Health Care Regulation Across Europe
From Funding Crisis to Productivity Imperative
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Scarcely a month passes without some striking regulatory change in one European health-care system or another. New measures supplement, and often contradict, existing measures; reforms reform reforms. The regulators are spurred on by worry over the rising costs of maintaining their nations’ health and by fear for their national health-care budgets. As far as the industry is concerned, however, their efforts seem fidgety and generally misdirected—and often counterproductive.

Industry players, including insurers, hospitals, and pharmaceutical and medical technology (medtech) companies, complain of having to change direction repeatedly, sometimes at the expense of patients’ interests. They don’t want to be gazing continually into the crystal ball of regulation, seeking to recognize trends that will validate or undermine their long-term strategies. Instead, they want a plausible long-term perspective based on reliable boundary conditions for the health care landscape.

Their wish could be granted, in some measure at least, according to a study by The Boston Consulting Group. The study surveyed six European health-care systems: those of Switzerland and of the Big Five nations of the European Union (EU)—France, Germany, Italy, Spain, and the United Kingdom. Switzerland was chosen to round out the list in order to serve as a comparison to the Big Five. On the one hand, the country lies at the heart of Europe and boasts a very large pharmaceutical industry; on the other hand, it has a far smaller population than any of the Big Five and is not an official member of the EU. Despite its outsider status, Switzerland is still very much affected by health care regulation in the EU.

The Widening Gap Between Costs and Funding

First some background. The issue of health care varies considerably from country to country in terms of urgency and political priority, yet all European governments are facing the same fundamental challenge: how to finance their health-care systems without demanding too many sacrifices from the electorate. And that shared concern is producing some striking similarities in their approaches to regulation.

Put simply, despite major reforms, the cost of health care in all six of the surveyed countries has been outgrowing the funding base for some time. Since 1990, overall health-care expenditures in these countries have grown on average by about 80 percent, while the gross domestic product (GDP) of the group has grown by only about 25 percent. And this divergence is expected to continue during the coming decades. (See Exhibits 1 and 2, page 2.) In this environment, there will be an ever-widening

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2. Switzerland was chosen to round out the list in order to serve as a comparison to the Big Five. On the one hand, the country lies at the heart of Europe and boasts a very large pharmaceutical industry; on the other hand, it has a far smaller population than any of the Big Five and is not an official member of the EU. Despite its outsider status, Switzerland is still very much affected by health care regulation in the EU.
Exhibit 1. Health Care Expenditures Will Continue to Outpace GDP and Wages


Indexed values were calculated using 2005 as the base year; the calculations used local currencies.

Exhibit 2. Health Care Financing Will Claim an Ever-Greater Percentage of GDP


Note: In projecting the health care expenditures of Italy and Switzerland, we used country-specific residuals to model the cost containment scenario; for the United Kingdom, we used average residuals to model the cost containment scenario.
gap between the demand for (and cost of) health services and the system’s ability to supply (and finance) those services.

In fact, increases in the supply of health care services, far from satisfying demand, tend to generate still more demand. That demand will grow indefinitely, it seems, fueled by patients’ continually expanding expectations not just for more but also for better services—services that tap the latest technological developments and the deepest medical expertise. In five of the surveyed countries, for example, while the total number of general practitioners remained virtually unchanged between 1995 and 2004, the number of specialists grew from 384,000 to 479,000—a rise of almost 25 percent.3 And between 1997 and 2004, the number of CT scanners increased from 11.2 for every 1 million people to 14.4.4

With the demand for and the cost of health care services rising, a corresponding increase in funding is needed. But funding is under stress. Wages and taxes are growing at an even slower rate than GDP as European countries, under pressure from globalization, compete to hold down tax and labor costs in order to retain and attract investment. And the potential to expand the funding base is largely exhausted. In most of the surveyed countries, almost 99 percent of those required to contribute to public-health-care funding are already doing so in full, and many of the applicable sources of income, including capital gains and property rentals, are already being tapped and have become part of the contribution base.

Finally, the problem is compounded by high unemployment rates in many countries. These rates adversely affect the dependency ratio—that is, the ratio between the number of people who contribute economically to the social welfare system and the number who receive benefits. To aggravate matters, the dependency ratio is expected to deteriorate further in most European countries over the next 50 years, with fewer and fewer people financing the welfare of the broader population.

