

COMMENTS

AN APP A DAY KEEPS THE DOCTOR AWAY: LIABILITY ANALYSIS OF THE BREAST CANCER ALLY APP

*Alexandra Regan Abernethy**

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I. INTRODUCTION

As technology develops, the medical community around the globe attempts to incorporate these advancements. Medical technology is used by physicians in a variety of ways to better inform patients. Telemedicine devices such as websites and mobile apps have been among these medical technology developments.² One recent development in medical technology is the Breast

* University of Wisconsin Law School, J.D. Candidate 2018.

Cancer Ally app. The Breast Cancer Ally app, created by the University of Michigan, has several symptom trackers and diagnostic tools for patients undergoing treatment for breast cancer that expose the creators of the app to significant liability.³ The Breast Cancer Ally app as is exposes the creators to liability for tort law issues of physician licensing, medical malpractice, and informed consent.

When a user of the app follows the treatment recommendations or relies on the expertise of the app for symptom management, the app is then acting as a medical professional providing specialized knowledge. With the specialized knowledge comes liability for when the suggestions prove ineffective and potentially delay the correct course of treatment or management. In addition to the professional liability issues, there are also information security concerns. The security issues arise when individuals disclose confidential medical information, which is then released in a database breach.⁴ Without more precautions taken to protect user medical and personal information, there may be information security suits from users of the apps, especially given the sensitive nature of the medical information disclosed.

II. BACKGROUND

Physicians are constantly seeking new ways to keep their patients involved in the medical care process and on top of their required treatments. The doctors at the University of Michigan have designed an app for mobile devices called the Breast Cancer Ally.⁵ Doctors prescribe the app to patients who were recently diagnosed with breast cancer by one of the University of Michigan physicians.⁶ This specific technology has several functions for patients including daily reminders, symptom tracker, and communication between physician and patient.⁷ Additionally, the app covers all stages of treatment including, diagnosis, surgery, chemotherapy and radiation.⁸

2. Laura Landro, *Doctors Prescribe New Apps to Manage Medical Conditions*, 2015 THE WALL STREET JOURNAL ONLINE, Nov. 9, 2015, <https://www.wsj.com/articles/doctors-prescribe-new-apps-to-manage-medical-conditions-1447094444> [<https://perma.cc/MC44-SZGR>].

3. Nicole Fawcett, *U-M Launches New App for Breast Cancer Patients*, U-M COMPREHENSIVE CANCER CENTER (Nov. 10, 2015, 9:45 AM), <http://www.mcancer.org/news/archive/u-m-launches-new-app-breast-cancer-patients> [<https://perma.cc/44N7-U3NF>].

4. Gartner, Inc., *Gartner Says More Than 75 Percent of Mobile Applications Will Fail Basic Security Tests Through 2015*, GARTNER PRESS RELEASE (Sept. 14, 2014), <http://www.gartner.com/newsroom/id/2846017> [<https://perma.cc/6AZY-YQQG>].

5. Fawcett, *supra* note 2.

6. *Id.*

7. *Id.*

8. *Id.*

A. *Background of the Breast Cancer Ally App*

1. Goals of the App Creators

Several factors motivated the doctors to develop this new patient care technology, specific to breast cancer patients. The developer of the app, University of Michigan Medical School faculty, Michael Sabel, M.D., stated:

We went to each specialist involved in breast cancer care and asked, ‘If you could have someone follow your patients after they left the office or the hospital, what would you want to remind the patient or encourage the patient to do?’ We then went to our patients and asked them a similar question: ‘What are the things you need after you leave us?’⁹

The physicians needed technology to assist breast cancer patients in following through with the various treatments prescribed to them. As it was not possible for physicians to follow their patients into their homes, this mobile app was the next best step.

Concern over conflicting outside information also motivated the creators of the Breast Cancer Ally app. One of the creators explained, “[w]ith the overwhelming volume of medical information available online, patients are increasingly getting medical information from outside sources.” This information can be inaccurate and incompatible with the patient’s medical situation. In addition, it can lead to a lack of communication between patient and physician.”¹⁰ If the prescribing physician is able to communicate with the patient through telemedicine, it could decrease the desire of the patient to turn to outside information. In this sense, the purpose of the app is to better control the information that the breast cancer patient is relying on.

The Breast Cancer Ally app has three main goals. The creators intended for the app to help patients better understand their diagnosis, make informed decisions about treatment, and learn about resources available both during and after treatment.¹¹ Essentially the creators want to remind the patients of important educational information, but also make recommendations that are tailored to the individual patient.¹²

9. Jan Dizon, *Breast Cancer Care: Now There’s an App for That*, TECH TIMES (Dec. 22, 2015), <http://www.techtimes.com/articles/118913/20151222/breast-cancer-care-now-theres-an-app-for-that.htm> [<https://perma.cc/P3TU-4CPN>].

10. MEDICAL SCHOOL AT UNIVERSITY OF MICHIGAN, *U-M Breast Cancer Ally*, https://innovation.medicine.umich.edu/portfolio_post/u-m-breast-cancer-ally/ [<https://perma.cc/F85Z-HREY>] (last visited Nov. 19, 2017).

11. *Id.*

12. *See* Fawcett, *supra* note 2.

