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EVOLUTION OR REVOLUTION IN TELEHEALTH REGULATION

*by: George Horvath**

A frequently repeated adage, attributed to a wide range of authors and orators, holds that a serious crisis should never be allowed to go to waste.[1] The moment in which we find ourselves renders this adage particularly timely. Responses to one of the defining crises of our age—the COVID–19 pandemic—have mostly been reactive. This includes the responses of multiple actors involved with telehealth. Congress, federal regulators, state legislatures, state regulators, private insurers, and health care providers, confronting the challenges of the pandemic, have responded by making ad hoc adjustments to the regulation and use of telehealth. Moving the conversation beyond this reactive posture, Professor Deborah Farringer's article, *A Telehealth Explosion: Using Lessons from the Pandemic to Shape the Future of Telehealth Regulation*, surveys the history of telehealth regulation, the pandemic-era adjustments, and recent proposals for the future finds an opportunity instead. The article seeks to put a crisis to good use—taking "advantage of the momentum that the COVID–19 public health emergency has created"—to inform the creation of "a comprehensive and integrative approach" to telehealth regulation.[2]

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[1] Rahm Emanuel, Opinion, *Let's Make Sure This Crisis Doesn't Go to Waste*, WASH. POST, Mar. 25, 2020, https://www.washingtonpost.com/opinions/2020/03/25/lets-make-sure-this-crisis-doesnt-go-waste/ [https://perma.cc/9DK4-PUBL] (quoting himself from 2008 and stating "[n]ever allow a good crisis to go to waste"); Myron F. Weiner, *Don't Waste a Crisis—Your Patient's or Your Own*, 5 MED. ECON. 227 (1976) (stating "[i]f you have a . . . crisis in your own life, whatever you do, don't waste it."); *see* THE DICTIONARY OF MODERN PROVERBS 60 (Charles C. Doyle et al. eds., 2012) (stating the terms "[a] crisis is an opportunity" and "[d]on't waste a crisis" have roots in the New Testament and Chinese proverbs); *e.g.*, *Quotes by Winston Churchill*, THE BEST QUOTATIONS, https://best-quotations.com/authquotes.php?auth=15 [https://perma.cc/AD79-QAED] (last visited Nov. 30, 2021) (stating "[n]ever let a good crisis go to waste").

[2] Deborah R. Farringer, *A Telehealth Explosion: Using Lessons from the Pandemic to Shape the Future of Telehealth Regulation*, 9 TEXAS A&M L. REV. 1, 30 (2021).

I find it possible to read *A Telehealth Explosion* in two ways: as an article with narrow aims and as an article with much broader aims. Parts I and II present these two readings. In Part III, I situate the broader reading within the context of earlier expansions of federal regulation of the health care enterprise to pose the question of how likely it is that the current crisis can be put to the good use that Professor Farringer seeks.

I. A NARROW READING

In one possible reading, *A Telehealth Explosion* is an important but self-limited contribution to a growing body of scholarly work focused on telehealth regulation.[3] *A Telehealth Explosion* expressly disclaims a desire to offer specific proposals, instead urging that the path forward be data-driven and guided by five "key factors" that regulators and legislators should consider as they craft a new regulatory regime.[4] The article might be interpreted as falling within a genre of scholarship in which an author painstakingly identifies a major problem but eschews the work of fashioning a set of specific responses in favor of setting out a framework for others' use.