The Health Care Vortex and the Drivers of Demand

As long as people get sick and frail, health care services will remain in demand. That demand rises rather than declines with advances in medicine: previously untreated diseases become treatable, and formerly lethal diseases become manageable chronic conditions. So while mortality rates fall for some diseases, morbidity rates—the prevalence of those diseases—often tend to rise. For example, in Germany between 1990 and 2005, deaths from heart disease decreased from 351 to 262 per 100,000 people, but cancer morbidity increased from 422 to 519 cases per 100,000 people—largely because of more refined diagnostic tools and improved treatment options.

Consequently, the demand for health care services is not just continuous but continuously increasing, feeding a “vortex” in which demand is further whipped up by six underlying drivers. These drivers, which intensify the surge in health care expenditures, are greater wealth, innovation, consumerization, specialization, changing demographics, and changing lifestyles. (See Exhibit 3, page 4.)

Here is how the vortex is powered. As societies acquire greater wealth, people become less accepting of disease, more aware of health issues and their own health, and more assertive in pursuing good health and living a longer and more enjoyable life. Their demands are satisfied, to some extent, by innovation, which provides novel treatments and services in health care—at a price. For example, while the mortality rate for ischemic heart disease was reduced by half between 1970 and 2000 in the six surveyed countries—mainly owing to advances in medical treatment—the average cost per hospital stay for patients with this disease more than doubled.

People in wealthy societies also tend to be better educated and, with the aid of the Internet, to make more informed decisions about their own health.

3. These figures exclude Italy, where comparable data were unavailable.
4. These figures exclude the United Kingdom, where data were not available for the full period.
care. This not only drives up the general demand for health care services but also provokes patients’ interest in and demand for new treatments—a phenomenon known as consumerization. To satisfy this demand, more specialization develops, resulting in more numerous and more differentiated or tailored services.

The changing demographics of many European countries add to the pressure. Aging is often cited as a particular burden on health care budgets, but its impact is usually overrated. In Germany, for instance, only one-third of the expected growth in health care expenditures can be attributed to additional costs incurred by an aging population.

Finally, the changing lifestyles that result from greater wealth and education are bound to affect health care expenditures—although their precise effects are not yet understood. Very likely the changes cut both ways: on the one hand, they increase the incidence of obesity and, of course, geriatric illnesses; on the other, they reduce alcohol consumption and smoking rates.

Variability Among Countries

The health care vortex operates in all countries, but it doesn’t affect them all equally—and it presents them with different challenges for the future. Several factors contribute to this variability.

First, GDP has grown—and will continue to grow—at different rates in different countries. Second, as previously noted, variations in unemployment levels and in the average age of the population mean that dependency ratios will differ and squeeze financing for health care with differing degrees of intensity. Consequently, some countries will hit the crisis point much sooner than others—that is, the point at which the increase in health care expenditures offsets the net growth in salaries, and people
have less money in their pockets even though both the economy and salaries are growing.

Finally, countries will vary in the degree of political consensus they can muster around the need for further reforms. Countries whose governments are willing and able to introduce a set of structured and well-paced reforms are likely to face less pressure on their health-care spending than those that are forced by political circumstances to dilute planned reforms or to reverse the effect of existing reforms.

Put all these factors together, and the future of health care financing looks gloomier for Germany, Italy, and Switzerland, where economic growth and employment rates—and thus dependency ratios—are less encouraging than in France, Spain, and the United Kingdom. (See Exhibit 4.) These prospects could change fairly quickly, however, as the evolution of health care systems can be greatly influenced by political decisions.

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To elucidate this changing regulatory landscape, we have classified the various regulatory measures
into four categories. (See Exhibit 5.) Each category affects a different stakeholder or combination of stakeholders, but the basis for differentiation is the motive behind the measures themselves: to expand the funding base, ration services, contain costs by means of government intervention, or enhance the productivity of the health care system.

**Expanding the Funding Base.** Regulations that seek to inject more money into a country’s health-care system are often short-term and designed to plug holes in financing. They usually have only a limited impact because the funding base is typically already very broad, and most income components are already being abundantly tapped—particularly in tax-funded systems, such as those of Italy, Spain, and the United Kingdom.

