



Better Healthcare through Hospital Avoidance: A Path to Providing Healthcare in the Home

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Before the COVID-19 pandemic, hospitals and outpatient clinics accounted for 99 percent of all medical visits.¹ Though that share has dropped during the pandemic, it remains greater than 90 percent.² However, in an increasingly distributed, digital world, providing an overwhelming share of health care in highly capital-intensive environments makes less and less sense. By nature, capital-intensive environments are burdened by high fixed costs.³ And by default, these environments rely on physicians for the provision of care. But the services of other licensed medical professionals are less expensive and are likely to be just as effective, even with little physician oversight. Centralizing services in a hospital makes sense for procedures and types of care requiring bulky equipment, a sterile environment, or both, but advances in technology and the evolution of consumer habits now permit a larger share of healthcare to be delivered in the home, in retail clinics, and in other nonhospital and non-outpatient settings.

Proven models exist for the provision of such care.⁴ These models achieve comparable or better outcomes at lower cost by making the most of

- nondoctor medical personnel,⁵ including both licensed healthcare professionals and non-licensed workers who can supplement licensed personnel with expertise in areas such as social work and digital technology;
- the internet and mobile phones (for telemedicine); and
- more transparent and direct methods of payment for healthcare services.

Shifting the provision of healthcare away from unnecessarily costly settings to homes and retail clinics will require changing how healthcare is regulated. Specifically, we recommend reforms in five areas:

- Scope of Practice
- Modes of Payment
- Medical Devices
- Patient Health Data
- Telemedicine

Reforms in each area interact with and amplify reforms in the others, making simultaneous adoption a more effective means of changing the medical system. For example, offering a greater share of healthcare in the home incentivizes the development of innovative home healthcare technologies; innovative home healthcare technologies, in turn, increase the effectiveness and overall appeal of home healthcare. Similar positive feedback loops exist for the self-ownership of patient health data, for increases in price transparency, and for increased market competition.⁶ The provision of healthcare in the home also allows for stronger patient-provider relationships by allowing healthcare providers to more directly observe the context within which symptoms develop and the consequences of care that patients ultimately experience.

SCOPE OF PRACTICE

Problem: Restrictive regulations on scope of practice reduce the number of innovative, cost-lowering, and quality-raising methods of healthcare delivery.

Solution: Regulation at the state level should be amended to expand the scope of practice for licensed, nonphysician medical personnel.

At the state level, scope-of-practice laws prevent nurse practitioners (NPs) and physician assistants (PAs) from performing many tasks of which they are fully capable but that doctors, who are more highly paid, are currently required by regulation to perform in outpatient clinics or hospitals.⁷ Health policy analyst Hilary Barnes and coauthors find that expanding scope of practice for NPs increases the likelihood of NPs working in primary care between 13 and 20 percent, depending on levels of Medicaid reimbursement.⁸ These findings support the idea that PAs and NPs are underutilized, especially in primary care. Loosening scope-of-practice restrictions also allows NPs and PAs to work in diagnostics and treatment in the home as well as in other low-cost settings such as retail clinics.⁹ Therefore, scope-of-practice reform is important for encouraging home and retail healthcare.

Although physicians are capable of performing house calls, allowing NPs and PAs to perform them would amplify the cost savings of home healthcare by increasing the number of personnel who can

provide healthcare in the home. House calls could even be performed by interdisciplinary teams of NPs, PAs, social support workers, and health coaches performing a variety of diagnostic tests, treatments, and preventative measures that are tailored to the patient.¹⁰ These house calls would reduce the likelihood that patients have to visit a hospital or outpatient clinic, thus saving patients money on care that is not or does not need to be capital-intensive. Additionally, house calls led by NPs could reduce the use of doctors in home healthcare, which would also reduce costs. A study performed in the United Kingdom of one medical practice shows that two hours of nurses' time with patients freed three hours of time for the doctors at that practice to perform surgery.¹¹ To achieve similar savings elsewhere, scope of practice must be expanded for NPs and PAs, who are naturally positioned to work at the core of an expanded home healthcare system.

