

2023

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Recommended Citation

Polina DeClue, *Health Monitoring From Home: Legal Considerations of Wearable Technology in Telemedicine*, 26 SMU Sci. & Tech. L. Rev. 111 (2023)

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Health Monitoring From Home: Legal Considerations of Wearable Technology in Telemedicine

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ABSTRACT

The COVID-19 pandemic created the necessity to access medical care from one's home, giving rise to a new standard of healthcare through "telemedicine." However, although efficient in many ways, the most significant limitation of telemedicine was the inability of doctors to monitor their patients' conditions remotely. Wearable devices, also known as "wearables," provide a way to bridge the gap. Over the last five years, wearables grew to be one of the fastest-growing industries in healthcare, seeing over \$5 billion in growth. However, this also came with a myriad of legal concerns that may prevent wearables from being utilized efficiently. This case note discusses three legal issues that arise from the utilization of wearable technology in telemedicine: the effects of wearables in cases of medical malpractice and the scope of liability of doctors, the effects on the standard of care and the traditional doctor-patient relationship, and privacy and confidentiality concerns from utilizing third-party wearables to collect patient data. In order to fully utilize the potential of wearables in the healthcare industry, specific regulatory frameworks should be adopted to address such concerns.

I. INTRODUCTION

The COVID-19 pandemic gave rise to a new standard of healthcare in the form of "telemedicine", which is the delivery of healthcare services through virtual platforms that creates more opportunities for patients to be treated at a faster and more economical rate from the comfort of their homes.¹ Many see this technological advancement as favorable, and there has been over \$5 billion of growth in the industry in the last couple of years.² However, there are some legal concerns that stem from utilizing wearable

DOI: <https://doi.org/10.25172/smustr.26.1.7>.

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1. See *The Integration of Enhanced Connectivity and Wearables to Support the Evolution of Telemedicine*, IEEE (May 27, 2022), <https://transmitter.ieee.org/connectivity-wearables-and-the-evolution-of-telemedicine/> [<https://perma.cc/VUB9-B7WY>].
2. See *Personalized technology driving \$5 billion growth wave in personal health device market*, INFORMA TECH (Jun. 11, 2019), [https://omdia.tech.informa.com/OM003785/Personalized-technology-driving-\\$5-billion-growth-wave-in-personal-health-device-market](https://omdia.tech.informa.com/OM003785/Personalized-technology-driving-$5-billion-growth-wave-in-personal-health-device-market) [<https://perma.cc/PXB9-YVLM>].

technology in telemedicine due to the general newness of the technology.³ Although wearable technology has developed a lot over the last decade, it is still a field that is largely unregulated between the federal government, the states, and different medical practices.⁴ This case note aims to analyze three main legal issues that stem from its use in telemedicine: (1) increased possibilities for medical malpractice and questions of liability; (2) changes in the standard of care offered to patients; and (3) privacy and confidentiality concerns that come with utilizing third-party technology in healthcare.

II. BACKGROUND

With the creation of the internet and the greater availability of personal electronic devices to the American public, the practice of telemedicine was born.⁵ Defined, telemedicine is healthcare that is “provided without an in-person office visit.”⁶ Usually this involves a patient explaining his or her complaints virtually by utilizing a computer, tablet, or smartphone, after which the healthcare provider provides a recommendation or diagnosis.⁷ Most telemedicine is done through either talking directly with a healthcare provider, sending and receiving messages, or remote health monitoring.⁸

In 1993, the American Telemedicine Association (“ATA”) was created, which provided an organizational structure to the quickly expanding avenue for this form of healthcare consulting.⁹ However, it was not until the COVID-19 pandemic when telemedicine became a need and not just an alternative to traditional healthcare.¹⁰ In the midst of the pandemic, healthcare providers found new ways to offer services to their patients without exposing vulnera-

