ENVISIONING THE FUTURE HEALTH CARE SYSTEM

Richard S. Saver**

“Attempts to forecast the future are notoriously involved in much difficulty and uncertainty.”

“Predicting the future of health care is a tricky business.”

Envisioning the future health care system is a seemingly daunting task. Forecasts about the health care system have often proved erroneous. Nonetheless, in this symposium on American’s future health care system several leading health law scholars take up the challenge anew. The symposium authors identify key trends, critical junctures, and significant decision points shaping the path of the health care system. They delve into the wider implications of these developments for health law, policy, and ethics.

Why is it both so important and yet so difficult to envision the future health care system?

As for its value, looking forward underscores what matters at present. Scholarly attention to recurring patterns and tensions likely to persist, as well as new questions and opportunities emerging,

** Arch T. Allen Distinguished Professor of Law, University of North Carolina School of Law; Professor (Secondary Appointment), University of North Carolina School of Medicine; Adjunct Professor, University of North Carolina Gillings School of Global Public Health.


provides a more robust accounting of the conditions and influences that animate the health care system. Further, this is an opportune time to consider the future. With the implementation of the Patient Protection and Affordable Care Act (ACA),\(^3\) the health care system is underway with a historically significant transition to expanded coverage, new insurance marketplaces, and changes in the delivery system. In these early years of the ACA rollout, certain assumption made by legislation’s architects will be tested. It is also a critical time for the ACA’s overall existence, as it continues to attract vigorous political opposition even after surviving review by the Supreme Court for the second time in three years.\(^4\)

Apart from the ACA, other factors seem poised to initiate significant change. Advances in genetics and personalized medicine, for example, will likely result in very different clinical care, with wider use of screenings and predictive testing. Policy-makers are anticipating this transformative potential. The White House recently announced its new Precision Medicine Initiative, which calls for large investments in research funding, and leveraging new developments in genomics.\(^5\) If successful, the future health care system will be one in which providers can select optimal medical treatments that account for differences in individuals’ genes, environments, and lifestyles.

However, one must be wary about predictions. The health care system suffers from considerable complexity, with many moving parts and multiple stakeholders.\(^6\) Moreover, a tangled confluence of external forces powerfully influence the health care system and, likewise, health law, including politics, the economy, the complicated interplay between governmental health care programs and private insurance, the traditional authority of the medical profession, other interest group pressures, and the increasing importance of organizational design and governance as more care is delivered


through institutional providers and larger delivery organizations. As such, there is a sense that the health care system operates in a state of constant revision, if not chronic crisis, making forecasts highly unpredictable.

On the other hand, there is also a sense that in health care the more things change the more things stay the same. Recurring themes and patterns are likely to matter for the future. The fundamental tension underlying the health care system to date, how to balance optimally the iron triangle of cost, quality, and access, points to the inevitable fault lines and challenges moving forward. Other long-standing controversies will likely continue as well, including the corporatization of health care, the proper authority and responsibility of the medical profession, reliance on private markets versus governmental health care, and rationing.

This dual potential for both persistence and radical change, leading to challenges ahead both old and new, can be seen across five important dimensions of the health care system, many of which our symposium authors collectively address: the delivery system; health care insurance and coverage; medical advances and new technology; the provider-patient relationship; and public health.

THE DELIVERY SYSTEM.

The ACA tries to overcome traditionally problematic fragmentation in the delivery system by favoring integrated delivery structures that link providers more tightly together, such as medical homes and accountable care organizations (ACOs). The ACA also furthers pay-for-performance trends by introducing incentive programs and payment method changes to the Medicare program, such as shared savings and bundled payments for episodic periods of care.

It is quite possible, therefore, that the future delivery system will feature large provider networks closely integrated clinically, financially, and administratively, with significant oversight and data-
tracking of clinicians in the trenches in order to coordinate and standardize care. The future may also see a complete break away from the much criticized fee-for-service reimbursement system.