Loosening scope-of-practice regulations also allows other forms of nonhospital healthcare to become more prevalent. A rapid growth in the use of retail clinics, for example, has occurred in areas where regulation of NPs and PAs is less stringent. In 2017, Kaiser Permanente and Target announced a joint effort to open 31 retail clinics in Southern California over three years.¹² As of 2020, the two partners had successfully opened all 31 clinics.¹³ Walgreens and LabCorp have also partnered to provide lab services at their retail clinics.¹⁴ Meanwhile, Johns Hopkins is among the service providers that have been providing Medicare services in patients' homes through the Independence at Home Demonstration, a test program of the Centers for Medicare and Medicaid Services.¹⁵ At the same time, states such as Tennessee have proposed legislation to make it easier to use electronic and telecommunications technologies to provide home healthcare in rural communities.¹⁶

Although scope-of-practice reform is designed to allow NPs and PAs to take over many medical tasks in nonhospital settings, the benefits of such reform—such as cost savings—spill over into hospitals and outpatient clinics as well. A study from the *Journal of Nursing Regulation* estimates that states with greater scope of practice for NPs have outpatient costs that are 17 percent lower and prescription drug costs that are 11 percent lower for Medicaid patients.¹⁷

An additional regulatory reform that would augment looser scope-of-practice restrictions and help realize the potential of home healthcare is the development of a new medical specialty that one might term “digital health worker.”¹⁸ This role would complement NPs and PAs by focusing on digitally supported record keeping and simple diagnostics. The training for digital health workers would emphasize proficiency in digital technologies, basic knowledge of anatomy and medicine, and excellence in preventive care. In addition to improving patient outcomes directly, a category of healthcare workers focused on digitally supported diagnostics would also help manage the time cost of keeping digital health records, which physicians have long noted as being a major barrier to their use of digital health record-keeping systems.¹⁹ Empowering digital health workers to gather and organize patient health data at home or in retail clinics without a physician present would save physicians time on diagnostics and record keeping and would potentially reallocate a greater share of routine tasks to NPs and PAs.

MODES OF PAYMENT

Problem: The norm of third-party payment for healthcare services decreases price transparency, making healthcare provided outside of hospitals difficult to price.

Solution: States should implement a legal structure supporting innovative modes of payment (such as direct payment) for healthcare and create a state medical price database.

The provision of accessible and affordable healthcare and the availability of health insurance are not the same. Insurance is a tool that, ideally, helps patients gain access to and pay for healthcare. But having insurance does not mean that medical facilities are geographically within reach, that enough medical providers are available to meet patient needs, or that people have the money to pay the insurance premiums, deductibles, and copays. Even people with employer-provided insurance can experience large, complex, and indirect costs under the current insurance-hospital care model. One study shows that, from 2017 to 2018, out-of-pocket healthcare costs increased 12 percent for inpatient, outpatient, and emergency care.²⁰ The same study finds that this increase is pushing people into lower-cost healthcare settings outside of inpatient and outpatient venues. Giving patients more choices for receiving care outside of hospitals and outpatient clinics can therefore help patients avoid rising healthcare costs.

The healthcare industry in America is dominated by two primary sources of payment: private insurance and government programs (Medicare and Medicaid). Both of these payment sources pretend to be insurance, but in healthcare, the word “insurance” doesn’t mean what it means in any other areas, where it typically pays for catastrophic and unforeseen problems. Health insurance is effectively prepayment for health care, and it is slow to respond to healthcare innovations such as cheaper venues for providing primary and chronic care (such as the home). Therefore, increasing the amount of care provided outside of hospitals requires shifting away from third-party payment toward a system where patients pay directly for a greater share of routine care.

Direct payment has the potential to bring market discipline to the provision of nonemergency healthcare. As in other industries, the competition and transparency inherent with direct payment would put downward pressure on prices in the healthcare industry, making nonemergency care more affordable, and it would incentivize increased quality.

Some movement toward direct payment is already occurring in the form direct primary care (DPC). In the DPC model, patients directly pay providers a simple monthly fee for most routine medical care instead of relying on insurance to pay for them. Though DPC is primarily used for hospital and outpatient visits, it also includes visits via communication technology (an example of what is known as telemedicine) and home-based medical visits.²¹

The first state to allow DPC was West Virginia, which did so in 2006.²² As of 2020, the number of states allowing DPC had increased to 29.²³ If the remaining 21 states and the District of Columbia

were to pass DPC laws of their own, they would expand the noninsurance options available for their citizens to pay for their healthcare, promoting greater price transparency in the medical system. But despite the potential benefits, providers may be reluctant to use this business model without a legal structure in place that differentiates it from insurance. In order to facilitate competition between DPC and traditional models of healthcare provision, state regulators need to clarify the legal status of DPC.