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3. See Mitchell Panter, *Potential Legal Implications of Telemedicine and Telehealth*, LAW TECH. TODAY (Jan. 25, 2021), <https://www.lawtechnologytoday.org/2021/01/implications-of-telemedicine-and-telehealth/> [https://perma.cc/2XJK-5C5J].
 4. See GlobalData Thematic Research, *Wearable Technology: Regulatory Trends*, MINING TECH. (Feb. 3, 2022, 4:15 PM), <https://www.mining-technology.com/comment/wearable-technology-regulatory-trends/> [https://perma.cc/SX5L-VUJ6].
 5. See Scott A. Borgetti, MD, et al., *Telehealth: Exploring the Ethical Issues*, 19 DEPAUL J. HEALTH CARE L. 1, 1 (2018).
 6. *What is telehealth?*, TELEHEALTH.HHS.GOV, <https://telehealth.hhs.gov/patients/understanding-telehealth/> [https://perma.cc/XEM9-PWLZ].
 7. See *id.*
 8. See *id.*
 9. Borgetti, *supra* note 5, at 2.
 10. See Jane E. Blaney, *Hidden in Plain Sight: How COVID-19 Revealed the Need to Incorporate Wearable Devices into Patient Care*, 13 HEALTH & LIFE SCI. L. 41, 41 (2020).

ble populations.¹¹ The Center for Medicare and Medicaid Services (“CMS”) quickly identified an “urgency to expand the use of technology to help people who need routine care and keep vulnerable beneficiaries . . . in their homes while maintaining access to the care they need.”¹²

In the past couple of years, telemedicine has come to incorporate “wearable technology.”¹³ Wearable technology, or “wearables” are devices “that can be worn or mated with human skin to continuously and closely monitor an individual’s activities, without interrupting or limiting the user’s motions.”¹⁴ These wearables collect the data of users’ personal health and exercise profiles on electronic devices such as Fitbits and smartwatches.¹⁵ At one point only rudimentary step-counters, wearables are now becoming increasingly health-focused.¹⁶ While “the first generation of mobile apps and wearables have concentrated on the acquisition of fitness and wellness data,” the “trending direction for the next generation is [toward] self-curation of clinical data and social determinants of health data and sharing those data with smart diagnostic services.”¹⁷ This allows health metrics such as vital signs (heart rate, blood pressure, respiratory rate, oxygen saturation, body temperature) as well as cardiovascular functions, sleep patterns, general activity patterns, and gait and joint functions to be collected.¹⁸ The data is then easily utilized by both the physician and the patient in a database to make diagnoses and track patient conditions.¹⁹ This system is particularly useful in providing remote patient monitoring services or corroborating reported symptoms.²⁰

11. *See id.*

12. *Id.*

13. *See id.*

14. Mostafa Haghi et al., *Wearable Devices in Medical Internet of Things: Scientific Research and Commercially Available Devices*, 23 HEALTH INFORMATICS RES. 1, 4–5 (2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5334130/pdf/hir-23-4.pdf> [<https://perma.cc/4EXB-RKX4>].

15. Blaney, *supra* note 10, at 42.

16. *See id.*

17. *Id.* at 43.

18. Ralph J. Mobbs et. al., *COVID-19 is shifting the adoption of wearable monitoring and telemedicine (WearTel) in the delivery of healthcare: opinion piece*, 8 ANNALS OF TRANSLATIONAL MED. 20, 2–3 (2020).

19. *See* Sudeep Pisipaty, *The Integration of Wearables into Telehealth*, HEALTH RECOVERY SOLUTIONS (2022), <https://www.healthrecoveryolutions.com/blog/telehealth-integration-of-wearables> [<https://perma.cc/C5UQ-6VHL>]; Mobbs, *supra* note 18, at 3.

20. *See* IEEE, *supra* note 1.

III. LEGAL CONSEQUENCES

Although technology has been rapidly advancing, the regulation on its use in telemedicine has remained largely unchanged—and unmonitored.²¹ This created a new challenge in health law with three primary legal consequences.²² First, utilizing external data and conducting medical examinations and treatments virtually may create less than accurate results, resulting in incorrect diagnoses, prescriptions, or medical advice.²³ This may create a medical malpractice suit where the “fault” of the medical professional is blurry.²⁴ Not only will new wearable technology most likely see an increase in medical malpractice claims, but it will also make them exponentially more difficult to prove.²⁵ Second, the nature of telemedicine and wearables alters the standard of care that has been established and well-regulated in traditional healthcare.²⁶ Critics are divided on whether the standard of care will drop or improve through the utilization of wearables.²⁷ Lastly, utilizing third-party technology presents some obvious privacy concerns with patient data.²⁸ Wearables may create situations where data is vulnerable to breaches or utilized for unethical means such as targeted advertising.²⁹