At the same time, the health care delivery system of the future may not look much different. The ACA allows ACOs to be formed from existing virtual networks of large medical groups and their affiliated hospitals, rather than require more radical restructuring of hospital-physician groupings. Moreover, the push for integrated provider networks is hardly new and one could be understandably pessimistic about whether true integration and transformative change will ever be achieved. The 1990s, for example, saw hospitals acquire many community physician practices as part of a strategy to build integrated delivery systems. But these system-building efforts had many bumps in the road, in part because of the difficulty experienced by hospital-run health systems in managing formerly independent physician practices. A recurring theme has been the tension between reform efforts aiming for integration of providers within larger, centrally run health care organizations and protection of independent physician authority. Likewise, consolidation of medical practices and corporatization of medicine continues to be seen as a threat to physician professionalism.

Further, arguably health care reform has not gone far enough and merely continues many pathologies of the current reimbursement system. The ACA, for the most part, keeps intact traditional fee-for-service, only tinkering at the margins with experiments such as bundled payments and the shared savings program for ACOs. And shared savings, without more, may be too mild an incentive to leverage significant change in ACO network hospitals’ and physicians’ practice patterns.9

HEALTH CARE INSURANCE AND COVERAGE

The ACA has ushered in a dramatically different era of coverage, as the number of uninsured individuals dropped by about 25% in 2014, the first year that the new exchanges under the law were

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10 Nicholas Bagley, Bedside Bureaucrats: Why Medicare Reform Hasn’t Worked, 10 GEO. L. J. 519, 575 (2013).
Moving forward, the ACA promises to bring greater security to vulnerable community members. Individuals who become sick, change jobs, or face employment termination will no longer face pre-existing conditions exclusions, differential pricing based on health status, or other obstacles to buy health insurance. By defining a standard benefits package for health plans participating in the insurance exchanges, the ACA also tries to eliminate problematic gaps in coverage, pushing for wellness visits, preventive screenings, mental health services, and other services increasingly recognized as important for health promotion.

On the other hand, the ACA’s expanded coverage framework may easily crumble. It is important to remember that health care coverage is different than health care access. Concerns have arisen that newly covered patients, in particular patients added into expanded Medicaid programs and patients enrolling in low cost plans on the new insurance exchanges, are not actually able to obtain timely care with providers. Medical practices may be unwilling to accept new Medicaid patients. Meanwhile, several of the low cost health plans on the new insurance exchanges offer networks comprised of a very limited number of providers or providers located far way geographically, resulting in highly restricted access to care. Further, there are concerns that insurers may be strategically evading the ACA’s restrictions on excluding higher cost patients. Reports suggest that some health plans are imposing higher cost-sharing for certain drugs in their plan formularies, which may discourage sicker patients from enrolling. Moreover, it is not clear that the ACA will ultimately succeed in harmonizing understandings of what health

11 Margot Sanger-Katz, Has the Percentage of Uninsured Been Reduced?, N.Y. TIMES (Oct. 26, 2014), available at http://www.nytimes.com/interactive/2014/10/27/us/is-the-affordable-care-act-working.html?_r=0#uninsured (Additional coverage was achieved through combination of the employer and individual coverage mandates, the new exchanges, and expanded Medicaid).


benefits should be core and essential as part of insurance coverage. Because regulators opted to allow states considerable flexibility in defining the standard benefits package to be offered on their exchanges, based on a benchmarked employer group health plans in each state, the standard benefits package that must be offered by health plans can actually vary considerably between exchanges.15

Rationing is another inevitable challenge for the future. Health care is of seemingly endless supply, and some services offer marginal or no benefit but at great cost. Private and public payers have long struggled to come up with optimal methods for limiting reimbursement of services with limited value without engaging in crude costing and incurring public outcry, as happened in the managed care backlash of the 1990s. To evade further controversies, the health care system has long relied on a system of more indirect rationing, such as through health plan formulary restrictions, vaguely worded coverage criteria leading to discretionary denials by claims administrators, or differentially reimbursing providers for certain services. There is every reason to expect that the future health care system will likewise prefer to ration behind-the-scenes.