Another innovative method of paying for healthcare is voluntary communal funding. Voluntary communal funding is another way that healthcare can be both directly funded and directly provided primarily peer to peer. An emerging model of voluntary communal support known as the Village model is one example of how peer-to-peer healthcare can work. In the Village model, seniors can “age in place” (i.e., remain at home and thereby delay or avoid moving to institutional senior care settings) by helping each other pay for or perform simple chores and travel to medical appointments. Such networks are a potential vehicle for older residents of neighborhoods to finance their own healthcare by sharing fixed costs in the form of a monthly fee.

In 2017 there were 220 Villages throughout the United States, with 30 to 40 percent accepting younger members.²⁴ Villages don’t bring healthcare providers into the home in the same way that home healthcare does. Instead, they help get people to traditional hospital and outpatient care while also aiding them with health-related concerns in their homes for which people typically have to use insurance, such as installing railing or bars. Although the Village model does not represent a drastic shift from the hospital-based system, it still brings portions of healthcare into the home via novel funding mechanisms in a way that serves patients and promotes price transparency for healthcare services more than do traditional models.

Villages can also fill the gaps in Medicare. The National Institute on Aging notes that many of the at-home services that aging in place requires “might” be covered or are “sometimes” covered by Medicare.²⁵ For example, “Medicare might pay for a home health aid,” and mobility devices “are sometimes covered by Medicare.”²⁶ Villages have been able to provide these services to fill the gaps in the current healthcare coverage of aging Americans.

State governments have largely acted favorably toward this model of organizing healthcare payment and provision. They should continue to do so, and they should further enhance it. In 2013 the American Bar Association noted a potential for liability owing to the volunteer nature of many of these communities.²⁷ Because Villages have proliferated since 2013 and continue to do so, states should clarify the issue of liability for the voluntary services provided in communities, which will remain an important issue for Villages.

Perhaps the largest obstacle to innovation in the payment for healthcare is the lack of quality-adjusted, transparent prices for healthcare services. Without knowledge of both the price and quality of service options, patients simply cannot make meaningful comparisons, even among routine and nonemergency services.

High prices in healthcare is partly a principal–agent problem. Because insurers, not patients, negotiate healthcare prices, and because insurance as prepayment for healthcare is so prevalent, insurers may have little motivation to negotiate for lower prices. But moreover, the prices listed for procedures or medicines administered in hospitals or outpatient clinics are not actual market prices; nobody pays those prices—not even insurance companies, Medicare, or Medicaid—because providers and insurers negotiate on listed prices, even for routine services. Such opaque pricing can persist in and is driven by third-party payment.

Our focus thus far has been on modes of payment for routine and nonemergency healthcare, but how much of American healthcare actually involves those kinds of care? If routine and nonemergency care (which are easily shoppable) were rarely provided, then a system heavily reliant on third-party payment would be more plausible, because emergency care is not easily shoppable. However, the American College of Emergency Physicians reports that only 2 percent of US healthcare spending is on emergency care,²⁸ suggesting that 98 percent of medical spending is potentially shoppable. Were the needed information available, patients could compare the prices and quality of such services. In addition, roughly 35 percent of all services and 43 percent of services paid for by employer-sponsored insurance could use patient payment price comparisons.²⁹ So although the exact amount of spending that could be affected by reform is impossible to measure, this research suggests that between roughly 35 percent and 98 percent of all healthcare spending in the United States is potentially able to benefit from increased choice and price competition afforded by direct payment.³⁰

Achieving transparency involves more than just overcoming the principal-agent problem. It is also about gathering better data on quality of care, on which front there is a role for the state. Aggregating reliable data on quality of care is a significant challenge, but doing so will allow people to move out of an unresponsive insurance system and start using new and innovative modes of payment for routine care. Ideally, a database that includes prices would also include quality-of-care data to promote a dynamic pricing system that is quality adjusted. This would allow patients in need of routine and nonemergency care to price shop and select the provider that they find most appropriate. As in other industries, transparency would create an incentive for healthcare providers to compete on both price and quality as data become more readily available.