A. Liability in Cases of Medical Malpractice

Telemedicine, in general, presents an interesting dynamic between traditional doctor and patient interaction.³⁰ Although virtual, the risks associated with diagnosing a patient incorrectly or offering incorrect medical advice remain as high, if not higher, in telemedicine as in traditional medicine.³¹

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21. See GlobalData Thematic Research, *supra* note 4.
 22. See generally Panter, *supra* note 3.
 23. See Stephanie L. Carman et al., *Wearable Medical Devices Can Raise Issues for Healthcare Professionals*, CHIEF HEALTHCARE EXEC. (Oct. 30, 2018), <https://www.chiefhealthcareexecutive.com/view/wearable-medical-devices-can-raise-issues-for-healthcare-professionals> [https://perma.cc/DGP2-LG4F].
 24. See Joanna Cunningham, *Is Technology Helping or Hindering Medical Negligence Mortality Rates?*, HEALTH TECH ZONE (Oct. 4, 2022), <https://www.healthtechzone.com/topics/healthcare/articles/2022/10/04/453668-tech-nology-helping-hindering-medical-negligence-mortality-rates.htm> [https://perma.cc/7T5A-GXBU].
 25. Carman et al., *supra* note 23.
 26. See Tyler D. Wolf, *Telemedicine and Malpractice: Creating Uniformity at the National Level*, 61 WM. & MARY L. REV. 1505, 1512–13 (2020).
 27. See, e.g., Borgetti, *supra* note 5, at 5; Blaney, *supra* note 10, at 41.
 28. Panter, *supra* note 3.
 29. See *id.*
 30. See Borgetti, *supra* note 5, at 4.
 31. See generally Carman et al., *supra* note 23.

This has led some scholars to come to the assumption that switching to an all-virtual form of patient care may see an increase in medical malpractice suits.³² The first issue in evaluating medical malpractice through the lens of telemedicine is establishing whether these suits can even be brought.³³ “In a case of medical malpractice, a physician-patient relationship has to exist.”³⁴ Currently, it is unclear if utilizing telemedicine and wearable devices creates enough of a patient-physician relationship to have the duty of care which is necessary to prove liability in a medical practice suit.³⁵ In the context of telemedicine, many states regulate malpractice suits by prohibiting virtual medical services before a physician and a patient are able to establish this relationship through an in-person exam.³⁶ This however, negates the point of telemedicine, which is to provide more accessible and affordable healthcare from the comfort of a patient’s home.³⁷ On the other hand, the allowance of physicians to make diagnoses or valid medical conclusions without in person visits may create a blame-shifting scenario if a medical malpractice suit does arise.³⁸ Doctors may be able to blame third-party technology, which creates a “who’s fault is it?” spiral in telemedicine.³⁹ Essentially, the utilization of wearable technology in telemedicine creates two scapegoats for doctors; they are able to say that technology is not offering reliable data points to make accurate medical diagnoses or they may be able to claim that the patient was able to alter or influence the data.⁴⁰

It is also important to address the dangers of physicians’ overreliance on wearable technology.⁴¹ Although data is very important in making critical healthcare choices, it does not replace the training and technical skillset of a medical professional to offer individualized medical opinions.⁴² If a doctor begins to utilize wearables more to support a decision, some nuances of a patient’s condition may be missed in favor of pure numbers.⁴³ It is further not hard to imagine a scenario where vitals and the data pulled from technology

32. See, e.g., Panter, *supra* note 3; Cunningham, *supra* note 24.

33. See Panter, *supra* note 3.

34. *Id.*

35. Carman et al., *supra* note 23.

36. Panter, *supra* note 3.

37. See Blaney, *supra* note 10, at 48.

38. Cunningham, *supra* note 24.

39. See *id.*

40. See Blaney, *supra* note 10.

41. See Cunningham, *supra* note 25.

42. See generally *id.*

43. See Borgetti et al., *supra* note 5, at 4.

reflects healthy status resulting in the physician missing a critical health risk.⁴⁴