2. Symptom Tracker

The first of three key functions of the Breast Cancer Ally app is the toxicity tracker.¹³ This allows patients to input symptoms they are experiencing, and obtain specialized recommendations based on those symptoms.¹⁴ The mobile application website explains, “[t]his can help patients manage the side effects of chemotherapy. The app asks several questions each day about potential side effects and delivers specific information based on the patient’s answers.”¹⁵ These symptoms can be updated throughout the course of treatment, leading to a continued notification process.¹⁶

The Breast Cancer Ally app allows for several categories of treatment symptoms to be monitored. These key symptom categories are: pain, shortness of breath, skin problems, fever, fatigue, nausea and vomiting, or headaches.¹⁷ These provided recommendations can be at home care recommendations based on the information collected by the app, as well as when to call-in information.¹⁸ The “when to call” information prompts the patient to when it is time to notify their physician directly.¹⁹

3. Daily Reminders

The second key function of the Breast Cancer Ally app allows for patients undergoing treatment for breast cancer to obtain daily reminders regarding their treatment plan.²⁰ These reminders are specialized to the patient depending on their diagnosis and course of treatment.²¹ Patients using the Breast Cancer Ally app receive daily reminders for a variety of treatment steps including tube drainage, chemotherapy appointments, and physical therapy.²² An example of a reminder that an actual user of the Breast Cancer Ally app could receive pertains to surgery follow-up. The app creators explain:

Patients having surgery to remove axillary lymph nodes in their underarm may have difficulty with shoulder movement afterward. This can be avoided by doing daily shoulder exercises. Currently, patients receive a handout describing the

13. *Id.*

14. *Id.*

15. *Id.*

16. *Id.*

17. *Id.*

18. *Id.*

19. *Id.*

20. UNIV. OF MICH. HEALTH SYS. COMPREHENSIVE CANCER CTR., *Breast Cancer Ally*, <http://www.mccancer.org/breast-cancer/resources/breast-cancer-ally> [https://perma.cc/CN23-RH2J] (last visited Nov. 19, 2017).

21. Fawcett, *supra* note 2.

22. *Id.*

exercises. With the mobile app, patients get a daily reminder as well as instructions. The app can also track their progress.²³

The daily reminders portion of the Breast Cancer Ally app also provides the patients with a daily calendar full of appointment reminders.²⁴

4. Communication with the Prescribing Physician

The final key function of the Breast Cancer Ally app is communication between the breast cancer patient and the prescribing physician.²⁵ This allows patients to communicate directly with the physicians through an internal communication network provided within the app.²⁶ Breast Cancer patients have the ability to ask any questions or discuss any concerns with their doctors, without having to go through the traditional in-person office visits or phone calls.

Doctors are also able to communicate with their patients through educational tools provided in the Breast Cancer Ally app.²⁷ In contrast to the educational health tools provided on the internet more generally, the educational tools provided in this University of Michigan app are specially tailored for the individual patients.²⁸ This weeds out any unnecessary information, and allows the educational information to be more relevant and relatable to the patient using the app.

B. Background of Telemedicine Generally

Telemedicine is defined as:

The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, [and] research and evaluation, . . . all in the interests of advancing the health of individuals and their communities.²⁹

23. *Id.*

24. *See* UNIV. OF MICH. HEALTH SYS. COMPREHENSIVE CANCER CTR, *supra* note 19; Fawcett, *supra* note 2.

25. Fawcett, *supra* note 2.

26. *Id.*

27. *See id.*

28. *See* Brian Wu, *The University of Michigan Breast Cancer Ally App*, IMEDICAL APPS (Nov. 24, 2015), <http://www.imedicalapps.com/2015/11/university-michigan-breast-cancer-ally-app/> [<https://perma.cc/97LS-3FD9>].

29. Bradley J. Kaspar, *Legislating for a New Age in Medicine: Defining the Telemedicine Standard of Care to Improve Healthcare in Iowa*, 99 IOWA L. REV. 839, 844 (2014).

This health care ranges from diagnosis to treatment of a variety of health issues patients encounter.³⁰ “By employing various equipment, including video networking, audio devices, medical monitoring equipment, and software applications, a typical computer can be used to facilitate medical treatments.”³¹ The Breast Cancer Ally app by the University of Michigan is a modern example of telemedicine, which is presenting unique legal issues in adapting to the modernizing technology age.

1. How Telemedicine is used

Physicians, for a variety of reasons, use telemedicine to assist in the treatment of their patients. “Telemedicine uses telecommunication systems to deliver health care at a distance.”³² This medical communication “uses a combination of medical information, technology, and telecommunication networks to furnish healthcare expertise to physicians and patients.”³³ “A functioning telemedicine system includes a combination of hardware and software, telecommunication networks, standard operating procedures, a need for medical information, and a willingness for healthcare providers to dispense medical information.”³⁴

This technology has been used to help at risk populations such as those in remote rural areas, those with great economic need, and prisoners.³⁵ Modern telemedicine has been used in three distinct categories: “(1) interaction between patient and doctor, (2) remote mentoring, and (3) remote surgery.”³⁶

The Breast Cancer Ally app deals with the interaction between patient and doctor in a variety of ways. The ability to interact in real time with doctors allows patients who are unable to physically go in to the doctor’s office, due to geographic isolation or physical disability, still get the same level of care with their physician.³⁷ In the context of the Breast Cancer Ally app, this real-time communication allows for breast cancer patients to obtain medical information and medical care in real time without actually going to the physician’s office.

30. Paul Spradley, *Telemedicine: The Law is the Limit*, 14 TUL. J. TECH. & INTELL. PROP. 307, 308 (2011).

31. *Id.*

32. Flodgren G et al., *Interactive Telemedicine: Effects on Professional Practice and Healthcare Outcomes*, COCHRANE (Sept. 7, 2015), http://www.cochrane.org/CD002098/EPOC_interactive-telemedicine-effects-professional-practice-and-healthcare-outcomes [<https://perma.cc/C5HR-USFM>].

33. Nancy Luhn, *Medical Licensure and Telemedicine: Necessity or Barrier?*, 25 SUFFOLK TRANSNAT’L L. REV. 165, 167 (2001).

34. *Id.* at 167-68.

35. Spradley. *supra* note 29.

36. *Id.* at 312. Remote mentoring refers to interactions between physicians, rather than between a patient and a physician.