New Hampshire has demonstrated that there is a role for the state governments in achieving price and quality transparency. The New Hampshire Insurance Department collects anonymized insurance claims data to estimate the cost of various procedures and the quality of various healthcare providers in the state.³¹ It then makes those data available on a state-administered medical pricing hub. Although 15 other states have all-payer claims databases, New Hampshire's stands alone by not only including data on both cost and quality of care, but also by providing tools to disentangle the price differences of various insurance companies.³² The hub offers pricing information for various procedures with and without insurance. Data on quality are presented in a simple manner, with a brief explanation of how to use the data in combination.

A transformation of the health insurance system in the United States will likely take decades, if it occurs at all. Paying for primary care, routine care, and chronic care without insurance would be the first step toward lowering prices and increasing quality for those kinds of care. The reforms we suggest here would lay the groundwork for addressing the role of insurance in American health-care by allowing noninsurance methods of payment and by encouraging greater price transparency and competition among providers of routine healthcare.

MEDICAL DEVICES

Problem: Federal regulation for new medical devices is unnecessarily burdensome, and approval is slow, deterring investment and reducing the development of new medical devices.

Solution: The FDA should adopt a faster approval process for new medical devices and lessen restrictions on the personal use of noninvasive medical testing kits and biometric devices in particular.

The FDA seeks to safeguard the health and safety of Americans from potentially dangerous procedures, drugs, and devices through a review and approval process. In doing so, the FDA must balance both speed and caution: being overly hasty and being overly cautious can cost people their health or even their lives. Unfortunately, the FDA has usually tended too much toward caution, which entails a slower approval process. One reason for this tendency might be that the harm caused by a new device or treatment is obvious, but the harm caused by delaying a potentially beneficial—or even lifesaving—device or treatment is less visible.³³ This creates an incentive for regulators to protect themselves from the consequences of the more easily seen effects of approving a procedure, drug, or device too soon than the less easily seen effects of a delay in healthcare innovation.

Faster FDA approval would encourage technological innovation as medical device companies compete with each other, particularly through the development of biometric sensors and artificial intelligence diagnostic tools and through investment in telemedicine technologies. This innovation would drive down costs and drive up quality, and the benefits of any technological improvements would likely also accrue to hospitals and outpatient clinics, not just homes and retail clinics.

The process for getting new medical devices approved for use in the United States is burdensome. It not only delays the use of lifesaving and cost-saving devices, it also discourages innovation and, thus, the development of future devices.³⁴ Although the effects of regulation on medical device development are less studied than those on, for example, pharmaceutical development, both endeavors have fundamental similarities and are likely to experience similar effects—and pharmaceutical companies are sensitive to regulatory delays.³⁵ Delaying the development of pharmaceuticals by three months is associated with a decrease in the number of new FDA applications in all drug categories. And just as with pharmaceuticals, hindering innovative medical devices from coming to market likely decreases research in that field in favor of incremental changes.³⁶

One way to help get new medical devices to market faster is to reform and expedite the approval process. Doctors trained in the use of those devices could, at their discretion, use them during the extended FDA approval process. Speeding up the regulatory review process would not only get more lifesaving technologies into medical professionals' hands, it would also provide an incentive to invest more in these technologies, because helping them get to market more quickly is more attractive to investors. The FDA has taken minor steps in this regard, such as reducing delays on medical device approvals and streamlining the digital health software approval process, but faster methods of regulatory approval are still needed to help develop the medical devices that facilitate the provision of healthcare inside and outside of hospitals.

The FDA has already implemented a model for regulating new technologies more quickly. Recognizing the speed at which software development occurs, the FDA developed the Digital Health Software Precertification (Pre-Cert) Program in order to have a faster-moving and more dynamic system for quickly developing technologies.³⁷ Such a program should also be used for the development of medical devices. One advantage of doing so is that lower-risk devices would not have to go through as lengthy of a review process. Thus, devices such as biometric sensors and disease testing kits could be developed and brought to market faster, and in greater numbers and variety.

Faster device approval does have potential downsides. For example, with regard to the 510(k) process, which allows for approval of products that are “substantially equivalent” to a device already on the market,³⁸ one study focusing on medical implants finds that “device recall is not an uncommon event.”³⁹ That said, such risks can be minimized by reserving faster approval processes to noninvasive devices, such as those used for diagnostics. Thankfully, the technologies used outside of hospitals are often biometric sensors, testing kits, and other diagnostic tools. A faster system of approvals would therefore be well suited for bringing new medical technology into homes and retail clinics without forgoing safety concerns.