MEDICAL ADVANCES AND NEW TECHNOLOGY

Presumably, the health care system of the future will look very different because of medical progress. Decades ago, developments in germ theory and infection control led to a radical reworking in the delivery of care. Similarly, the new genetics revolution promises to bring a new treatment orientation that relies more heavily on predictive testing, screenings, and prevention. Health care has also experienced the “technological imperative,” the zealous push to use cutting-edge technology.16 New devices such as magnetic resonance imaging have, shortly after their introduction, rapidly diffused into practice and become common aspects of clinical care. Advances


impacting the future health care system are likely to be equally transformative.

On the other hand, no matter what is next cutting-edge, the health care system will inevitably struggle, as it does currently, with how to optimally adopt new medical insights and technology into a system of limited resources. New technology can be inflationary, escalating medical costs but offering only marginal benefit. And the health care system has continual difficulty in evaluating the value of new technology and flexibly responding. Important clinical information, including safety risks, often only comes to light after new products earn regulatory approval and are more widely diffused into practice following clinical trial testing with a limited number of subjects. Once new technology is disseminated, it has proven hard to unwind and to change practice patterns based on new information.

In addition, access to new technology, often highly contested, will likely remain so in the future. Critically ill patients desperate for new treatments have made difficult access demands, leading to litigation and policy changes, but it is doubtful that consensus will be reached anytime soon. With each new medical advance, difficult macro-allocation decisions for the health care system have to be made. Also each new medical advance introduces potential interest group pressures and stakeholder conflict, as a new technology threatens to supplant incumbents’ products and services.

**PROVIDER-PATIENT RELATIONSHIP**

The doctor-patient relationship operates at the center of the health care system. Recognized in law as a special relationship and one that imposes quasi-fiduciary duties, it guides most major decision-making. Physicians act as trusted agents and learned intermediaries in helping their patients navigate the range of treatment options. Health law, medical norms, and professional ethics generally expect that the physician will zealously pursue the best interests of her individual patients. The relational pull is so strong that the strong preference for doing what is best for the

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individual patient can actually lead to suboptimal decision-making for the health care system as a whole, for example by undervaluing actions to advance population health, the interests of future patients, and society overall.\(^\text{18}\)

The contours of, and expectations about, the relationship have not been static. Thus, the ideal vision of the benevolent yet paternalistic physician of the 1950s and 1960s, who made key decisions for the patient’s clinical benefit, has been replaced, in the wake of the bioethics and patient rights’ movements, by a different view. The physician is now expected to respect patient autonomy to a greater degree, in recognition that clinical expertise alone is not all that matters and that some decisions are only answerable by considering each patient’s values and lifestyle choices.

Even more recently, another shift in the common understanding of the doctor-patient relationship has occurred. Reflecting in part the increasing corporatization of medicine, patients have come to be seen not just as vulnerable individuals in need of care and respect, but as active consumers in the health care marketplace. The patient-as-consumer perspective assumes that patients should have rights to a significant amount of information in order to freely exercise choice of treatment and provider. The corollary is that patients also have responsibilities to be prudent purchasers of goods and services, including assuming increasing responsibility, economic and otherwise, for their own health care.

It will be interesting to see whether the contours and understandings of the doctor-patient relationship will continue to morph into the future. There has been new emphasis and research on the key role of trust in the doctor-patient relationship to activate the healing process,\(^\text{19}\) as well as the value of shared decision-making between providers and patients for improving the quality and efficiency of care.\(^\text{20}\) As such, there may be efforts to reorient the

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\(^\text{19}\) See Mark Hall, \textit{Law, Medicine, and Trust}, 55 STAN. L. REV. 463, 470-482 (2002).