The remaining available measures follow one of two main approaches. Some seek to raise health care premiums; these measures are very unpopular with the public, so they tend to be applied only in “funding emergencies.” Others seek to allocate extra funding to health care by shuffling tax revenues among public budgets. These measures are usually more acceptable to the public and are applied routinely and fairly easily in tax-funded systems. They are also becoming ever more common in insurance-funded systems (such as those of Germany, France, and Switzerland) and are strengthening governments’ influence over the payer industry.

**Rationing Services.** As the funding gap grows, this lever will increase in importance. More and more, regulators will ration or withdraw subsidies for products and services that they deem nonessential, such as dentures, eyeglasses, and hydrotherapy. Increasingly, however, any savings gained through such measures will be more than offset by the stream of pricey innovations—brachytherapy for prostate cancer and cochlear implants for hearing

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**Exhibit 5. Regulatory Levers Fall into Four Categories**

<table>
<thead>
<tr>
<th>Stakeholder affected</th>
<th>Expanding the funding base</th>
<th>Rationing services</th>
<th>Containing costs through government intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulator</td>
<td>Expanding the funding base</td>
<td>Benefit catalogs</td>
<td>Access limitations</td>
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<td></td>
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<td>Price cuts</td>
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<tr>
<td>Payer/Purchaser</td>
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<td>Benefit catalogs</td>
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<td>“Clawbacks”</td>
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<tr>
<td>Provider</td>
<td></td>
<td>Reduced service levels</td>
<td>Price ceilings</td>
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<tr>
<td>Supplier</td>
<td></td>
<td></td>
<td>“Jumbo” reference pricing</td>
</tr>
<tr>
<td>Patient</td>
<td></td>
<td></td>
<td>Reference pricing</td>
</tr>
</tbody>
</table>

**Source:** BCG analysis.

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The text continues with a detailed breakdown of the regulatory levers, including measures such as premium increases, copayments, and tax reallocation.
impairment, for example—that demand inclusion under general coverage. As a rule, rationing is difficult to implement in the Internet age, with patients now very well informed and able to exert public pressure. A case in point is the recent campaign in the United Kingdom to authorize National Health Service prescriptions of Genentech’s Herceptin for patients with early-stage breast cancer.

**Containing Costs Through Government Intervention.** When regulators cannot actually cap the use of products and services, they can target the profits of individual players in the health care sector. Such dirigiste measures, favored by some of the more interventionist governments, range from forced price cuts and price ceilings to industry “clawbacks.” In Italy, for example, pharmaceutical companies in 2005 were compelled to pay back €870 million into the coffers of public health care because the overall budget set by regulators had been exceeded. This “contribution” was effected through mandatory discounts and price cuts.

The evidence suggests that most of these interventions have limited effect. Usually, health care suppliers and providers adapt to such measures, lobby successfully against their continuation, or circumvent them by developing exceptions.

One class of dirigiste interventions is taking hold across Europe, however: *reference pricing* of pharmaceuticals. This approach involves assigning drugs to various subclasses according to their active ingredients and therapeutic effect, and then using their average price—or some other benchmark price—to set the maximum amount for reimbursement, leaving patients to pay the difference. Manufacturers are thereby pressured to rein in pricing, and in recent years, some drug prices have been cut by more than 30 percent.

We expect to see expanding use of this tool across Europe in the future, including more intricate or hard-hitting versions. An example is Germany’s “jumbo” reference-pricing scheme, which uses broader categories of drugs—such as statins and proton pump inhibitors—and includes prices of generics when calculating the reference price for patented as well as off-patent pharmaceuticals.

**Enhancing Productivity.** Of all the regulatory measures, those that seek to enhance productivity have the greatest potential to transform health care in Europe. As Exhibit 5 shows, this category comprises a much larger variety of measures than the others. It also engages all the main stakeholders—regulators, payers, providers, suppliers, and patients—and moves them toward the common goal of improving the operational efficiency of the health care system. (See the sidebar “The Promise of Productivity,” page 8.)

**A Move Toward Convergence—with Qualifications**

Many of these regulatory levers have been available for some time, and the ideas behind most of them are not particularly new. What is new, though, is the way they are being wielded: far more consistently, pervasively, and effectively across Europe. For example, almost every country has embraced the concept of diagnosis-related groups (DRGs), and most have some kind of reference pricing for pharmaceuticals in place.