Recently, Lucira Health developed an at-home COVID-19 testing kit. To its credit, the FDA used emergency authorizations to approve this testing kit quickly.⁴⁰ However, the FDA also required a prescription in order to acquire the kit. Such restrictions have been a pattern with the FDA for decades. Even getting the FDA to allow pregnancy tests at home took years of legal struggles, and to date the only at-home tests not requiring a prescription are for HIV.⁴¹ The FDA should allow more nonprescription at-home testing. In the short term, doing so would spare an already-strained healthcare system. In the long term, normal market pressures would lower prices and increase the quality of future tests, not only for COVID-19, but for many other diseases as well by letting basic diagnostics take place outside of hospitals and outpatient clinics.

Another example of burdensome device approval regulations are the regulations on commercially sold devices that interpret biometric data. Once a Fitbit, cell phone, or similar device becomes able to collect a certain amount of information, even if that information is kept private to the user, the device suddenly gains the FDA as a regulator. As a result, companies such as Apple have

“dumbed down” their devices so as to limit the amount of biometric data they collect and thus avoid regulation by the FDA. These devices can now collect data only for low-risk technologies, such as those used for “maintaining or encouraging a healthy lifestyle.”⁴² Although the emphasis on low-risk technologies is well placed, disallowing companies from exploring diagnostic tools sets a hard limit on the retail tech sector’s ability to drive medical innovation. Such decisions by tech companies slow down the development of new biometric devices that could raise the quality and lower the cost of healthcare.⁴³

Throughout other sectors of the economy, technological innovation is what drives down costs and improves quality, and there is no reason to think that healthcare would work differently.⁴⁴ Reforming the review process for noninvasive medical devices would promote more safe, personally administered, at-home testing. It would also promote the development of improved and inexpensive biometric sensors, which would facilitate the provision of healthcare outside of hospitals more generally. Finally, this reform would drastically reduce healthcare costs by not requiring medical personnel to be involved in simple tests, as is already the case with pregnancy tests, and by allowing medical personnel whose services are less costly than those of physicians to perform more of the diagnostic services patients cannot provide for themselves.

DATA OWNERSHIP

- Problem:** Most states either fail to specify the ownership of patient health data or they grant ownership of patient health data to healthcare providers, complicating the development of interoperable patient health data systems.
- Solution:** States should pass legislation that gives patients ownership of their own health data, which would allow data systems developers to know the legal rights and boundaries associated with patient health data and allow them to create interoperable data systems.

Interoperability is about making information accessible across computer systems. Consumers have come to expect interoperability in many aspects of life, and they have come to expect the wide range of choices that interoperability affords. For example, different internet browsers can access the same websites.

Interoperability should also extend to healthcare, meaning that different healthcare providers could access the same patient health data. Such interoperability would facilitate the shift away from providing healthcare only in high-cost settings by allowing patient health data to be easily shared with lower-cost healthcare providers.

Physicians, NPs, and PAs need access to patient health data in order to provide adequate healthcare. Although federal law requires healthcare providers to make patient health data accessible to patients and transferrable to other providers,⁴⁵ the transfer process often costs money and time.

As of 2005, a copy of a short medical record cost up to \$55, a copy of a long medical record cost up to \$585, and a copy of either one took up to 30 days to receive.⁴⁶ Because providers may need to access medical records from numerous other providers during the course of treating a patient, these costs can add up quickly; and the high cost of sharing patient health data is especially burdensome to home healthcare providers and retail clinics.

Interoperability would allow patients to move between hospitals (for emergencies or care requiring high capital costs) and other types of providers (for routine and nonemergency care), but such convenience is less common when ownership of individuals' medical data is spread among multiple providers and when potentially different legal regimes apply.