Other critics argue, however, that wearables may reduce the risk of malpractice in telemedicine.⁴⁵ First, wearables offer the unique benefit of being able to eliminate human error to overall improve accuracy. At every step of a medical exam, an error may be made with inputting data or misinterpreting conditions.⁴⁶ The streamlined process of wearables collecting the data rather than the physician themselves may result in higher accuracy and fewer estimations.⁴⁷ Further, while patients may otherwise be able to inaccurately describe their symptoms, or neglect to mention them at all, the data collected from wearables in situations of remote monitoring may corroborate the doctor's presumptions and lead them to make a more informed diagnosis.⁴⁸ This lends itself to better record-keeping, as devices such as smartwatches are able to pull more data points outside of only the one collected in a traditional medical exam.⁴⁹ Patient monitoring both pre and post exam will offer physicians a more comprehensive profile of their patients at no cost of their own time/efforts.⁵⁰

But there are some questions that arise with the use of wearables in telemedicine. How comprehensive is the data? What about doctors who televisit with those in another state? Most states require a physician to be licensed in the state they are practicing medicine.⁵¹ So far, there has not been a clear regulation on cross-jurisdictional boundaries in telemedicine and wearable technology.⁵²

B. Standard of Care

A fundamental question with the use of wearables in telemedicine is how it will impact the standard of care that physicians are expected to perform at.⁵³ On one hand, there are certain positives that the use of wearable

44. See, e.g., *MacDonald v. Schriro*, No. CV 04-1001-PHX-SMM (MHB), 2008 U.S. Dist. LEXIS 54712 (D. Ariz. July 17, 2008) (plaintiff alleging that doctor engaged in medical malpractice by failing to examine his knee properly and ignoring his symptoms during a telemedicine consult).

45. See, e.g., *Cunningham*, *supra* note 24.

46. See *id.*

47. See *id.*

48. See *id.*

49. See *id.*

50. *Mobbs*, *supra* note 18, at 5.

51. *Panter*, *supra* note 3.

52. See *id.*

53. *Blaney*, *supra* note 10, at 46.

devices can bring.⁵⁴ The use of wearables can create more direct patient-monitoring opportunities in telemedicine.⁵⁵ A continuous “stream of data on variables such as gait metrics can provide physicians with a better understanding of a patient’s health that was not possible in a controlled . . . clinic[al] setting.”⁵⁶ If doctors have access to patient vitals for the first time, they may be able to offer more tailored and personalized treatment.⁵⁷ This should theoretically lead to a higher standard of healthcare.⁵⁸ Use of wearables can also alert healthcare providers to symptoms or patient needs earlier on.⁵⁹ If a patient is exposed to COVID-19 or is experiencing vitals that are irregular, a doctor may be able to utilize the data to intervene earlier than before.⁶⁰ Therefore, wearable technology in health care may prove to be an important factor that can improve access for patients.⁶¹ For example, if a patient has a chronic disease or has some other barrier to treatment, the data created by the technology provides a way for a provider to stay engaged with the patient and their condition.⁶² Wearables can also “provide physicians with a more well-rounded picture of the patient when making a treatment decision.”⁶³ Specifically, they will “allow physicians to monitor lifestyle changes or habits that may affect a chronic condition, such as physical activity, stress management, and breathing.”⁶⁴ Wearables can also be used to reinforce patient compliance with prescribed treatment.⁶⁵

However, there are also negatives to consider. The practice of medicine has always relied on the patient-doctor relationship and establishing trust between the two.⁶⁶ “These relationships are vital because a patient’s honest account of their symptoms and exposure history . . . help the clinician diagnose and treat often complex conditions.”⁶⁷ Some skeptics of telemedicine view the use of technology in healthcare to be “innately cold” and state that it “poses a risk of depersonalizing the doctor-patient relationship, potentially

54. *Id.*

55. *Id.* at 49

56. Mobbs, *supra* note 18, at 5.

57. Blaney, *supra* note 10, at 49.

58. *Id.* at 50.

59. *Id.* at 49.

60. *Id.*

61. *Id.* at 51.

62. *Id.*

63. Blaney, *supra* note 10, at 47.

64. *Id.*

65. *Id.* at 49.