\(^\text{20}\) See Emily O. Lee & Ezekiel J. Emanuel, \textit{Shared Decision Making To Improve Care and Reduce Costs}, 368 NEW ENG. J. MED. 6 (2013).
relationship, including adjusting the background legal rules and ethics guidance, in ways that foster increased trust and joint decision-making. On the other hand, concerns about health care costs, and efforts to have patients experience more skin in the game through increased cost-sharing, may accelerate the swing toward viewing the doctor-patient relationship as merely another supplier-consumer relationship and one not necessarily deserving special treatment. Looking forward, other trends likely to impact and strain the provider-patient relationship include the disruption of long-standing care connections and the decline of smaller medical practices. Patients more often are finding that their insurance no longer covers care with their long-standing physicians, due to a change or restructuring of their health plans, resulting in a restricted network of providers. Moreover, as more physicians join larger multidisciplinary groups and health systems, patients may find that their key relationship is with the larger institutional provider that arranges for a spectrum of care, rather than the individual primary care physician of the past.

PUBLIC HEALTH

Research suggests that health and wellness may depend more on factors such as the built environment, food intake, lifestyle choices, wealth status, and other social determinants than on access to traditional episodic care.21 For all the money spent on health care in the United States, arguably better health outcomes could be achieved by allocating a greater portion of the same money away from direct clinical care and toward public health, including addressing social determinants of health.

Despite its importance, public health has historically been marginalized from the rest of the delivery system. Public health has operated in its own silo, relegated to public health agencies and safety net providers. It has also been considerably underfunded for years while public health responsibilities are confusingly dispersed among many federal, state, and local governmental entities. Moreover, there is lack of integration of public health

activities with the rest of the health care system, including importantly with private health care providers, reflecting the deep schism between individual health and public health.

A key question for the future is whether the individual-public health divide can be overcome. Recent public health crises attracting attention, such as the spread of Ebola and rise in measles outbreaks, have reinforced the value and importance of traditional public health activities such as surveillance, vaccination, hygiene, and other means of infection control. But the health care system has lurched from crisis to crisis in the past without a radical restructuring of public health’s role in the delivery system. Perhaps an even more important development is emerging research on the connections between health and social determinants, such as income level, race, education, community safety, and exposure to new technologies.22 This research raises new questions for law and policy moving forward, including whether to strengthen providers’ role as stewards of population health, have providers more directly engage with social determinants of health, make non-providers more accountable for their impact on social determinants, and rely on government to address root causal factors.

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The symposium authors examine the future health care system across many of the preceding dimensions. In REMS as a Competitive Tactic, Professor Jordan Paradise considers a changing regulatory framework in which the Food and Drug Administration (FDA) may require that drug manufacturers adopt risk evaluation and mitigation strategies (REMS) as a condition for approving a new drug or for continued distribution and marketing of already approved medications. These required risk control strategies can include medication guides for patients, limitations on prescribing and

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promotion, and communications to health care providers.

When used appropriately, REMS help enhance the health care system’s interaction with new technology, offering an additional, flexible means of regulatory oversight for improving drug utilization, marketing, and prescribing. REMS may also help control costs by minimizing adverse reactions and highlighting risk information that can be used by payers to restrict or selectively reimburse particular uses of medications.

But as Paradise describes in her article, despite this considerable promise, the new REMS legislation may be creating unintended consequences, including driving drug costs higher and damaging the quality of care. Paradise considers evidence that certain pharmaceutical companies are strategically exploiting REMS to restrict generic drug competition, such as refusing to supply generic competitors with drug samples for bioequivalence testing by relying upon REMS distribution restrictions. Another potential anticompetitive development is the assertion by certain pharmaceutical companies of patent rights over certain treatment and delivery methods, necessary for safe clinical care, contained in FDA-approved REMS. The new regulatory approach also complicates the provider-patient relationship, as certain REMS programs limit the physician’s traditional independent prescribing authority and supplant the physician’s usual role as learned intermediary.

