving the use of an unapproved medical device may raise false claims or fraud and abuse concerns.” *Id.*

166. *See* Burke Jr. et al., *supra* note 3, at e300.

167. *Id.*; *see also* Standards for Privacy of Individually Identifiable Health Information, 67 Fed. Reg. 53182 (Aug. 14, 2002) (codified at 45 C.F.R. pts. 160, 164).

adherence to state and federal laws regulating the security of this information in its 2017 Operating Procedures.¹⁶⁸

Providers shall comply with all federal and individual state laws and regulations regarding child privacy, including but not limited to [the Children’s Online Privacy Protection Act], [the Health Insurance Portability and Accountability Act], [the Health Information Technology for Economic and Clinical Health Act] and [the Family Educational Rights and Privacy Act]. All existing laws and regulations regarding patient privacy and confidentiality, including laws pertaining to protection of privacy when minors consent for their own health care, apply to telehealth encounters just as they do for traditional encounters; however, there may be additional language specifically for security of patient privacy and confidentiality when care is delivered via telehealth.¹⁶⁹

Further, the ATA advises that the provider should always ensure that a secure connection is maintained throughout the duration of the telehealth encounter.¹⁷⁰ In the event the provider becomes aware that there is a security concern which may leave private information susceptible to being compromised, the ATA advises termination of the encounter immediately.¹⁷¹ Recording of a telehealth encounter creates additional special considerations.¹⁷² If a telehealth encounter is recorded, the telehealth practitioner must be aware of applicable state laws for recording these encounters and is required to notify the patient—or in the case of a child, the child’s guardian or legal representative—that the encounter is being recorded, as well as to obtain consent prior to recording the encounter.¹⁷³ If a telehealth encounter is recorded, a copy is also to be timely made available to the patient, if requested, and in accordance with any other applicable policy determinations regarding recordings.¹⁷⁴

Another area of importance in security involves the transfer of digital images taken in the course of the patient’s care to ensure that such images are properly maintained and transmitted safely by means of a secure connection.¹⁷⁵ The ATA cautions particular care with regard to children in this area: “The transmission of pediatric patient images, in particular,

168. AM. TELEMEDICINE ASS’N, *supra* note 1, at 4.

169. *Id.*

170. *Id.*

171. *Id.*

172. *Id.*

173. AM. TELEMEDICINE ASS’N, *supra* note 1, at 4.

174. *Id.*

175. *Id.*

represents a special situation which is subject to numerous state and federal regulations regarding both private health information and child privacy.”¹⁷⁶

Thus, it is critical that a telehealth practitioner is mindful of both state and federal laws regarding these issues of security.¹⁷⁷

IV. THE PROS AND CONS OF TELEHEALTH USE FOR PEDIATRIC CARE

Like any new advancement in a particular field, the pros and cons of the use of telehealth for pediatric care are being scrutinized as a means of providing access to traditional health care services.¹⁷⁸

A. *Benefits of Telehealth in Pediatrics*

One of the major benefits of the use of telehealth in pediatrics is the access to care that is created for children who would otherwise be disadvantaged by distance/location or specialized health care needs.¹⁷⁹

There is significant disparity in the geographic distribution of pediatric physicians across the country, resulting in many underserved regions. Underserved communities are most commonly found in rural regions but can include suburban and urban settings. This maldistribution of workforce results in differential access and is at least partly to blame for differential health outcomes between rural and nonrural populations, particularly for those children with special health care needs. The literature shows that access barriers related to distance can be partly addressed with the use of telemedicine technologies, which can also minimize burdens of parents and other caregivers missing work, children missing school, and costs and risks associated with travel.¹⁸⁰

The availability of these services to children who would otherwise not have them also leads to a greater quality of care.¹⁸¹

Another benefit of the use of telehealth in pediatrics is that it can increase the expertise of pediatricians which, in turn, can increase the amount of time pediatricians have for treating additional children resulting in greater

176. *Id.*

177. *Id.*

178. See James P. Marcin et al., Comm. on Pediatric Workforce, *The Use of Telemedicine to Address Access and Physician Workforce Shortages*, 136 PEDIATRICS 202, 203–06 (2015).

179. *Id.* at 203, 205.

180. *Id.* at 203.