66. Borgetti, *supra* note 5, at 44.

67. *Id.*

damaging it irrevocably.”⁶⁸ Further, physicians tend to have a better “grasp or ‘feel’ of the psychological state of the patient” which helps with the flow and direction of the consultation.⁶⁹ By limiting this factor to the patient-doctor relationship, a doctor’s intuitive sense in consulting and diagnosing may also be corrupted.⁷⁰

It is also important to recognize the biggest factor in why wearable technology would decrease the standard of care: the limitations of the wearables themselves.⁷¹ Current wearables on the market may be accessible to some but present a challenge to patients who cannot afford such expensive monitoring devices.⁷² Therefore, the standard of care and capabilities of remote-patient monitoring would become reliant on peoples’ economic status.⁷³ And while the current consumer-grade devices may be accessible, their functionality is still extremely limited by medical standards; they are simply not validated or precise enough to be clinically useful.⁷⁴ On the other hand, current medical-grade devices are bulky, not easily accessible to the general public, and lack user-friendliness.⁷⁵ This issue can only be solved in one way: time and continued development. By establishing wearables as an integral part of providing telemedicine, technology will continue to adapt to fit the needs of physicians and patients relying on such devices. Further regulation of devices would provide uniformity that is needed to increase the standard of care.

Currently, the United States has a very fragmented approach to measuring the standard of care for medical practitioners.⁷⁶ Instead, all fifty states are moving in their own approaches; there is no one set standard of care policy that outlines safe practices in the realm of telemedicine.⁷⁷ Telemedicine provides an exciting opportunity to fix this. By promulgating that “physicians shall be held to the same standards of appropriate practice as those in traditional physician-patient settings that do not include a face-to-face visit,” telemedicine and wearable technology can be essentially credited as a valid form of treatment and eliminate some of the concerns presented by critics.⁷⁸

68. *Id.*

69. Mobbs, *supra* note 18, at 5.

70. *See id.*

71. *Id.*

72. *Id.*

73. Borgetti, *supra* note 5, at 7.

74. Mobbs, *supra* note 18, at 5.

75. *Id.*

76. Tyler D. Wolf, *Telemedicine and Malpractice: Creating Uniformity at the National Level*, 61 WM. & MARY L. REV. 1505, 1510 (2020).

77. *Id.* at 1517.

78. *Id.* at 1513.

C. Privacy and Confidentiality Concerns

One of the most significant concerns that come with utilizing wearable technology in telemedicine is confidentiality and privacy concerns.⁷⁹ The very nature of medical technology is to gather sensitive and private information.⁸⁰ This comes with three primary concerns: (1) the federal regulatory framework and individual state policies currently do not offer safeguards to protect personal health information in the specific context of telemedicine; (2) the data collected by third-party technology may often be seen and utilized by third-parties, often without the consent or knowledge of the user; and (3) there is a much higher risk that hackers may obtain data collected from wearables used in telemedicine as opposed to data collected from traditional physician visits.⁸¹

Currently, there are no regulations on healthcare data that are collected by third-party devices and apps.⁸² While there are regulatory frameworks in place depending on the type of data collected by wearable technology, there is no overarching federal statute governing privacy in consumer wearables, especially pertaining to telemedicine.⁸³ The closest statute that would apply would be the Health Insurance Portability and Accountability Act (“HIPAA”) which governs the collection and use of patient health data.⁸⁴ Under HIPAA, “covered entities,” which are most often healthcare providers, are required to protect “individually identifiable health information.”⁸⁵ However, this Act simply does not yet extend far enough to cover third-party technologies, which most wearables are categorized as.⁸⁶ Because third-party developers of wearables do not classify as “covered entities,” the Act fails to protect the continued usage of the data beyond the physician’s usage of it.⁸⁷ The U.S. Food and Drug Administration (“FDA”) further failed to regulate wearables.⁸⁸ While the FDA is responsible for regulating mobile health apps utilized by wearables, it stated that it “won’t vigorously regulate devices as

79. See generally Kenny Gutierrez, *Privacy in Wearables: Innovation, Regulation, or Neither*, 13 HASTINGS SCI. & TECH. L. J. 21, 23–24 (2022).

80. *Id.* at 22.

81. Alexandra Troiano, *Wearables and Personal Health Data: Putting a Premium on Your Privacy*, 82 BROOK. L. REV. 1715, 1724 (2017).

82. Gutierrez, *supra* note 79, at 28.

83. Troiano, *supra* note 81, at 1731.

84. See *id.* at 1731–32; *Summary of the HIPAA Privacy Rule*, HHS.GOV, 1, 1, <https://www.hhs.gov/sites/default/files/privacysummary.pdf> (Oct. 19, 2022) [<https://perma.cc/WGH9-FTQ6>].

85. *Id.* at 2–3.