The regulatory agendas of all the European governments now include many of the same issues, thanks in part to the escalation in international exchanges—often informal—of information and best practices. The EU has a more formal vehicle, the open method of coordination (OMC), for exchanging policy information in areas including health care, but the organization seems content to facilitate rather than centralize and coerce.

Individual countries have started learning from one another, and instead of conducting speculative regulatory experiments are now adopting solutions whose efficacy has been proved elsewhere. In Hungary, for instance, a large set of measures, based broadly on the experience of the six surveyed countries, was recently implemented within the space of just a few months.

Convergence is a slow process, however, and we are still a long way from a uniform regulatory regime across Europe. Certain regulatory levers...
The Promise of Productivity

Regulators have decided, it seems, that the best way to balance the demand for and cost of health care is to improve the operational efficiency of the health care system. They aim to develop a more integrated approach to treatment by coordinating the different groups of stakeholders more effectively and empowering the patient as decision maker. But how exactly are these elusive objectives to be achieved? Broadly speaking, the regulatory levers addressing this productivity challenge fall into three groups: levers to enhance transparency, levers to transfer financial risk, and levers to restructure publicly managed health-care markets.

Levers to Enhance Transparency. The goal of these regulatory measures is to provide insight into where and how value is created in the health care system. By conducting cost-benefit evaluations or by defining, implementing, and publishing productivity metrics, for example, they seek to enable patients and other stakeholders to make more educated decisions.

Levers to Transfer Financial Risk. By shifting more of the financial risk of health care financing to patients and health care providers, governments hope to encourage more economical utilization of resources. For example, patients in some countries now choose from a variety of health insurance options with flexible premiums and different levels of copayments. And there is widespread use of diagnosis-related groups (DRGs), a system of reimbursing hospitals for their services through standardized payments for specific diagnoses.

Levers to Restructure Publicly Managed Health-Care Markets. Measures to restructure health care markets or alter their dynamics should succeed in strengthening the competitive forces at work in health care and allowing new—often private—entrants to compete.

Some progress has already been made through the use of these levers. DRGs are now in place throughout Europe; although they vary considerably from country to country, they are bound to revolutionize the hospital sector wherever they have been embraced. At the same time, national agencies for performing cost-benefit analyses and assessing quality in health care are gaining prominence. These include the National Institute for Health and Clinical Excellence (NICE) in the United Kingdom, the Institute for Quality and Efficiency in Health Care (IQWiG) in Germany, the Italian Pharmaceutical Agency (AIFA), and the French National Authority for Health (HAS). These organizations differ in scope, objectives, and performance, but all are motivated by a common purpose: to generate more transparency and thus drive productivity—not just through more efficient delivery but also through higher-quality care.

Many industry incumbents remain skeptical of—and even resolutely opposed to—this new regime, even though it may offer them considerable opportunities. Stakeholders that can forcefully demonstrate the value of their products or services, whether in patient outcomes or in general productivity, will thrive in this environment. It all boils down to being able to prove their claims. To that end, some players may need to acquire new competencies or sharpen existing ones. Meanwhile, regulators must keep looking for standard, universally agreed-upon definitions and measures for assessing value in health care—still a somewhat distant goal.

Although most regulators agree that enhancing productivity is the most effective category of levers for transforming health care, several other key stakeholders remain skeptical. They argue that these measures are misguided and their benefits unproved, that the health care system is far too complex to grasp in its entirety, that the issues are too delicate to be analyzed exclusively from an economic angle, and that the information available is simplistic and inadequate for creating “league tables” that rank and compare hospitals, specialists, and so on. Fearing that they will be challenged for...
apparent inefficiency or poor results, these critics strongly oppose regulators’ emphasis on increased transparency and prefer the status quo.

They may have a case. The drive to enhance productivity through transparency is only as good as the information that feeds into the assessments of the system—and such information is often incomplete or selective, especially since the available systems and standards are so numerous and complex. So the benefits do tend to be skewed, favoring some players at the expense of others.