In only one state, New Hampshire, do patients legally own their health data. In 21 states healthcare providers own patient health data, and in the remaining 28 states plus the District of Columbia, no law establishes who owns patient health data.⁴⁷ Again, states should emulate New Hampshire, in this case by enacting laws similar to the New Hampshire Board of Medicine's 332-I. This law explicitly makes patient health data the property of the patient.⁴⁸

Regulations from the US Department of Health and Human Services do require that providers give patients access to their medical records,⁴⁹ but they do not give patients ownership of their records. As part of a multibillion-dollar industry, providers sell patient health data to brokers for research purposes (though the Health Insurance Portability and Accountability Act [HIPAA] requires data to be anonymized first).⁵⁰ Patients receive neither compensation for these sales nor notice that a sale has even taken place, but patients should be able to determine whether and under what conditions they share their data.

Furthermore, for an interoperable patient health data system to function, the legal framework around data sharing must be predictable. Giving patients ownership of their data (as opposed to giving ownership to hospitals or doctors) would create such predictability.

Fully portable, self-sovereign patient health data may sound far-fetched, but research groups are already seeking better ways to keep digital medical records secure while allowing those records to be easily shared. By using the blockchain to access doctors' records for individual patients, the MedRec program at the Massachusetts Institute of Technology is giving patients access to their full health histories in one place.⁵¹ The blockchain has the potential to reduce the costs of aggregating voluntary, anonymized data from diverse sources while achieving the goals of portability and self-sovereignty mentioned earlier.

TELEMEDICINE

Problem: Federal regulations restricted telemedicine options before the COVID-19 pandemic, and although some regulations have been relaxed during the pandemic, these changes may not be permanent.

Solution: Make permanent the modifications to reimbursement policies and the revisions to HIPAA that have been enacted during the COVID-19 pandemic, with the goal of maintaining the momentum toward increased telemedicine use that has developed during 2020 and early 2021.

Telemedicine reduces the cost of routine doctor's visits. It has been of great benefit for rural communities, which are often harder to serve, and is also used by the Department of Veterans Affairs, which uses telemedicine to serve patients at home.

Although the benefits of telemedicine are disproportionately large for rural areas, its provision should not be limited only to those areas. Allowing Medicare to reimburse telemedicine in nonrural settings has been a useful step in expanding the role of telemedicine during the pandemic. Additionally, allowing Medicare patients to use telemedicine across state lines has given them access to a larger pool of physicians. Lastly, allowing the prescription of controlled medications via telemedicine would allow patients greater access and cost savings. Though some people may abuse remote prescriptions, this risk can be mitigated by allowing doctors to prescribe only refills via telemedicine (patients would still need to visit their doctor for the initial prescription), which would still lower costs and expand accessibility for chronically ill patients.

Medicaid has followed the example of many private insurers and increased reimbursement rates for telemedicine to equal in-office visits. For example, in Louisiana, Medicaid pays \$33.95 for telemedicine visits and \$62.65 for in-office visits.⁵² During the COVID-19 pandemic, however, increasing telemedicine payments to achieve parity between telemedicine and in-office visits may yield several benefits, one of which being that social distancing would be more financially viable.⁵³ However, once the pandemic is over, the rate of reimbursement for telemedicine should be decreased from its pandemic level. Whereas the prior reimbursement level may have been too low, one of the promises of telemedicine is cost savings. Telemedicine reimbursement after the COVID-19 pandemic should be less than parity but greater than it was previously.

Telemedicine has been a boon during the COVID-19 pandemic, especially to home healthcare.⁵⁴ Prior HIPAA requirements regarding what technologies could be used to provide telemedicine were waived, allowing for greater use of telemedicine in 2020.⁵⁵ HIPAA-compliant services existed before the pandemic, but during the pandemic doctors have relied on smartphones and other technologies that were previously not allowed by HIPAA. If HIPAA and other federal regulations revert to their prepandemic state, then the use of telemedicine will be more difficult because doctors will not be able to use the technologies they prefer.

Since the beginning of the COVID-19 pandemic, 28 percent of doctors have used free software such as Skype to arrange meetings, and 22 percent have used electronic health record-keeping products.⁵⁶ Forty-three percent of doctors expect telemedicine visits to decrease or stop altogether after the pandemic, whereas 39 percent expect to use it just as frequently or more frequently. Only 10 percent of doctors expect to stop using telemedicine completely after the pandemic.