181. *Id.* at 204.

efficiency of pediatric care.¹⁸² As has been acknowledged, there is a shortage of pediatricians, and the ability of the current pediatricians to be able to care for more children is of vital importance to this specialty.¹⁸³

Additionally, it has been suggested that the use of telehealth in pediatrics can improve quality of care.¹⁸⁴ The AAP has cited multiple reasons why this is the case.¹⁸⁵

First, by increasing health care access for children, particularly for children living in rural communities, the use of telemedicine technologies can help reduce missed appointment rates, increase adherence to recommended therapies, and help ensure the appropriate frequency of recommended physician visits. Second, studies have shown that telemedicine can enhance both comfort and facility in managing specific medical subspecialty issues.¹⁸⁶

Further, the use of telehealth can not only improve communications between the pediatrician and patient/family but can also lead to ensuring more comprehensive care than the patient would have experienced otherwise.¹⁸⁷

B. *Disadvantages of Telehealth in Pediatrics*

Perhaps the biggest challenge facing telehealth practice involving pediatrics is that choosing to develop a startup—and what becomes a stand-alone practice—is not seen as being compatible to the current best practices for pediatrics, especially if it is truly divorced from in-person care.¹⁸⁸ Specifically, the AAP has cautioned that the model embraced by these types of telehealth service providers is contrary to the prevailing model for providing pediatric services.¹⁸⁹

The use of telemedicine care by virtual health care providers, such as those linked to retail-based clinics, entrepreneurs, or insurers whose business model is to provide health care services to patients via smart phone, laptop, or video-consult kiosk without a previous physician-patient relationship, previous medical history, or hands-on physical examination, other than what can be accessed via the

182. *Id.* at 203.

183. *See* Marcin et al., *supra* note 178, at 203.

184. *Id.* at 204.

185. *See id.*

186. *Id.*

187. *Id.* at 203.

188. Marcin et al., *supra* note 178, at 205.

189. *Id.* at 205–06.

technology, can undermine the basic principles of the [Patient-Centered Medical Home] model.¹⁹⁰

According to the AAP, “[i]n isolation, the use of virtual telemedicine care represents the antithesis of the medical home model of quality pediatric care: [C]are that is patient-centered, comprehensive, team-based, coordinated, accessible, and focused on quality and safety.”¹⁹¹ Additionally, the AAP raises a number of issues with regard to providing pediatric care in this way.¹⁹²

Virtual health care services are provided episodically and are lacking the essentials of the patient’s medical record. Increasing fragmentation of care is the result, which leads to incomplete or redundant services and wastes health care dollars. More importantly, virtual telemedicine care in isolation does not provide timely and comprehensive follow-up with the patient and the medical home.¹⁹³

The AAP cautions parents against relying on a telehealth model of care, arguing that while it may sound appealing for a variety of reasons, the model does not promote the best interests of the child’s health care.¹⁹⁴

A major disadvantage of having a telehealth practice are the significant costs associated with such a practice.¹⁹⁵ The AAP has described the extent of these costs as follows:

The implementation of telemedicine requires an initial financial investment in equipment, software, and telecommunications. There are often ongoing costs associated with maintenance of technology and personnel costs associated with training and technical support. These costs can represent a significant barrier for pediatric physicians and other clinicians who care for children. The underserved practices and locations most likely to benefit from telemedicine are probably those least likely to afford the initial financial investment or ongoing maintenance.¹⁹⁶

190. *Id.* at 205.

191. *Id.*

192. *Id.* at 206.

193. Marcin et al., *supra* note 178, at 206.

194. *Id.* at 206. “Although such novelty care appeals to parents because it can be faster, more convenient, and more affordable than an office visit, the loss of continuity of care, quality of care, and patient safety shows why this telemedicine care model should not be embraced.” *Id.*

195. *Id.*

196. *Id.*

This will be particularly burdensome to a telehealth startup which does not have the luxury of any connection to a hospital or medical facility to potentially assist in this type of financial investment.¹⁹⁷

Another challenge facing telehealth practitioners which has already been substantially addressed by the various legal issues is the fact that telehealth practice laws vary by state.¹⁹⁸ “All physicians practicing intra- and interstate telemedicine must comply with state licensing and other practice rules in every state in which they practice, in person and via telemedicine.”¹⁹⁹

An additional cost that must be inevitably born by the telehealth practitioner is to cover the cost of medical malpractice insurance, as previously discussed.²⁰⁰