Truly improving the quality and flow of information will take not only greater coordination among the stakeholders in health care but also considerable investment from them—neither of which is readily forthcoming. Consequently, transparency initiatives still tend to be conducted and managed at the national-government level, and they continue to require a great deal of financial and regulatory support in order to work successfully.

The Obligation of Stakeholders to Contribute Value

Enhancing the productivity of the health care system should greatly help moderate growth in health care expenditures. However, it is unlikely on its own to resolve the issue of financing, especially in countries with increasingly unfavorable dependency ratios. Alongside an increase in the efficiency of health care delivery, therefore, we expect to see an increase in private financing—and hence in opportunities for private providers of services.

With regulation growing more stringent, the economics of health care will no longer allow players to be complacent or to carry on as before. Rather, to remain competitive, pharmaceutical and medtech companies, hospitals, and payers alike will need to revisit their strategies and adapt their business models to the changing environment. To prosper, they will have to deliver true innovation; otherwise, they will be forced to compete simply on cost. They will need either to provide products and services that generate demonstrable value or to tap into new sources of revenue emerging from private markets.

Pharmaceutical Companies. Regulatory measures have for some time been exerting a downward pressure on drug prices. That pressure will intensify as more effective measures for cost containment spread across Europe and as cost-benefit evaluation gradually becomes the standard basis for setting reimbursement levels for drugs.

Competing on Cost or Value. Drugs will increasingly undergo the scrutiny of evidence-based medicine, and those patented drugs that prove poorly differentiated will have to compete with generics on price. Only truly innovative products will capture a significant price premium, and a major squeeze on margins will result. Many companies are already responding to this prospect with short-term cost-cutting measures, but in the face of upcoming regulation, they will also need to critically review their strategies for managing their product portfolio and product life cycles.

Thinking European. With all European health-care systems compelled to improve productivity, the concept of the independent, country-centric sales organization is being challenged. Many country-specific organizations will downsize, while Europe-wide organizations or headquarters will require additional resources to engage the common regulatory themes that are spreading across Europe. The new responsibilities of these broader organizations will include forecasting specific regulatory measures and coordinating responses to them.

Integrating Across the Health Care Value Chain. For selected medical conditions, pharmaceutical companies might consider integrating forward into the provider arena in order to ensure that they capture the maximum value from their drug innovations. This approach will support the emergence of new models for optimizing the care of patients with chronic conditions through disease management.

Medtech Suppliers. Regulation will have an indirect if not a direct impact on the medtech industry. As hospitals, impelled by DRGs, strive to boost the productivity of their services, they will have to con-
tinually reevaluate medical devices, equipment, and supplies as a component of their costs. They will also seek significant rebates for medtech products that are lacking in innovative value and therefore are easily replaceable.

**Competing on Cost or Value.** Medical equipment companies will focus on innovation in order to capitalize on favorable health-economics studies and capture value from the market. In the case of MRI and CT scanners, for example, companies might reduce the cost per scan while expanding the utilization base by introducing new applications. In this way, they could continue growing the market for their imaging equipment. Meanwhile, companies specializing in medical supplies will need to think big, seeking merger opportunities in order to gain scale as the market for poorly differentiated products moves to consolidate.

**Thinking European.** Health technology assessment—gauging the outcomes of medical interventions—is on the rise, increasing the emphasis on proven value. Medtech companies must not only create innovative products but also explore novel commercial strategies, which call for greater coordination across Europe. Medical device manufacturers, for instance, might initially introduce new products to those markets that offer higher reimbursements and only later venture into markets where cost pressures are intense.

**Integrating Across the Process Chain.** In their efforts to reduce costs while optimizing the quality of care, companies will seek to manage the process workflow more effectively by integrating as many different technologies as possible. To that end, General Electric acquired the life sciences company Amersham, for instance, for its portfolio of diagnostic imaging agents, and Siemens gained in vitro diagnostic capabilities through its acquisition of Diagnostic Products Corporation. Such strategic approaches should lead to novel treatments that enhance the productivity of the health care system.

**Hospitals.** Pressures on hospitals are particularly intense and have already created profound changes. From the viewpoint of regulators, hospitals have been guilty of overcapacity, poor customer service, and inefficient processes and cost structures. To improve efficiency and limit reimbursement, regulators have introduced DRGs and have “re-regulated” the market to allow for more competition from private providers.