Paradise’s article serves as a reminder that the continual introduction of new technology into the health care system creates unstable pressures that make optimal regulation more difficult. Indeed, the REMS episode demonstrates that interested stakeholders can find new and creative ways to leverage new technology for their benefit. One clear question moving forward is what will the FDA do? One is left wondering why there has been regulatory inaction at present even if, as Paradise suggests, this may be due to disparate factors, including limited agency resources. A critical question, therefore, for the future health care system is whether any adjustments will be made to the evolving regulatory framework. Will it be possible to strike a better balance between restricting anticompetitive conduct under the cover of REMS but still leave in place legitimate control and distribution programs necessary to mitigate risk in the use of approved drugs?

Professor Sonia Suter likewise considers the complex interaction
between new technology and the health care system. In *Genomic Medicine-New Norms Regarding Genetic Information*, Suter describes a transition underway from traditional clinical genetics to genomic/personalized medicine. Advances such as the ability to sequence the whole genome are becoming faster, more accurate, and more affordable. Suter envisions a future health care system in which far greater and qualitatively different genetic information will be generated, applied to many more patients, and interpreted by many disparate providers with different levels of training and expertise with such information.

The interesting question Suter explores is whether the health care system is ready for the new era of genomics/personalized medicine. Suter suggests not. She notes several ways in which the law, ethical rules, and norms underlying traditional clinical genetics will be challenged. For example, traditional approaches to informed consent may need to be reexamined given the sheer volume and complexity of the new information generated.

Another concern Suter raises is whether patients are fully ready for what lies ahead. Although proponents often claim genomic medicine promotes patient autonomy, by providing more personalized information to help guide decision-making, Suter suggests it may in fact undermine autonomy. Suter worries that the continual push toward more genetic information disclosure, which she sees as inevitable in the near future, will end up eroding patients’ rights to choose not to know certain information. Suter further cautions that some of the new genetics information made available to patients will not correspond to good treatment options, raising the risk of discrimination and stigma as patients will be placed into various risk categories without clearly available treatment pathways. The likely cascade of new genetics information also has implications for the future of the doctor-patient relationship. As patients are expected to receive detailed genetic information, this may increase, Suter notes, their obligations to deal with the information and possibly diffuse providers’ responsibilities.

Suter offers a nuanced, insightful analysis of the significant implications arising from the acceleration toward a new era of genomics medicine. The trends she describes cut across, and raise challenges for, many dimensions of the health care system, from new technology to the doctor-patient relationship and even to health care
insurance as payers will have to determine how to optimally reimburse for certain genomics analysis. In short, as Suter convincingly argues, health law, policy, and ethics still have much work to be done as the march toward genomic medicine moves rapidly ahead.

While Suter envisions genomics analysis quickly diffusing into clinical practice, Professor Katherine Van Tassel has a somewhat different perspective about the health care system’s interaction with medical advances. In *Forty Years After Its Adoption, Modernizing EMTALA To Improve Quality, Cost, and Equal Access*, Van Tassel argues that the system has been too slow to adopt clinical outcomes data and effectiveness research. Van Tassel explores the difficulties in moving to a modern, evidence-based model of medical practice. She describes how the custom-based standard of care remains the normative model, even though customary care can negatively impact health care quality, cost, and access.

Van Tassel focuses in particular on how the Emergency Medical Treatment and Active Labor Act (EMTALA), the anti-patient-dumping statute, may be impeding the transition to evidence-based medical practice. According to Van Tassel, the courts have generally interpreted EMTALA to require that physicians care for a patient in the emergency room using the same treatment as an individual with similar symptoms would have customarily received in that particular hospital. This helps perpetuate customary, but questionable, care. Van Tassel worries in particular that if there is a conflict between customary and evidence-based treatment choices, physicians are more likely to choose customary care to avoid EMTALA liability for their hospitals.