Reading *A Telehealth Explosion* in this way, one particular concern is the limited focus on the quality of care that telehealth can provide. Admittedly, Professor Farringer highlights the importance of quality to state regulators, members of Congress, and the telehealth industry,[5] and in one key factor urges state legislators and regulators to analyze emerging data "to understand where telehealth might actually generate quality of care concerns."[6] But in other places, concerns

[3] *See, e.g.*, Laura C. Hoffman, *Shedding Light on Telemedicine & Online Prescribing: The Need to Balance Access to Health Care and Quality of Care*, 46 AM. J.L. & MED. 237 (2020); David A. Hoffman, *Increasing Access to Care: Telehealth During COVID–19*, 7 J.L. & BIOSCIENCES 1 (2020); Mei Wa Kwong, *Telehealth and Public Programs - Evolution of Telehealth Policy in Medicare and Medicaid*, 15 J. HEALTH & BIOMED. L. 7 (2019).
[4] Farringer, *supra* note 2, at 39.
[5] *Id.* at 8-9, 35-37.
[6] *Id.* at 44.

about quality appear to go unrecognized. One example is in the discussion of whether requirements for an in-person evaluation, before care is delivered remotely, should be eliminated. The article states that "from a medical perspective" the reasons for requiring an initial in-person visit are to allow for "(1) verifying and authenticating the patient, (2) disclosing physician identity and credentials, and (3) obtaining necessary consents."[7] In considering whether to eliminate these requirements, regulators should balance these concerns against the restrictions on competition and the availability of medical and pharmacy services that the requirements impose.[8] But this framing overlooks the critical medical reason for a face-to-face encounter from a provider's perspective: An initial face-to-face visit allows the provider to gather clinical information that is difficult if not impossible to obtain remotely. Providers gather some of this information from subtle findings on the physical examination, such as the slight parasternal heave that may indicate an enlarged ventricle or the slight bobbing of the head (DeMusset's sign) that may indicate severe aortic regurgitation, which even state of the art technologies cannot yet replicate remotely. [9] But a great deal of information is also gathered from behavioral clues that, in person, can signal discomfort with a topic, unexpressed concerns, or a tendency to minimize or dramatize complaints, but that could be missed entirely in an online encounter. An initial visit helps a clinician establish a broad and deep understanding of each patient, which can inform later remote follow-up evaluations. In some contexts, the quality of care afforded by an initial in-person evaluation must be weighed alongside the other concerns.

[7] *Id.* at 10 & n.61 (quoting a discussion of when a provider-patient relationship is established as contained in a report by the Federation of State Medical Boards).
[8] *Id.* at 38.
[9] Jonathan Abrams, *Physical Examination of the Heart and Circulation*, *in* ESSENTIAL CARDIOLOGY: PRINCIPLES AND PRACTICE 99, 102 tbl.3, 112 (Clive Rosendorff ed., 2d ed. 2006).

The discussion of the five key factors also reflects a limited focus on quality. Quality features prominently only in one of the factors: "State laws should be for the purpose of promoting efficiency and quality care, not protecting against new competitors."[10] Even here, the framing emphasizes what regulation should not be (a cartelization of services) rather than how regulators should think about ensuring the quality of care. My point is that quality is a crucial factor that legislators and regulators must consider. The regulatory environment that existed before the pandemic limited the development of telehealth and, concomitantly, the development of clinical data on the outcomes that are achieved when care is delivered remotely.[11] This data will eventually emerge in piecemeal fashion as clinicians study the quality and value of telehealth in very specific aspects of practice.[12] Moving forward, it is crucial that a comprehensive regulatory approach incentivize the generation of such data and ensure that it is considered by legislators and regulators every step of the way.

A second concern focuses on how some of the proposals in *A Telehealth Explosion* could be accomplished. One of the Farringer factors urges state legislators and regulators to eliminate barriers to competition and restrictions on services. But state laws and regulations that erect barriers and impose restrictions are often deliberate features rather than inadvertent bugs. State licensure of physicians, for example, has been supported by physicians in part to limit the availability of competing medical services.[13] How are such laws and regulations to be eliminated

[10] Farringer, *supra* note 2, at 43-44.
[11] *Id.* at 2.
[12] *Cf.* Hoffman, *supra* note 3, at 241-42 (reviewing research studies examining telehealth and remote prescribing in two specific clinical contexts: antibiotics for pediatric respiratory infections and antibiotics for adult respiratory infections).
[13] PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 102 (updated ed. 2017) (explaining that allopaths sought early state licensing laws to "protect . . . against competition from untrained practitioners"); Aaron Edlin & Rebecca Haw, *Cartels by Another Name: Should Licensed Occupations Face Antitrust Scrutiny?*, 162 U. PENN. L. REV. 1093, 1107 (2014) (providing examples of how licensure and associated regulations are used to limit the availability of medical services).

when state actors and many of their politically powerful constituents have strong reasons to maintain them?