**Optimizing Processes.** To maximize value from DRGs and thus increase capacity utilization and, ultimately, market share, hospitals must continuously improve the efficiency of their processes. The optimization of patient flows according to disease areas is at the core of achieving excellence in patient satisfaction, service, and outcome quality while reducing costs. Such improvements will necessitate further professionalization of the sourcing and logistics functions—more centralization and coordination, and more rigorous negotiation of contracts—as well as further outsourcing of services that are not central to health care delivery. Some private hospital chains, such as Asklepios hospitals in Germany, are already investing heavily in IT systems in order to enhance both the transparency and the productivity of their operations.

**Specializing.** Public hospitals in particular will need to reduce or discontinue some activities while focusing on improving productivity in areas where they have a competitive advantage and can gain scale and optimize revenues. Those that don’t take these steps risk joining the ranks of public hospitals that have recently closed. Such closures continue to present opportunities for private-provider groups that specialize in selected DRGs.

**Integrating Across the Health Care Value Chain.** Ambulatory and home-care services are on the rise. Over the next decade, up to one-third of hospital procedures in Europe are expected to migrate to outpatient environments, thanks in part to the increased availability of medtech devices that enable remote monitoring of patients. Organizing the total care of patients irrespective of provider type will become key to value creation. Payers will closely cooperate with or even invest in seamless-care provider organizations; this has already begun to happen in Spain and Switzerland. For hospitals this trend could represent an attractive opportunity to develop integrated-care models, provided that a seamless-care culture and a single reimbursement
schedule emerge to span both outpatient and in-patient settings.

Payers. Whether private insurance companies or regional purchasing boards, all payers are in the throes of a metamorphosis. On the one hand, as the funding gap continues to widen, governments are compelled to channel more public funds into the health care budget. That will increase government influence over the administration of the budget and further reduce the ability of public health insurers to manage their own financing base. On the other hand, all payers are facing greater demand from regulators for productivity, and it will be their task to put the resulting measures to work in the health care system.

Optimizing Processes. To meet regulators’ demand for enhanced productivity, all payers will need to enhance existing capabilities and build new ones. Merely optimizing purchasing and contracting processes will not be sufficient. These new and enhanced capabilities will require considerable investments in areas such as data availability and systems, transparency in terms of cost effectiveness and quality of treatment in selected disease areas, and the development of effective incentives to influence provider and patient behavior.

Expanding the Private Sector. As new forms of medical treatments arise, and as public health-insurance systems continue to reduce their coverage, patients will be required to contribute more to their own health-care expenses. Although this shift may translate simply into an increase in out-of-pocket contributions, in the right market environment it could represent an opportunity for private health insurers.

A further change is affecting private insurers: employer-financed health coverage is replacing traditional, individual-financed coverage. Insurers appreciate the lower risk profiles that the employer environment provides and can offer their services at very competitive premiums. In a market in which the growth of “full-coverage” insurance policies is slowing, private insurers seeking to increase their market share will need to expand the range of private and employer-financed supplementary insurance policies that they offer.

Integrating Across the Health Care Value Chain. All payers will need to rethink their role in the value chain. One option is to form close partnerships with new types of health-care service providers, such as managed-care organizations and disease management companies. Another is to manage the provision of care directly. Private health insurers, in particular, will selectively integrate forward into the provider sector by building or managing regional provider structures. In Spain, for instance, private health insurers are already managing the provision of health care for the entire population in some regions. One key requirement for insurers integrating in this way is the achievement of critical mass, whether in the overall number of covered lives or in regional concentration. Given the advantages of integrating into the provider sector, payers will likely consolidate heavily in countries where the private health-insurance market remains highly fragmented.

Regulation is in the driver’s seat. It is already having a profound impact on the delivery of health care in Europe, and it will continue to do so—in a less arbitrary, more “regulated” way than in the past. In the future, all the stakeholders in health care—throughout Europe—will face the same pressure: to boost productivity in order to prevent the costs of medical care from spiraling out of control.

Already, nearly all European governments have accepted this reality, and they are increasingly—albeit with varying degrees of urgency—drawing on a common repertoire of regulatory measures to deal with it. The remaining stakeholders must therefore not only respond but also take the initiative in adding value to the health care system—whether through innovative products and services or through improved efficiency.
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