37. *See id.*

2. Success of Telemedicine

Several studies have been done to determine the success of telemedicine compared to traditional medical techniques. One set of studies focused on patients undergoing treatment for heart failure using healthcare without telemedicine versus healthcare provided via remote monitoring.³⁸ The results of the study determined that there was no major difference in health outcomes for individuals using telemedicine versus those who did not.³⁹ There was a slight decrease in hospital admissions from 64% to 60% for patients using the telemedicine tools.⁴⁰ The same study found that for individuals undergoing treatment for blood pressure issues, those who used telemedicine were slightly more improved compared with usual care.⁴¹ These results are from a summary of 16 studies examining telemedicine and heart failure, so there is relative certainty in the statistical accuracy in these results.⁴²

Official studies have not been done on the success of the Breast Cancer Ally app specifically. A personal story regarding the success is provided from Jacqueline Tonks, 78, who had a mastectomy and underwent chemotherapy at the University of Michigan.⁴³ Part of her treatment involved tubes inserted under her arms to drain excess fluid. One of the features in the app helps to track and measure the volume of fluid in the drainage tubes. The patient was able to let her health team know when the drainage level was low enough to have the tubes removed at the doctor's office. Ms. Tonks said: she especially appreciates the daily reminders that pop up to remind her to perform a regimen of exercises that are recommended to help breast-cancer patients deal with shoulder movement difficulty and pain through the course of her treatment after lymph node removal, including which exercises to do and how many repetitions. "This keeps me on track, and it's very convenient."⁴⁴ While this is not an official study of the success of the Breast Cancer Ally app, it demonstrates that for at least one patient it allows the treatment course to be more manageable.

III. ANALYSIS

Several liability issues come with app technology such as the Breast Cancer Ally app. Telemedicine issues such as licensing, malpractice liability, and informed consent all come into play with the Breast Cancer Ally app. In addition to these more traditional liability issues there is also legal concern regarding the security of medical information that is disclosed through the database technology used in the breast cancer app.

38. Flodgren G et al., *supra* note 31.

39. *Id.*

40. *Id.*

41. *Id.*

42. *Id.*

43. Landro, *supra* note 1.

44. *Id.*

A. Licensing Issues

In order to practice medicine, one needs to be licensed by the medical board of the state they intend to practice in.⁴⁵ “Licensure establishes clinical and academic standards, and enables states and countries to identify and regulate their physicians.”⁴⁶ The standards set forth by the state boards ensure competent medical care is given by all practicing physicians.⁴⁷ These licensing requirements are in place to protect the patients as well as well as physicians should liability issues occur.⁴⁸

“A license to practice medicine is not generally required to simply provide information unless a patient-physician relationship is created by providing a diagnosis or recommending treatment.”⁴⁹ Once medical information crosses the line from purely educational to specialized recommendations or treatment, licensure issues come in to play.⁵⁰ The licensure is needed because “the provision of specific advice with regard to diagnosis and treatment or prevention may create a patient-physician relationship and thus the potential for malpractice liability.”⁵¹ The requirements for licensure of physicians vary state by state, and the rules governing these licenses vary on a state-by-state basis as well.⁵²

As licensure is governed at the state level, telemedicine can provide a unique challenge to these licensing rules. Telemedicine by definition is accessible no matter where you are geographically.⁵³ If individuals can obtain medical directives and information across state lines, then the physicians who are treating them might face serious licensing issues.⁵⁴ Presumably, the physicians aren’t licensed to practice in all fifty states, so their telemedicine would need to be restricted to only the jurisdictions they are currently licensed in. There are some state level exceptions to the licensing requirements.⁵⁵ “Traditionally, the three primary exceptions include: the exception for physicians from bordering states, out-of-state physicians providing consultations of limited duration or consistency, and emergency exceptions.”⁵⁶

Several state legislatures have attempted to rectify this licensure issue as it pertains to telemedicine specifically.⁵⁷ “Modification of state medical-licensure

45. See Luhn, *supra* note 32, at 169.

46. *Id.*

47. *See id.*

48. See Erin K. Grunzke, *Long-Distance Doctors: The Crossroads of Telemedicine Licensure in Illinois*, 89 Ill. B.J. 362, 363-64 (2001).

49. Philip M. Kober, *Regulating Medicine on the Internet*, 83 Wis. Law. 12, (Feb. 2010).

50. *Id.* at 13.

51. *Id.*

52. See Luhn, *supra* note 32, at 169.

53. *Id.* at 168.

54. Grunzke, *supra* note 47, at 363.

55. Christopher J. Caryl, *Malpractice and Other Legal Issues Preventing the Development of Telemedicine*, 12 J.L. & HEALTH 173, 185 (1998).

56. *Id.*

57. Kober, *supra* note 48, at 13.

laws has been proposed to clarify the applicability of the laws to situations in which medical advice is proffered over the Internet, but this has created considerable resistance among state governments.”⁵⁸ Considering the pushback legislatures have faced in clarifying this issue, the licensure of physicians employing telemedicine is still an unsettled area of law.⁵⁹ There is some progress, however, as “[s]everal states have amended their statutes defining the practice of medicine to include telemedicine.”⁶⁰ An example of a modification to licensure laws in Telemedicine occurred in California.⁶¹ “California was at the forefront of telemedicine legislation with an all-encompassing bill that governs consent requirements for consultation, physician licensure, unprofessional physician conduct in telemedicine, and payment for services.”⁶²

Interstate implementation of these telemedicine inclusive laws could be difficult to enforce, as Congress has not identified a federal telemedicine licensing standard.⁶³ Proponents of a national system of medical licensure have identified several approaches to effectively enforce a national standard.⁶⁴ “One proposal is that physicians performing telemedicine services consider the patient located in another state to be electronically transported to the physician’s state.”⁶⁵ Furthermore, “[s]ome national licensure proponents support creation of a federal licensing system to supplement state physician licensing.”⁶⁶ This arguably would be permissible for Congress to regulate through the commerce clause.⁶⁷ “Assuming that telemedicine has a substantial effect on interstate commerce, Congress may regulate the practice of telemedicine.”⁶⁸ This heavily debated subject includes arguments about federalism and the right of the federal government to control policies that are incidentally related to interstate commerce.⁶⁹

These licensing issues can have serious penalties for physicians using telemedicine. Practicing medicine in a state without that state’s license is a criminal offense and “[s]tates may prosecute persons who practice medicine without obtaining a state license.”⁷⁰ “Compliance with a medical practice act is important because a physician practicing medicine without a license may expose him/herself to civil and criminal charges, whereas a physician practicing medicine within a state or country where the physician has a license is free from

58. *Id.*

59. *Id.*

60. Caryl, *supra* note 54, at 184.

61. Grunzke, *supra* note 47, at 364.

62. *Id.*

63. *Id.* at 363.