A broader reading of the article answers this question. If *A Telehealth Explosion* were simply urging the ongoing use of data to inform policy as regulators consider the five Farringer factors, the article's goals might be viewed as relatively modest. Such a reading would, in my view, be a mistake. *A Telehealth Explosion*, more broadly read, packs a much bigger bang. Articles that fall within that genre of scholarship referred to above—articles that identify a problem and how to think about it without actually doing the nuts-and-bolts work of solving the problem—can, if done well and if read by the right audience, define the problem and structure the approaches to solving it. These articles can thus determine the possible set of outcomes that will emerge. Professor Farringer, drawing on the history of telehealth and telehealth regulation, and looking over the lessons learned during the pandemic, is doing just this.

But it is possible to read *A Telehealth Explosion* even more broadly, not as a roadmap for evolution but rather as a plan for revolutionary change. At the same time that it disclaims the desire to offer specific proposals, *A Telehealth Explosion* offers a number of specifics in the service of creating "a comprehensive and integrative approach" to telehealth regulation. And these specifics would involve a substantial expansion of federal control. The next Part examines this broader reading.

II. A BROADER READING

Telehealth is subjected to a polycentric set of regulatory inputs. As Professor Farringer summarizes, regulation before the pandemic subjected telehealth to

> an intricate and sometimes conflicting regulatory structure involving state laws and regulations in the domicile state, state laws and regulations in other states, federal laws and regulations, federal reimbursement rules, state reimbursement

> rules, and all applicable laws, regulations, and contractual provisions of commercial insurers.[14]

And as Part III of the article demonstrates, the federal and state responses to the pandemic, including the waivers that several federal agencies have granted, have done little to cut through this Gordian knot of conflicting statutes and regulations. Not surprisingly, then, the first key factor—really a set of concrete proposals—that Professor Farringer articulates is that it is "imperative for the federal government and states to work together to create a regulatory regime that is less complex and less confusing."[15] But how is this to be done? After all, the states remain motivated, among other things, to erect barriers to entry by out-of-state providers and pharmacies.

The answer toward which *A Telehealth Explosion* appears to turn is substantially to centralize telehealth regulation under the federal government, notably the Department of Health and Human Services (HHS). I have noted how an article like *A Telehealth Explosion* can determine the direction and even the outcome of attempts to solve difficult problems by setting the terms of engagement. Professor Farringer's first key factor uses this concept, arguing that "Congress, in coordination with HHS, should establish a definitional framework for telehealth services."[16] Doing so would "ensure that the states and federal government are operating off the same general terms and from the same general premise."[17] The federal government would thus set the terms, the structure, the rules, and the objectives for telehealth regulation. One intended result is that the "states will be better able to engage in legislative redesign that creates

[14] Farringer, *supra* note 2, at 39.
[15] *Id.* at 40.
[16] *Id.*
[17] *Id.*

consistency between the state and federal governments and among the states."[18] With Congress and HHS setting the terms, this state-level redesign would create consistency with federally established terms and objectives.

Further support that *A Telehealth Explosion* sees centralizing telehealth regulation under the federal government as the best way forward is found in the suggestion that the federal government "create incentives that would encourage states to coordinate with one another and with the federal government on a basic regulatory structure for telehealth."[19] How the federal government would do this is not elaborated, but the suggestion seems to encompass the possibility of a grant program in which Congress would make substantial funding available to states that adopt the HHS framework. This kind of grant program could help convert the seeming precatory language that state actors evaluate the effect of state laws and regulations into something with more bite.[20]

The need for the federal government to play a dominant role in a "comprehensive and integrative approach" to telehealth regulation also arises from the current regulatory regime, the deficiencies of which the remaining Farringer factors address. The second key factor is the necessity of "reducing the controls at the state and federal levels that continue to tie telehealth services to a physical location."[21] This would include permitting the delivery of virtual services to a patient's home, allowing for the delivery of care across state lines, and eliminating the requirement that the rendering physician be licensed within the state to which care is delivered.