86. See Troiano, *supra* note 81, at 1733.

87. See *id.*

88. *Id.* at 1735–36.

long as they're not harmful and generally encourage healthy habits.”⁸⁹ This further establishes the “gap” which allows the second two privacy and confidentiality concerns pressing as wearables are further incorporated into telemedicine.⁹⁰

This lack of regulation creates a vulnerability for data to be exploited by third-party developers.⁹¹ Personal health information collected is often sold to companies or advertisers that may use the data to target advertisements to users without their knowledge or consent.⁹² However, while receiving personally targeted advertisements based on your exercise habits may seem trivial, the use of other health data may prove to be a malicious problem.⁹³ What if advertisements become exploitative of individuals suffering serious health conditions?⁹⁴ What if the data is further shared or bought by insurance companies, financial institutions, or employers?⁹⁵

There is also potential for data breaches or unauthorized disclosures when healthcare providers begin to utilize third-party technology or platforms to rely on making diagnoses or recommendations in their services.⁹⁶ “Any device that has the capability to store data . . . has the potential to have the data stolen.”⁹⁷ Currently, many wearables are not able to anonymize the data.⁹⁸ The data is certainly not anonymized when utilized in healthcare.⁹⁹ By utilizing a device that is vulnerable to hacking, healthcare providers are risking breaching their patients’ confidentiality and even allowing possible identity theft.¹⁰⁰

Going forward, it is important for healthcare providers and wearable technology developers to consider relevant questions. Should the data collected by wearable devices be entered into an electronic health record and tied to a specific patient?¹⁰¹ To what extent should the data be stored and

89. *Id.* at 1735.

90. *See generally id.* at 1733.

91. Gutierrez, *supra* note 79, at 28.

92. *Id.*

93. Troiano, *supra* note 81, at 1726.

94. *See id.*

95. *See id.*

96. Panter, *supra* note 3.

97. Troiano, *supra* note 82, at 1726.

98. *Id.* at 1730.

99. *Id.*

100. *See id.* at 1726.

101. *See generally* Paige Papandrea, Note, *Addressing the HIPAA-potamus Sized Gap in Wearable Technology Regulation*, 104 MINN. L. REV. 1095, 1111 (2019).

used?¹⁰² Further, it is prudent for policymakers to remedy possible privacy threats before the field expands and before large-scale breaches do occur.¹⁰³ By implementing mandatory federal regulations, such as the General Data Protection Law (“GDPR”) or expanding HIPAA to include third-party technology developers as “covered entities” when the devices are utilized in the sphere of telemedicine, the problem can be regulated before it becomes an issue.¹⁰⁴

IV. CONCLUSION

As wearable technology expands further into healthcare, it would be prudent for regulatory frameworks to address the legal concerns that may arise.¹⁰⁵ This case note discussed three possible issues with wearables in telemedicine: increased medical malpractice suits, lowered standards of care, and privacy and confidentiality concerns with utilizing third-party technology. These issues may be solved through the implementation of policy that creates uniformity amongst physician practices.¹⁰⁶

One of the critical implementations to help resolve these issues is the establishment of wearables as “medical devices,” meaning that their classification would be products that are used to “diagnose, cure, mitigate, treat, or prevent a disease.”¹⁰⁷ By gaining this classification, wearables would become more regulated by the FDA.¹⁰⁸ This would implement standards of care as well as address some of the privacy concerns outlined in this case note. Further, expanding the currently outdated HIPAA would afford greater protection to users relying on these devices in their medical treatments.¹⁰⁹

Currently, remote patient monitoring and healthcare services are becoming increasingly preferred by many, and non-critical patients are encouraged to stay away from the hospital if possible.¹¹⁰ This “new norm” should incentivize policymakers to address issues and encourage the continued development of health-monitoring technology.¹¹¹ The potential that wearables offer in the healthcare field only grows with each new development, but before they are fully incorporated into telemedicine, regulatory agencies must address the concerns of malpractice suits, the standard of care, and privacy.

102. *Id.* at 1114.

103. *Id.* at 1097.

104. *Id.*

105. *See id.*

106. *See id.* at 1095.

107. *See* Papandrea, *supra* note 102, at 1120.

108. *See id.* at 1121.

109. *See id.* at 1121–22.

110. Mobbs, *supra* note 18, at 5.

111. *See id.* at 4.