64. *Id.*

65. *Id.*

66. *Id.* at 364.

67. Caryl, *supra* note 54, at 188.

68. *Id.*

69. *Id.* (quoting *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970)); Grunzke, *supra* note 47, at 365.

70. Caryl, *supra* note 54, at 185.

penalty.⁷¹ The sentencing guidelines of these criminal charges vary by state, but the charge of practicing medicine without a license in that particular state may result in criminal sanctions.⁷² In addition to the criminal charge, the physician practicing without a state license opens him or herself up to civil liability through tort claims.⁷³

1. Licensing Issues and the Breast Cancer Ally app

While the Breast Cancer Ally app could face similar licensing issues as other telemedicine technologies, the licensing issue is assuaged by the fact that app users must be seeing a University of Michigan physician to be prescribed the app.⁷⁴ As the patients receive in person treatment while using the Breast Cancer Ally app, it is very likely that they remain in the state of Michigan throughout their use of the app.

There is still certainly the possibility that the Breast Cancer Ally app users travel outside of Michigan while undergoing treatment for their breast cancer. With new directives and diagnoses possible through the Breast Cancer Ally app, it is certainly still possible that physicians using the technology are practicing medicine in a state they are not licensed to practice medicine in.

There are several possible solutions to avoid licensing laws. A possible way to avoid violating licensing laws, while still prescribing the Breast Cancer Ally app to breast cancer patients, is directing them to remain in the state while undergoing treatment from University of Michigan. While that is a possible solution, it is not practical and could defeat the purpose of employing telemedicine in the first place.⁷⁵ Another approach is viewing the Breast Cancer Ally app as one of the exceptions to licensure laws: treatment that is limited in duration. As the app is only for breast cancer patients of the University of Michigan hospital, in theory they would only be out of the state for a limited amount of time.⁷⁶ If the patients were only out of the state of Michigan for brief periods, then the consultations with their physicians through the Breast Cancer Ally app could fall within the licensure exceptions. A problem with this approach is that only a few states recognize the limited consultation exception.⁷⁷ This could help circumvent the licensing issues telemedicine faces altogether.

A final and more drastic approach to avoid the potential medical licensing issues the Breast Cancer Ally creators could face is advocating for policy change at both the Michigan and national level of medical licensing. If there was a

71. See Luhn, *supra* note 32, at 170.

72. *Id.*; Christopher Guttman-McCabe, *Telemedicine's Imperilled Future? Funding, Reimbursement, Licensing and Privacy Hurdles Face a Developing Technology*, 14 J. CONTEMP. HEALTH L. & POL'Y 161, 171 (1997).

73. *Id.*

74. Fawcett, *supra* note 2.

75. MEDICAL SCHOOL AT UNIVERSITY OF MICHIGAN, *supra* note 9 (explaining the goal of the app is to make breast cancer treatment more accessible to the patients regardless of where they are).

76. *Id.*

77. See Caryl, *supra* note 54, at 185.

national system of medical licensure then universal standards would apply regardless of state boundaries.⁷⁸ The creators of the app could advocate for such a change at the national level. Additionally, Michigan could adopt a law similar to that in California that includes the right to practice telemedicine in the state medical license coverage.⁷⁹ This would again require some form of lobbying and policy work on behalf of the University of Michigan at the state and national level.

B. Malpractice Liability Issues

Medical Malpractice includes, “(1) a duty owed by the physician to the patient; (2) a breach of that duty by the physician; (3) an injury to the patient; and (4) a causal link between the physician’s breach of duty and the patient’s injury.”⁸⁰ If any one of these elements is missing then the tort claim is unsuccessful. It must be clearly established that there was a duty owed by the physician and the breach of that duty lead to some injury to the patient.⁸¹

Additionally, tort medical negligence law is governed at the state level.⁸² “State law defines medical malpractice, though generally two factors must exist: (1) the existence of a doctor-patient relationship and (2) action on the part of the doctor that breached his professional duty of care.”⁸³ Therefore, in order to determine if there is the possibility of medical malpractice liability, it must be established that there is a doctor-patient relationship and that the doctor was acting in their professional capacity.⁸⁴

A doctor-patient relationship is “a consensual relationship in which the patient knowingly seeks the physician’s assistance and the physician knowingly accepts the person as a patient.”⁸⁵ This relationship is indicative of an individual relying upon the specialized knowledge of a physician to assist them in medical treatment and medical decisions.⁸⁶ The physician’s specialized knowledge, combined with the doctor patient relationship leads to the physician’s standard of care.⁸⁷ “The standard of care applied in a typical malpractice action is that of an average physician, exercising the degree of care and skill that is ordinarily exercised by the profession under the same or similar conditions in comparable surrounding circumstances.”⁸⁸

78. See Grunzke, *supra* note 47, at 363.

79. See *id.* at 364.

80. Kaspar, *supra* note 28, at 845.

81. See *id.*

82. See *id.* at 846.

83. Spradley, *supra* note 29, at 323.

84. See *id.*

85. *Id.* at 324.

86. See Shannon S. Venable, *A Call to Action: Georgia Must Adopt New Standard of Care, Licensure, Reimbursement, and Privacy Laws for Telemedicine*, 54 EMORY L.J. 1183, 1193 (2005).