To encourage wider adoption of evidence-based medicine moving forward, Van Tassel recommends that the EMTALA and related Centers for Medicare and Medicaid regulations be harmonized to require that hospitals make greater use of written protocols and check lists that rely on evidence-based clinical practice guidelines. She further suggests that this evidence be generally used as the benchmark for whether EMTALA’s equal treatment requirements have been satisfied.

One may quibble with Van Tassel’s recommendations for relying so heavily on clinical practice guidelines (CPGs), as this assumes that there are high-quality, unbiased, well-accepted CPGs that can be
generated for and applicable to most emergency room situations, a questionable proposition.\textsuperscript{23} One also wonders where individualized medicine fits into her vision of the future, as physicians may have very good reasons to depart from CPGs in individual circumstances. All that aside, Van Tassel’s article pointedly and persuasively illustrates that health law needs to adjust to medicine’s new trajectory. If a transition is underway to evidence-base medicine that can reduce unwarranted clinical variation and improve quality, then health law’s traditional reliance on medical custom, in EMTALA and other contexts, indeed seems outdated.

Another significant movement forward for the health care system concerns the expansion of coverage as individuals obtain health insurance on newly designed exchanges for the individual and small-group insurance markets. This is the subject of the article, \textit{How Insurers Are Competing Under the Affordable Care Act}, by Professors Catherine Swartz, Mark Hall, and Timothy Jost. The ACA restricts insurers participating on the exchanges from excluding coverage for pre-existing conditions and charging differential pricing based on a subscriber’s health status. Instead of competing via risk-selection to enroll lower cost patients, health plans are now supposed to be competing on quality and the overall value of their products. The authors test this assumption by looking at the nature of insurer competition in six states for 2014, the first year the new insurance exchanges were in operation.

Their analysis of the state in play on the ground reveals some interesting developments. First, they find that geography matters. Some states have seen competition where insurers offer plans with many different variations of cost-sharing for enrollees. But in other states the competition has been primarily about variation in the providers in each plan’s provider network. Even more important, they find the nature and degree of competition varies not just between states, but often between different rating areas within the same state. For example, a key regional variation they report is that plans with limited provider networks are more likely to be offered in areas with less dense population and that have a high number of poor and uninsured residents. Second, while the authors find some

evidence of price competition, they find less evidence of quality competition. The long-standing difficulty of making meaningful quality comparisons between providers apparently continues to challenge, even under the ACA rollout.

A third and troubling finding concerns conduct by carriers that seemingly attempt to continue risk-selection, despite the ACA’s prohibitions. The authors suggest that the surprising large number of plans with restricted provider networks could be an attempt by carriers to evade certain enrollees, as such plans would be more unattractive to high cost patients with complex health care needs. The authors note that the ACA’s risk adjustment process, which became effective in 2015, should offer some financial help to plans that enrolled higher cost enrollees, and this could change the incentives for carriers. Nonetheless, this study ominously suggests that health insurer competition in the future will continue to involve indirect risk-selection.

The study is, even by the authors’ own admission, a limited snapshot. It looks at just six states and only in the first year of operation of the new exchanges. But, as the authors explain, their study provides an important reference point by which to evaluate and measure forms of competition that may emerge in later years and in other states. Also, their identification of potential problems, such as the apparent continuation of risk-based selection, provides a warning sign of potential trouble spots ahead with the continued rollout of the ACA. Regulators will need to pay careful attention to these ongoing developments in the exchanges and consider adjusting the governing rules if the health care system is to be truly successful in transitioning to expanded coverage and value competition in the health insurance markets.

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Only time will tell whether the vision of future health care depicted in this symposium is accurate and prescient. While envisioning the future health care system seems fraught with difficulty, the symposium authors ably respond to the task. Their contributions focus attention on forces shaping the health care system’s trajectory, identifying important developments and critical challenges now emerging and looming ahead that cut across the
system’s multiple dimensions. Their insightful analysis reminds us that, when it comes to health care, while present events may seem turbulent and especially significant, there are, inevitably, even more interesting times ahead.