[18] *Id.*
[19] *Id.*
[20] Congress's power to incentivize state conduct is expansive: Congress can induce states to take actions by conditioning the receipt of funds even though directly requiring those same actions exceeds Congress's Article I authority. Nat'l Fed'n of Indep. Bus. v. Sebelius, 567 U.S. 519, 577 (2012). This power is not unlimited; in Chief Justice Roberts's phrasing, Congress cannot create incentives that are so powerful as to amount to "a gun to the head." *Id.* at 80.
[21] Farringer, *supra* note 2, at 41.

Success would also depend on correcting reimbursement disparities, which is the subject of the fifth key factor. Although some of these steps are within the states' authority, the states' power to make significant change "is largely limited to either Medicaid or commercial insurance for residents of the state."[22] In fact, the states almost certainly lack the authority to untether virtual care from specific locations and require payment parity of telehealth services for half of their residents.[23] Thus, a robust federal regulatory role is necessary to achieve the goal of expanding access. And the final key factor—examining whether laws and regulations established to protect against "fraud, waste, and abuse[,] are… successfully controlling such ills or [are] instead creating needless obstacles [to] innovation"[24]—is under federal control already: These obstacles are created by fraud and abuse statutes and regulations that apply to Medicare.

Thus, under a broad reading of *A Telehealth Explosion*, achieving its aspiration of fostering "a comprehensive and integrative approach" to telehealth regulation will only be possible by creating a federally based regulatory regime. Given the incentives for states to behave in a self-interested fashion and the fact that individual states are not capable of resolving many of the problems in telehealth regulation, this would appear to be an appropriate area for federal regulation. Of course, any such move toward centralization raises a host of concerns over

[22] *Id.* at 41 & n.251.
[23] According to recent Census Bureau data, 17.8% of people are covered by Medicaid. KATHERINE KEISLER-STARKEY & LISA N. BUNCH, U.S. CENSUS BUREAU, HEALTH INSURANCE COVERAGE IN THE UNITED STATES: 2020, at 4 tbl.1 (2020), https://www.census.gov/content/dam/Census/library/publications/2021/demo/p60-274.pdf [https://perma.cc/82TR-QAH9]. Directly purchased plans cover 10.5%. *Id.* The state's authority to regulate commercial insurance is sharply limited by the preemption provision of the Employee Retirement Income Security Act (ERISA), which has interpreted to bar state regulation of self-funded employer sponsored health insurance. Erin C. Fuse Brown & Elizabeth Y. McCuskey, *Federalism, ERISA, and State Single-Payer Health Care*, 168 U. PA. L. REV. 389, 428-30 (2020). As a result, states may only regulate fully funded employer sponsored plans, which account for 39% of all employer sponsored plans. *Id.* The Census Bureau reported that 54.4% of people were covered by an employer sponsored plan. KEISLER-STARKEY & BUNCH, *supra* note 23, at 4 tbl.1. Thus, states can regulate the coverage of 21.3% of people. In total, states can regulate the coverage of 49.6% of people.
[24] Farringer, *supra* note 2, at 42.

federalism and the already eroded tradition of state primacy in regulating health care.[25] I wish to avoid these concerns and instead seek to answer a question: Is Professor Farringer's proposal likely to succeed?