On top of allowing more telemedicine technologies to be used, HIPAA has also been relaxed to skip auditing of prior patient-physician relationships.⁵⁷ By doing so, Medicare can reimburse health-care workers for telemedicine delivered to nonrural patients. Telemedicine deregulation by other agencies has compounded the effects of HIPAA's changes. The Centers for Medicare and Medicaid Services is allowing Medicare to fund telemedicine provided across state borders, and the Drug Enforcement Agency is allowing the prescribing of controlled substances via telemedicine.⁵⁸

Once the pandemic has ended, the use of telemedicine will likely decline from any peak reached during the crisis. However, it need not return to its prior low level. By keeping the reforms to telemedicine regulation adopted during the pandemic, low-cost, in-home care can be achieved in America.

CONCLUSION

Hospitals will remain a necessary part of American healthcare for the foreseeable future. But they are not the most efficient place to service all healthcare needs. Much of the healthcare provided in hospitals has high fixed costs and requires physicians to administer, and a lot of routine and nonemergency healthcare could be provided in less expensive but equally effective home and retail settings. Compared with hospitals, home and retail healthcare has lower fixed costs and less expensive staffing, specifically for routine or nonemergency care. Additionally, increased price and quality competition in these settings can act to drive innovation for somewhere between roughly 35 percent and 98 percent of healthcare services.

Scope-of-practice reform would allow NPs and PAs, whose services are less expensive, to treat routine issues in homes and retail clinics. This reform would reduce the cost of providing care outside of hospitals and thereby encourage more use of such venues. These benefits would spill over into hospitals because NPs and PAs could provide less expensive care in hospitals and inpatient clinics as well. Finally, digital health workers could help with diagnostics and with managing medical health records, which could increase doctors' time with patients and decrease the time doctors spend on administrative record keeping.

High healthcare costs are already pushing people into nonhospital settings, which are more affordable for many patients. Shifting responsibility for the payment for routine care from third parties (via private and public insurance) to patients and others who directly consume the care requires

a regulatory framework for DPC and a liability framework for peer-to-peer (e.g., Village model) healthcare provision. Doing so also requires price transparency. However, prices are obfuscated by the current third-party payment system. In order to break the cycle of third-party payment and opaque pricing, state governments should provide healthcare price and quality data in much the way that New Hampshire's has—with an online clearing house of data.

The tendency of regulators to be overly cautious (because mistakenly approving a device is more risky to regulators' careers than mistakenly waiting to approve a device) and regulatory delays limit innovation in medical devices. Medical device regulation, especially for new diagnostic and biometric devices, should be lessened to increase innovation, benefiting both home healthcare and hospital care. Noninvasive biometrics and diagnostic tools (at-home testing kits, Fitbits, and phone data) are the safest places to start deregulation.

Interoperability is needed for home healthcare and retail healthcare providers to obtain patient health data and share those data with other healthcare providers. Create an interoperable system requires clarity about who owns the data. Federal regulations require providers to give patients access to their own health data, but state regulations are inconsistent in determining who owns patient health data. Only New Hampshire clearly states that the data are owned by the patient. Providing legal clarity that health data are owned by the patient protects patient rights and privacy, allows for portability between healthcare providers (both inside and outside of hospitals), and facilitates the responsible use of large, anonymized datasets for research and innovation in diagnostic tools. Clearly specified patient ownership of data would enable data portability by removing the legal hurdles to interoperability.

Telemedicine reduces the costs of and increases access to healthcare in many communities. The changes that the US Department of Health and Human Services made to HIPAA, as well as regulatory changes by the Drug Enforcement Agency and Medicare, should be made permanent after the pandemic to continue the cost savings and accessibility increases telemedicine provides. Private communications tools such as Zoom and Skype should continue to be allowed, even if they were not on HIPAA's list of approved tools before the pandemic. The changes to HIPAA and Medicare to allow reimbursement for telemedicine provided to nonrural patients and for telemedicine provided across state lines has increased access to healthcare services during a public health emergency, but the changes will also lower costs after the emergency is over. The Drug Enforcement Agency's allowing of controlled substances to be prescribed via telemedicine should be kept (especially in cases where the medicines had already been prescribed for an extended period owing to a chronic issue). Changes in Medicare reimbursement should be rolled back partly, but not to prior levels.

Regulatory reforms regarding scope of practice, modes of payment, medical devices, data ownership, and telemedicine can help to bolster healthcare provision outside of hospitals. They can also increase the quality of routine and nonemergency healthcare in America while reducing costs.

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