87. See *id.* at 1191.

88. *Id.*

In addition to the application of specialized knowledge, the type of information the physician is providing can influence the creation of a doctor-patient relationship, and therefore, the level of medical malpractice liability created.⁸⁹ The information provided by a physician to a patient can be classified as educational, consultation, and diagnosis or treatment.⁹⁰

Educational communication between a physician and a patient is the least likely to create medical malpractice liability through the creation of a doctor-patient relationship.⁹¹ An example of a medical educational tool that is available to the public is the WebMD website.⁹² While much of the American public looks to these educational tools on a regular basis, “incorrect diagnoses or inaccurate information is not likely to create liability for the provider.”⁹³ There are not specific recommendations for treatment that are individualized to the patient through an expert medical opinion, just general information available to the public. This educational platform does not involve a duty of a physician to a particular patient they interact with in a professional capacity.⁹⁴

A consultation is more likely to create a doctor-patient relationship than educational communication; therefore, the risk for medical malpractice liability is higher with this kind of interaction.⁹⁵ There are occasions when consultation can create this relationship, namely “[i]f a patient reasonably believes that the service she is receiving will eliminate the need for traditional face-to-face medical treatment then the practitioner will probably be subjected to malpractice liability.”⁹⁶ It is through this total reliance on the physician’s knowledge that a simple consultation can create this doctor patient relationship. A way to circumvent this is “an effective method of notice”, which “will be necessary to help physicians avoid malpractice liability when the intention is to provide limited services.”⁹⁷ This notice would inform the patient that the consultation does not eliminate the need for traditional medical treatment.

With diagnosis and treatment, the doctor-patient relationship often is created; therefore, the possibility for medical malpractice negligence is often present as well.⁹⁸ The level of diagnosis and treatment however can be difficult to ascertain when it comes to telemedicine, because the patient is not interacting

89. Spradley, *supra* note 29, at 326.

90. *Id.*

91. *See id.*

92. WebMD, *About WebMD*, <http://www.webmd.com/about-webmd-policies/default.htm?ss=fr> [<https://perma.cc/T9Q4-LT2W>] (last visited Nov. 4, 2017). WebMD is a free online educational tool that allows for the public to input symptoms and generates information on various medical conditions. There is often synopsis of what the condition is, how it is caused, typical courses of treatment, along with an extensive list of symptoms. There are not particular suggestions generated through WebMD, just free medical information acting as an educational tool.

93. Spradley, *supra* note 29, at 326.

94. *Id.*

95. *Id.* at 327.

96. *Id.* at 328.

97. *See id.*

98. *See id.*

with the physician in the traditional doctor's office setting.⁹⁹ In navigating less settled areas of medical malpractice negligence, courts have held that a factor-balancing test should be employed to determine duty of care using "fairness under contemporary standards—that is, would reasonable persons recognize and agree that a duty of care exists."¹⁰⁰

For medical malpractice negligence, there must be a violation of the duty of care owed by the physician in the doctor-patient relationship.¹⁰¹ Generally, "[d]uty is the legal obligation a defendant owes to a plaintiff to conform to a reasonable-person standard of care in order to protect against unreasonable risks of harm."¹⁰² It is important to note however, that for medical malpractice there is specialized knowledge applied, and therefore the reasonable man standard is adjusted slightly. For medical malpractice negligence specifically, "the 'reasonable person' standard is elevated to that of a person with similar knowledge and experience in the field of medicine."¹⁰³

As medical malpractice is left to state common law jurisdiction, there are some variances among the states regarding the elements necessary to prove medical malpractice negligence.¹⁰⁴ For example, "[s]ome jurisdictions have also held that doctors have an additional duty to disclose the risks associated with a treatment plan and discuss possible alternatives."¹⁰⁵ There are also geographic elements that are determinative of whether the standard of care was met. "The locality rule holds the physician to the standard of care "exercised by physicians in the defendant's own community or locality."¹⁰⁶ The application of the local medical standards to medical negligence cases was the minority school of thought, "but use of the locality rule as a basis to evaluate physician skill and knowledge is becoming the minority."¹⁰⁷ This shift was caused by "[a]dvances in technology, standardization in medical schools, required physician certification, and increased availability of technology and resources no longer necessitate taking into account 'local' factors to qualify a standard of care."¹⁰⁸

In place of the locality rule, most jurisdictions have adopted a national standard of care for medical professionals.¹⁰⁹ "The competence-based duty of care requires that physicians meet a standard of medical knowledge or access to medical knowledge that is reasonably possessed or available to a physician with

99. *See id.* at 329.

100. *Greenberg v. Perkins*, 845 P.2d 530, 536 (Colo. 1993).

101. *Spradley*, *supra* note 29, at 324.

102. *Burroughs v. Magee*, 118 S.W.3d 323, 329 (Tenn. 2003).

103. *Spradley*, *supra* note 29, at 324.

104. *See id.*

105. *Id.*

106. Meghan C. O'Connor, *The Physician-Patient Relationship and the Professional Standard of Care: Reevaluating Medical Negligence Principles to Achieve the Goals of Tort Reform*, 46 TORT TRIAL & INS. PRAC. L.J. 109, 118 (2010).

107. *Id.* at 119.

108. *Id.*

109. *Id.* at 120.

like skills (i.e., the same specialty) throughout the United States.”¹¹⁰ This means physicians accused of medical negligence while treating breast cancer are compared against what is reasonable for breast cancer providers specifically, not physicians generally. Furthermore, the national standard of care follows a reasonable physician standard. Under the national standard of care, the physician must act with the “degree of skill and care ordinarily possessed by a reasonable and prudent physician in the same medical specialty acting under the same or similar circumstances.”¹¹¹ This adds the element that the physicians need to be objectively reasonable considering all of the circumstances at the time of the treatment, and again compared against what is reasonable in their field specifically.

1. Medical Malpractice law and telemedicine

The world of telemedicine as it pertains to medical malpractice negligence and liability is very unsettled law.¹¹² Because of the lack of clarity in the law, “many telemedicine experts and advocates, as telemedicine grows, malpractice complications are likely to create a new body of law.”¹¹³

There are individuals who advocate for a heightened duty of care for physicians using telemedicine as “[i]t could be argued that telemedicine practitioners should have a greater duty of care than traditional doctors because of the increased risk of misdiagnosis where the practitioner never personally encounters the patient.”¹¹⁴ Without having all of the information and insight a physician gains from a face-to-face interaction, there could be more errors made when it comes to diagnosis and selecting the course of treatment.