III. SITUATING THE BROAD READING WITHIN MODELS OF CHANGE

Change—even revolutionary change—is more likely to succeed if it follows a path that has yielded success in the past. In asking whether a proposal for an expanded federal role in telehealth regulation is likely to succeed, a comparison to three different paths, or models, that earlier expansions of federal regulation in health care have employed may be instructive. Before proceeding, it is necessary to state a few assumptions: that the proposal's goal is the creation of a federal-based regulatory regime, that demand for telehealth will remain strong, and that telehealth will represent a large portion of health care delivery from this point on.[26] Under these assumptions, a comprehensive approach will necessitate a large federal presence. It is also necessary to admit that many of the historical antecedents to which we might turn for insights are uneasy fits. The 20th century saw several dramatic expansions of federal authority over medical products—biologics, drugs, and medical devices. And from the mid-twentieth century to the present, we have seen expansions of the federal government's role in regulating and providing health care insurance. Although telehealth regulation involves products and insurance, *A Telehealth Explosion* is really discussing the regulation of a mode of delivery of health care services that is facilitated by new technologies. Recognizing this, I argue that the approach that

[25] *See* Patricia J. Zettler, *Toward Coherent Federal Oversight of Medicine*, 52 SAN DIEGO L. REV. 427, 454 (2015) (describing the role of federal regulation over many areas of medicine).

[26] The assumptions concerning the future demand for and the portion of delivery that will be supplied by telehealth seem reasonable. Before the pandemic, telehealth was the fastest growing mode of health care delivery and projected to account for $64 billion in annual health care spending by 2025. Hoffman, *supra* note 3, at 237-38. More recent projections have gone as high as $250 billion annually, although these have subsequently been the subject of cautions. Oleg Bestsennyy et al., *Telehealth: A Quarter-Trillion-Dollar Post-COVID19 Reality?*, MCKINSEY & CO., (July 19, 2021), https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/telehealth-a-quarter-trillion-dollar-post-covid-19-reality [https://perma.cc/N2NZ-R9RQ].

Congress and HHS took in regulating electronic health information in the Health Insurance Portability and Accountability Act (HIPAA) and the HIPAA Privacy Rule provides the most relevant model for comparison.

In one model of expanding the federal role in regulating aspects of health care, Congress has responded to highly publicized tragedies by defining an entire category of products, over which a federal agency will be given jurisdiction, and establishing a detailed statutory regime to be implemented by that agency. Early in the twentieth century, Congress rushed the Biologics Control Act into law after highly publicized episodes in which contaminated batches of the smallpox vaccine and diphtheria antitoxin killed scores of people.[27] Congress passed the original Food, Drug, and Cosmetic Act (FDCA) in 1938, shortly after the Elixer Sulfanilamide event in which more than a hundred people, mostly children, died from the toxic effects of a never-tested solvent used to dissolve a sulfa drug.[28] And Congress passed the Medical Device Amendments in 1976 in the wake of high-profile device problems such as the sepsis, spontaneous abortions, and maternal deaths caused by the Dalkon Shield intrauterine device.[29]

Superficially, the COVID–19 crisis, with over 822,000 deaths in the United States to date,[30] would seem to provide a close analogy. But each of the earlier instances differs from the COVID–19 crisis in a critical way: In response to the earlier crises, Congress responded by regulating the cause of the crisis (contaminated vaccines, untested drugs, defective devices), whereas regulating telehealth does not involve regulating the cause of the crisis (the SARS-CoV-

[27] Terry S. Coleman, *Early Developments in the Regulation of Biologics*, 71 FOOD & DRUG L.J. 544, 545-51 (2016).
[28] JAMES H. YOUNG, THE TOADSTOOL MILLIONAIRES: A SOCIAL HISTORY OF PATENT MEDICINES IN AMERICA BEFORE FEDERAL REGULATION 205 (2016); Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1761(1996).
[29] Jordan Paradise et al., *Evaluating Oversight of Human Drugs and Medical Devices: A Case Study of the FDA and Implications for Nanobiotechnology*, 37 J.L. MED. & ETHICS 598, 614 (2009).
[30] *Coronavirus Resource Center*, JOHNS HOPKINS UNIV. & MED., https://coronavirus.jhu.edu/ [https://perma.cc/E5K5-3TK6].