Another potential barrier with additional costs associated with care delivery with the use of telemedicine is related to malpractice insurance. Malpractice insurance most often covers in-person care and should cover care delivered to patients in remote health care facilities and possibly in other states. Physicians should review their current malpractice policy to be certain that the appropriate malpractice coverage that includes the treatment of patients using telemedicine is included.²⁰¹

This type of medical malpractice coverage will be extremely important for a telehealth practitioner that decides to practice telehealth in multiple states.²⁰² As the telehealth practitioner engages in practice in multiple states, the practitioner will be subjected to the applicable telehealth laws in all of those states, thereby creating a greater chance for malpractice to occur as well as the liability that can attach for technology malfunctions or errors.²⁰³

V. CONCLUSION

With the continued shortage of pediatricians and the ability of technology to allow parents to access health care services for their children in a variety of situations—from those who are living in rural areas to those

197. See Marcin et al., *supra* note 178, at 206.

198. *Id.*

199. *Id.*

200. *Id.*

201. *Id.*

202. See Burke Jr. et al., *supra* note 3, at e300.

203. *Id.*; see also FLEISHER & DECHENE, *supra* note 36 § 1.04(4)(c).

children who have special needs which makes a doctor's house call virtually a less stressful scenario—telehealth offers a variety of benefits to ensure children have access to and receive necessary health care.²⁰⁴ However, it is also clear that for any pediatrician or physician to decide to engage in telehealth services to provide pediatric care, it is critical that he or she is aware of the possible legal issues, consequences, and role that state laws, in particular, will play in impacting any sort of telehealth practice.²⁰⁵ Further, specific guidelines, such as those provided by the AAP and ATA, are essential for the specialized nature of pediatrics in treating and serving children as a population.²⁰⁶

Additionally, the development of technologies for use by parents in the home to assess their children are still in their infancy, making it difficult for entities like the ATA to take a position on their use and effectiveness in providing access to health care for children, or providing guidance otherwise on the use of such technologies.²⁰⁷ Overall, technologies for use in pediatrics have been slow to develop and gain approval with the FDA, generally.²⁰⁸ It is expected that guidance on these newer in-home technologies will develop over time, as the evidence of their use becomes more prevalent.²⁰⁹ However, those who manufacture and sell these products need to be aware of the regulations they will be subjected to, including approval by the FDA for medical devices, liability for latent defects, and other security regulations.²¹⁰

For entrepreneurs in telehealth to be successful in pediatrics, they are going to need to develop innovative ways of ensuring that this vulnerable population does not inevitably experience a greater hindrance to receiving adequate health care by splintering the care, which creates gaps between the telehealth services they provide and health care provided by the child's primary pediatrician—assuming the child has an established pediatrician.²¹¹ A disruption of care of this nature is discouraged by the AAP guidance for pediatric care.²¹² An independent telehealth provider of pediatric care can and should be done through coordination with the child's primary pediatrician—if the child has one—and immediate follow-up to ensure medical records are not only consulted, but updated to reflect the telehealth

204. Marcin et al., *supra* note 178, at 203.

205. See Burke Jr. et al., *supra* note 3, at e300.

206. See AM. TELEMEDICINE ASS'N, *supra* note 1, at 1–3.

207. *Id.* at 3.

208. Jenco, *supra* note 149.

209. See *id.*

210. See FLEISHER & DECHENE, *supra* note 36, § 1.04(4)(c); Burke Jr. et al., *supra* note 3, at e299; *Medical Device Overview*, *supra* note 147.

211. See Burke Jr. et al., *supra* note 3, at e296.

212. See *id.*

appointment and treatment.²¹³ In the alternative, if a stand-alone telehealth practitioner is going to engage in pediatric service, it will need to make fundamental operational changes by having a face-to-face with the child from the beginning and as a regular part of continued care, so as to discourage reliance on episodic telehealth visits which is currently discouraged by best practice standards in pediatrics, as detailed by the AAP.²¹⁴ If the doctor makes house calls again—now virtually—it must be in a way that ultimately benefits the long-term care and well-being of the child, rather than simply providing episodic care that disrupts the continuity of care for the child.²¹⁵

213. See Marcin et al., *supra* note 178, at 204, 206.

214. See Burke Jr. et al., *supra* note 3, at e296, e300; Marcin et al., *supra* note 178, at 206.

215. See Burke Jr. et al., *supra* note 3, at e296.