Not all legal scholars believe telemedicine should be subjected to a heightened duty of care. Some argue, “[w]here the telemedicine procedures are virtually identical to the traditional medical procedures, the standard of care should be the same. Likewise, where telemedicine is inferior to the traditional medical protocol, physicians should be on guard.”¹¹⁵ An example of this thinking in action is “a 2001 Colorado statute states that “[a]ny health benefits provided through telemedicine shall meet the same standard of care as for in-person care.”¹¹⁶ Additionally, “[i]n Texas, the Administrative Code states 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 clinical settings.”¹¹⁷

110. *Id.* at 122.

111. *Id.* at 120.

112. Spradley, *supra* note 29, at 307.

113. *Id.* at 325.

114. *Id.* at 329.

115. Caryl, *supra* note 54, at 199.

116. Kaspar, *supra* note 28 at 855.

117. *Id.*

Finally, some believe that telemedicine should have a lesser standard of care than traditional medical practices. “Hawaii enacted a statute in 2009 stating that telemedical care shall meet the ‘same standards of appropriate practice as those in traditional physician-patient settings that do not include a face-to-face visit.’”¹¹⁸ Taking that logic a step further, “some scholars have proposed a standard of care for telemedicine that shifts based upon the nature of the treatment. These scholars argue that certain types of telemedicine do not put doctors at a diagnostic disadvantage.”¹¹⁹

2. Application to Breast Cancer Ally app

The Breast Cancer Ally app would likely face medical malpractice issues if the advice from the app resulted in delayed or incorrect treatment, because it enters the realm of treatment and diagnostic functions.¹²⁰ The toxicity tracker makes specialized recommendations based on specialized symptoms that are input into the app by the patient.¹²¹ The recommendations populated by the Breast Cancer Ally’s toxicity tracker could very well be qualified as a diagnosis, therefore exposing the app creators to medical malpractice liability.

Additionally, the app could be treated by the law as a consultation device. If consultation is the purpose of the app, the creators are exposed to medical malpractice liability when one of the patients relies on the Breast Cancer Ally app recommendations in place of face-to-face recommendations.¹²² It is likely in either approach that a doctor-patient relationship is formed with the Breast Cancer Ally app, therefore exposing the creators and physicians to possible medical malpractice liability.

In determining the duty of care for physicians for the Breast Cancer Ally app, it would be my recommendation that they are held to the same standard as traditional physicians. In the case of the Breast Cancer Ally app, physicians are simultaneously treating the app users in person. Only current breast cancer patients undergoing treatment at the University of Michigan can have access to the app.¹²³ This simultaneous use of traditional in office care and telemedicine could avoid the liability issues that traditionally face telemedicine technologies.

It would be possible, however, that a unique standard of care be created for Breast Cancer Ally prescribing physicians. In determining the standard of care owed to a patient by a physician, the standard is that the physician must act with the “degree of skill and care ordinarily possessed by a reasonable and prudent physician in the same medical specialty acting under the same or similar circumstances.”¹²⁴ The same or similar circumstances could be a physician using a medical app in conjunction with in person medical treatments. Because it is

118. *Id.* at 856.

119. *Id.* (For example, examining a patient scan does not require face-to-face interaction with the patient).

120. Fawcett, *supra* note 2.

121. *Id.*

122. Spradley, *supra* note 29, at 328.

123. Fawcett, *supra* note 2.

124. O’Connor, *supra* note 105, at 120.

not common to have a doctor prescribe an app while simultaneously treating the patient in person, there would be a new standard of care created. This standard of care would need to determine what is reasonable in the situation where in person care and app use is ongoing.

Creators of the Breast Cancer Ally app could draw from their peers and work collaboratively to establish the reasonable standard of care for physicians in the same position. A positive of creating a hybrid standard of care between traditional treatment and telemedicine is physicians practicing in the field could directly give their input to establish the norms. If physicians are directly involved in establishing the standard of care, they would be more likely to be well informed as to what the appropriate level of treatment is. Unfortunately, cases alleging medical negligence prior to a well-established standard of care for telemedicine and traditional treatment combinations would be convoluted and complicated. The complexity involved in creating a new standard of care could result in inconsistent rulings and highly confused juries. Expert medical testimony would be needed to establish the new standard of care, from medical experts in the same field.¹²⁵ While this process is possible, it would be a highly contested and messy one. For that reason, I would suggest physicians frame their treatment as traditional medical care for the purposes of medical negligence allegations.

If this app technology were to be expanded, it would be critical to maintain the system technology the Breast Cancer Ally app currently uses. There must be simultaneous treatment in person for breast cancer at a hospital facility, such as the University of Michigan, with the telemedicine technology available to the patient once they go home.¹²⁶ This will not free the physicians and app creators from all medical malpractice liability, rather it will just allow them to be held to the same standard of care as other breast cancer physicians in their area.

C. *Informed Consent*

The medical notion of informed consent is based on the premise that “as long as one who suffers harm consents (in some legally meaningful sense) to bear the risk that leads to it, the injurer is not under a duty to protect the victim and is not at fault if an injury occurs.”¹²⁷ Therefore, if a physician meaningfully informs a patient of the harms associated with any given treatment, and the patient then consents to that treatment the physician is not legally at fault if those same harms occur.¹²⁸

Informed consent not only relieves physicians of tort liability, it is also a duty placed on physicians. Physicians “owe their patients a fiduciary duty, which includes an obligation to act exclusively in the patient’s interests and to disclose all information material to those interests.”¹²⁹ In order for a physician to follow

125. *Id.*

126. Fawcett, *supra* note 2.

127. Peter H. Schuck, *Rethinking Informed Consent*, 103 YALE L.J. 899, 902 (1994).

128. *Id.*

129. *Id.* at 916.

the wishes of a patient, the patient must be made aware of their options of treatment, as well as the risks associated with each of those courses of treatment.¹³⁰

The legal standard for what must be disclosed to a patient under informed consent varies by state. “In slightly over half the states, the legal standard for disclosure to patients is that which a ‘reasonable medical practitioner’ would provide.”¹³¹ This standard evaluates the reasonable physicians definition of what is reasonable or necessary to disclose. The other “disclosure standard in most other jurisdictions is that which would be sought by a prudent or reasonable patient, a standard that emphasizes the value of patient autonomy over that of professional judgment.”¹³² This approach places value on what a patient would expect to learn rather than what a physician thinks a patient needs to know.