2 virus). The direct relationship between the harm-causing agent and the regulatory response, which might break through legislative logjams, is not present.

In another model of federal expansion, in response to decades-long efforts to expand health care coverage, Congress created sources of funding and an extensive administrative bureaucracy to administer the Medicare and Medicaid programs and various aspects of the Affordable Care Act ("ACA").[31] It is difficult to argue that telehealth presents the same kind of long-term pent-up demand that preceded the creation of federal health care coverage for the elderly through Medicare or the expansions to coverage through the ACA.

Thus, the social conditions that these models have been used to address are not close matches to those that are present in this moment. Nor are these the models that *A Telehealth Explosion* is employing. Creating a detailed statutory regime akin to those in the Biologics Control Act, the FDCA, and the Medical Device Amendments is not the model that Professor Farringer is following. And although I read *A Telehealth Explosion* to advocate a strongly federal-centered regulatory approach, creating the equivalent of the Medicare, Medicaid, or ACA type program to provide coverage for telehealth services is not the model either.

Far more relevant is the HIPAA model. By the early 1990s, the promise of a new technology—electronic storage and transmission of health records—to improve health care had become apparent. At the same time, the dangers of electronically stored records, particularly the danger of compromised privacy, had become apparent as well.[32] And the existence of a tangled web of state-level privacy protections threatened to hamper the development of this promising

[31] *See generally*, THEODORE R. MARMOR, THE POLITICS OF MEDICARE (2d ed. 2000) (reviewing efforts to expand the federal government's role in health insurance between 1915 and the enactment of Medicare in 1965).
[32] Sharona Hoffman & Andy Podgurski, *In Sickness, Health, and Cyberspace: Protecting the Security of Electronic Private Health Information*, 48 B.C.L. REV. 331, 332-33 (2007) (discussing the persistence of these factors a decade later).

new component of health care. In response, Congress included in the HIPAA statute a subtitle intended

> to improve . . . the health care system, by encouraging the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information.[33]

The statute included a basic set of definitions establishing who was to be subjected to regulation and the object of that regulation, but ultimately left the development of the details to HHS.

Under a broad reading of *A Telehealth Explosion*, HIPAA provides a reasonable analogy to the key proposal for Congress and HHS to "establish a definitional framework for telehealth services."[34] Many of the same conditions are present now. Thanks in part to the pandemic, the promise of a new technology—telehealth—has now been amply demonstrated. As the examples of Zoom bombing have illustrated, the risks of this new technology are also now apparent. And the impediment that the existing tangled web of regulations poses to the realization of the technology's full potential is undeniable. In addition, the goal of encouraging the development of an exciting new technology is analogous. To be sure, the Privacy Rule has no shortage of detractors. But as a model for expanding the federal presence in health care regulation, HIPAA has been a success: There is no doubt that the terms, the structure, the rules, and the objectives of privacy regulation have been set by Congress and HHS.

[33] Health Insurance Portability and Accountability Act, Pub. L. No. 104–191, § 261, 110 Stat 1936, 2021 (1996).
[34] Farringer, *supra* note 2, at 40.

Another adage that is particularly relevant in the COVID–19 era is that "uncertainty is the only certainty."[35] Whether demand for telehealth will remain strong, whether clinical data will continue to support its use, and—relevant here—whether Professor Farringer's approach to the regulatory barriers that have stymied the development of telehealth will be adopted all remain uncertain. But in the effort to create a solution to a complex problem, adopting a model for change that has succeeded in the past is a promising choice.

[35] This quote is attributed to mathematician John Allen Paulos. John Allen Paulos's Quotes, GOODREADS, https://www.goodreads.com/quotes/504787-uncertainty-is-the-only-certainty-there-is-and-knowing-how. [https://perma.cc/HH9Z-6VJH] (last visited Dec. 29, 2021). As yet, the quote does not appear to have been attributed to Winston Churchill.