States also vary on how information must be disclosed to the patients. Some states have statutory schemes establishing the rules for informed consent, explicitly stating how the informed consent must occur.¹³³ “Increasingly, the disclosure is evidenced by a written form signed by the patient prior to treatment, which recites both the risks disclosed to her and her voluntary consent to treatment.”¹³⁴ In these jurisdictions, documentation is mandatory to establish that the physician gave the requisite disclosures to the patient.

1. Informed Consent and Telemedicine

Applying informed consent laws to telemedicine is more complex than the typical doctor patient informed consent practices. “Informed consent within the context of telemedicine may require disclosure of risks beyond those concerning patient treatment. In telemedicine, there may be risks involved in examination, diagnosis, and treatment.”¹³⁵ There are several stages of the treatment process that carry additional risks with telemedicine, and the patient must be informed of those additional risks as well as the original treatment risks.¹³⁶ Determining what exactly informed consent laws should look like in regards to telemedicine has been left up to the respective states.

When it comes to informed consent and telemedicine the main approach is a more extensive warning than traditional medical practices. “Arguably, a physician should inform the patient that: telemedicine is experimental; images of the patient, who may be naked for the medical examination, may be intercepted by a person not a party to the consultation; or the consulting physician may not be legally permitted to practice medicine within this state.”¹³⁷ This approach to informed consent and telemedicine, requires that the physician put the patient on

130. *Id.* at 906.

131. *Id.* at 916.

132. *Id.*

133. Mich. Comp. Laws Ann. § 333.17013 (West).

134. Schuck, *supra* note 126, at 917.

135. Caryl, *supra* note 54, at 200.

136. *Id.*

137. *Id.*

notice of all the potential liability that telemedicine exposes the patient to, and all of the ways in which telemedicine reduces their information security.

Some states, such as Texas have codified the rules surrounding informed consent and telemedicine. In their Administrative Code, Texas explains, “[b]efore providers can use telemedicine, they must: give their patients notice regarding telemedicine medical services, including the risks and benefits of being treated via telemedicine, how to receive follow-up care or assistance in the event of an adverse reaction to the treatment or in the event of an inability to communicate as a result of a technological or equipment failure.”¹³⁸ The patients must essentially be warned of all the ways in which telemedicine can fail before they agree to be a participant in it.

2. Application to Breast Cancer Ally app

The Breast Cancer Ally app is prescribed in Michigan and the University of Michigan Medical Center. Michigan law surrounding informed consent and breast cancer treatment is statutory. There is a statute titled, “Alternative methods of treatment of breast cancer; duty of physician to inform patient; standardized written summary or brochure; form; civil action.”¹³⁹

This statute provides a specific framework for physicians treating breast cancer of what needs to be disclosed when, as well as how the informed consent needs to occur. Breast Cancer Ally prescribers need to abide by these informed consent law because they are treating breast cancer, however they also need to consider the telemedicine aspect.

The Breast Cancer Ally app is unique from other telemedicine technologies because the patient is seeing the physician in person as well as communicating over the app.¹⁴⁰ This distinction from other telemedicine technology however, does not change the approach to informed consent. The app technology used in the Breast Cancer Ally app still carries with it an increased exposure to liability and security risks.

When physicians present the app to breast cancer patients, the physicians should inform the patient of certain risks associated with the app so that patients can fully consent to using the technology. Doctors prescribing the Breast Cancer Ally app should communicate the potential licensing risks that accompany using the Breast Cancer Ally app when a patient leaves the state.¹⁴¹ Doctors should also communicate the risk of relying on the app for medical advice, which could result in a delay of correct treatment.¹⁴² For this app in particular, the physicians need to make the security risks abundantly clear, as the Breast Cancer Ally app collects and maintains highly sensitive medical information. Should a security breach of the app occur, the users of the app would have their medical information files at risk of exposure.¹⁴³

138. Kaspar, *supra* note 28, at 851-52.

139. Mich. Comp. Laws Ann. § 333.17013 (West).

140. Fawcett, *supra* note 2.

141. *See supra* Part A of Analysis.

142. *See supra* Part B of Analysis.

143. *See infra* Part D of Analysis.

Verbal communication of these risks would likely be sufficient, but it would be beneficial to the app creators to also have a consent screen before users can agree to use the app. A screen that forces users to agree to the terms and conditions of the app could include an informed consent screen that again communicates the risks associated with using this specific telemedicine technology. If all levels of informed consent were present for both the treatment itself and the use to the app as telemedicine technology, there would not be liability issues regarding informed consent.

D. Security Issues for Sensitive Medical Information

There are strict laws governing the disclosure of classified and personal medical information in the United States; such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA).¹⁴⁴ Under HIPAA there is a privacy rule designed to protect personal medical information.¹⁴⁵ HIPAA covers “‘individually identifiable health information’ held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper, or oral. The Privacy Rule calls this information “‘protected health information (PHI).”¹⁴⁶ This protected health information relates to “‘the individual’s past, present or future physical or mental health or condition, the provision of health care to the individual, or the past, present, or future payment for the provision of health care to the individual.”¹⁴⁷ “‘A covered entity may not use or disclose protected health information, except either: (1) as the Privacy Rule permits or requires; or (2) as the individual who is the subject of the information (or the individual’s personal representative) authorizes in writing.”¹⁴⁸ The permitted disclosures are:

- (1) To the Individual (unless required for access or accounting of disclosures);
- (2) Treatment, Payment, and Health Care Operations;
- (3) Opportunity to Agree or Object;
- (4) Incident to an otherwise permitted use and disclosure;
- (5) Public Interest and Benefit Activities; and
- (6) Limited Data Set for the purposes of research, public health or health care operations.¹⁴⁹

Any other disclosure would violate the privacy rule established through the act.

144. Health Insurance Portability and Accountability Act of 1996, Pub. L No. 104-191.

145. U.S DEP’T OF HEALTH & HUM. SERVS., *Summary of the HIPAA Privacy Rule*, <https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html> [<https://perma.cc/H4XC-SFCR>] (last visited Nov. 19, 2017).

146. *Id.*

147. *Id.*

148. *Id.*

149. *Id.*

1. Information Security and Telemedicine

The development of telemedicine presents new challenges to information security as it pertains to medical records. “The Health Insurance Portability and Accountability Act of 1996 (HIPAA) continues to apply, but more laws and regulations may be needed in the Internet era to protect privacy and confidentiality.”¹⁵⁰ Heightened privacy concerns exist, because telemedicine and medical technology has a newfound vulnerability to outside actors. “With the development of telemedicine, a patient’s concern about an improper usage of or access to his medical information increases. Telemedicine and modern computer filing systems place patients’ private health care information at risk of improper use by health care workers, hospital staff, and computer hackers.”¹⁵¹

This vulnerability of telemedicine to system hackers is not just an empty threat, but also something that has been realized. “In May [of 2010], hackers broke into a medical records database in Virginia and demanded extortion payments after causing considerable damage. This was similar to a previous cyber attack in California that started in October 2008.”¹⁵² These cyber attacks lead to the exposure of classified medical information and costs both the app creators and app users privacy and money. The liability in these cyber attacks falls to the app creators and prescribers, because the responsibility placed on physicians by HIPAA holds them accountable for breaches of patient information.¹⁵³

2. Application to Breast Cancer Ally app

There is no information currently published on security breaches that have occurred with the Breast Cancer Ally app specifically, but there has been similar technology that encountered security problems. “A 2015 survey by Gartner, Inc. found that more than 75% of mobile apps on the marketplace fail basic security tests. IDG Research also reports that nearly three quarters of IT leaders have experienced a mobile data breach.”¹⁵⁴ These security tests are not as sophisticated as some hackers have become. Mobile apps are failing basic security tests at an alarming rate. While the accessibility of mobile apps is great for the consumer’s accessibility, it presents a unique security challenge to app creators.

This technology vulnerability coupled with the desirability of medical records and information is a dangerous combination. The sale of patient’s medical records and data is a multi-billion-dollar business, with that information

150. Kober, *supra* note 48, at 12.

151. Caryl, *supra* note 54, at 182.

152. Kober, *supra* note 48, at 10.

153. Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191.

154. Gartner Inc., *Gartner Says More than 75 Percent of Mobile Applications will Fail Basic Security Tests Through 2015*, GARTNER PRESS RELEASE (Sep. 14, 2014), <http://www.gartner.com/newsroom/id/2846017> [<https://perma.cc/6AZY-YQQG>].

being used to target the sale of products and pharmaceuticals.¹⁵⁵ Hackers are particularly interested in medical information because there is a strong resale market for that information. This desirable medical information is exactly the information that is disclosed through the Breast Cancer Ally app.

Users of the Breast Cancer Ally app disclose almost all of their personal medical information for the app to work properly. The exact course of treatment is recorded to generate specified at home workouts best suited for the patient.¹⁵⁶ Additionally, the app tracks and records appointment times in order to remind the Breast Cancer Ally app users of upcoming appointments.¹⁵⁷ Finally, the app allows breast cancer patients to communicate with University of Michigan doctors about the intimate details of their physical health throughout their entire breast cancer treatment.¹⁵⁸ All of this information paints a detailed picture of the Breast Cancer Ally app user's personal medical information and current medical treatments. This information is a highly desired commodity because it allows for highly targeted sales by pharmaceutical companies.¹⁵⁹

Breast Cancer Ally creators need to place heightened attention on the security features of the medical app they created. There needs to be training both on the part of the app users and app creators to ensure the safety of sensitive medical records. Users of the Breast Cancer Ally app need to be made aware of phishing schemes to obtain their password or log in information.¹⁶⁰ While the ultimate liability for a phishing scheme would likely not fall on the app creators, education on phishing helps promote the overall security of the Breast Cancer Ally app.

IV. CONCLUSION

Developments in medical technology are critical to maintain an engaged physician-patient relationship. A successful treatment hinges on a well-informed patient that is able to keep in often contact with their physician. This holds especially true with breast cancer patients, as cancer treatment can take many forms. The Breast Cancer Ally app is an important tool to maintain this engaged patient relationship and allow for a successful treatment and recovery for breast cancer patients. Despite the benefits of this telemedicine technology, there are liability issues with the app that the creators must consider.

The new medical technology employed in the app opens up increased liability for licensing, medical negligence, informed consent, and HIPAA violations. The ability to travel outside of state bounds presents typical

155. Jordan Robertson, *Your Medical Records Are For Sale*, BLOOMBERG NEWS, <http://www.bloomberg.com/news/articles/2013-08-08/your-medical-records-are-for-sale> [<https://perma.cc/59S4-WHTR>] (last visited Nov. 19, 2017).

156. Fawcett, *supra* note 2.

157. *Id.*

158. *Id.*

159. Robertson, *supra* note 154.

160. Merriam-Webster, *Definition of Phishing*, <https://www.merriam-webster.com/dictionary/phishing> [<https://perma.cc/3MYK-FCN2>] (last visited Nov. 19, 2017) (“[A] scam by which an e-mail user is duped into revealing personal or confidential information which the scammer can use illicitly.”).

telemedicine challenges with state licensing. As app users rely on the medical advice provided through the Breast Cancer Ally app, the physicians expose themselves to a heightened risk of medical negligence liability. Additionally, the physicians prescribing the app must inform the patients of both the risks of treatment and the heightened risk of telemedicine practices. Finally, the sensitive medical information that is disclosed by patients using the Breast Cancer Ally app heightens the potential for HIPAA violations on the part of the physicians.

In order to incorporate the necessary medical advances with breast cancer treatment, the Breast Cancer Ally app creators should make adjustments to best prepare for the increased liability potential.