



Statement before the House Committee on the Budget

Restoring the Trust for All Generations

Americans at or Near Retirement

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In 1954, about 40 percent of Americans who were diagnosed with colon cancer could expect to live five years. By 2004, that figure rose to almost 70 percent. Today most early-stage colon cancers can be cured.¹ Similarly, only 30 percent of those diagnosed with lymphoma in 1954 were alive five years later; today 90 percent of people who are diagnosed with Hodgkin's lymphoma and 75 percent of those diagnosed with non-Hodgkin's lymphoma can expect to be alive in five years, and the majority of patients can expect their tumors to be fully eradicated.²

Similar trends hold up across almost all types of disease. They're not confined to cancer, although that's where some of our best historical reporting can be found, so those data are frequently cited. The mortality rate from stroke, the third most common cause of death, has declined by 75 percent since the 1960s. Between 1970 and 2005, the life expectancy of the average American increased by 6.6 years; 4.7 years—over 70 percent—of the increase is due to reductions in deaths from cardiovascular disease. Technology played a major role in these outcomes.³

We aren't confined to making comparisons between periods separated by long stretches of time to show the benefits of medical progress. Even as we look across the advances made against human disease in just the last decade, we see sharp improvements in outcomes across many conditions. One analysis of patients with heart failure followed people in three recent six-year eras during which drug and device therapies were evolving. The first era was from 1993 to 1998, the second from 1999 to 2004, and the third from 2005 to 2010. All-cause mortality and sudden death were notably lower in the second and third eras than in the first.⁴

Similar trends hold true when we look at other areas of medicine that have benefited from rapid technological change over a short period of time. Over the last few decades, the treatment of early-stage breast cancer fits these characteristics by virtue of the introduction of more targeted drugs, along with the treatment of chronic diseases like arthritis.

More people with a wider range of acute and chronic ailments are being diagnosed earlier and living longer and more productive lives. These gains are a consequence of innovation in health care—not just in the technology that we use to diagnose and treat disease, but also in the way that we train and organize providers and arrange the delivery of health care services.

New technology not only improves long-term outcomes and lowers costs by reducing morbidity, but it can also help lower the immediate costs of treating different episodes of illness. One recent analysis found that a larger percentage of high-technology-intense hospitals had Medicare spending rates that were lower than the national average. About 65 percent of top technology hospitals had average Medicare spending rates per beneficiary that were below the national average, compared to 56 percent of the hospitals that were judged to have lower uses of new technology. The results were more pronounced for big hospitals. The overall Medicare spending of the high-technology

hospitals with more than 200 beds was lower when compared to a matched group of similarly sized hospitals.⁵

When we talk about innovation in health care, we often have in mind technological improvements from new drugs and medical devices. But innovation also encompasses the structure and delivery of health care services and the way that care is delivered. These include better ways of organizing the business of providing medical services—concepts such as the advent of home infusion, skilled nursing facilities, outpatient surgery centers, or outpatient rehab. Each of these was, at one time, a new concept, pioneered by entrepreneurs who were—in each instance—backed by venture capital. And each concept ultimately proved itself to be a more efficient way to deliver medical care. Each model eventually became mainstream.

Such advances in health care services and the delivery side of medicine often gets shorter shrift when we talk about innovation in health care. But the productivity gains that accrue from improvements in the organization and delivery of care can be equal to if not exceed the productivity gains produced by individual improvements in technology, such as a better drug or medical device. As stated in a commentary published on the AHRQ website:

When it comes to health care service delivery, patients, payers, and politicians are asking for improved results: better access, faster diagnosis and treatment, more convenience, greater sensitivity to cultural differences and health disparities, and so on. But if we continue to do what we've always done, we will get the results we have always gotten. Nor is it enough to merely pursue incremental improvement. The challenges we face today call for more novel approaches—in other words, innovation.⁶

But too often, we've crafted policies that lead to stagnant or declining productivity in delivery of health care, as well as the development of new services arrangements. Data from the Monthly Labor Review show that the output derived from the cost of labor and capital poured into health care—the classic measure of productivity—rose at a paltry 0.7 percent average annual rate over the last decade.⁷

Increasing regulation and complicated federal coverage, coding, and payment rules have, as I will attempt to show, a significant impact on suppressing many kinds of innovation. In considering Medicare's impact on access to and incentives for the development of new innovation, a lot of attention has been historically focused on Medicare's coverage process. This involves the agency's effort to examine whether a product or service is part of the defined group of benefits covered by Medicare.⁸ I will instead focus a lot of my analysis on the program's coding and payment process, which have an equal if not more profound impact on new innovation. As noted by clinical and legal experts at Boston's Center for Integration of Medicine and Innovative Technology:

While it is fairly straightforward to conceptualize a paradigm whereby a medical product or service is provided, subsequently billed under the appropriate code, with the appropriate professional and technical payment components applied for ultimate reimbursement, the existence of a variety of Medicare payment systems makes actual reimbursement much more complex in practice.⁹

This complexity serves as an obstacle to the development and adoption of new technology.

As a result of this influence, the pathways for innovation and entrepreneurship are more narrowly prescribed than they ought to be—often defined more by the prerogatives of government regulators rather than the vision of providers and entrepreneurs, the needs of patients, and the dictates of competitive markets. Medicare’s reimbursement considerations have an increasingly prominent role in the set of concerns entrepreneurs take when contemplating investment in new technologies. At particular issue are the prospective payment systems that Medicare has adopted for hospital inpatient and outpatient services. Under these arrangements, Medicare pays a fixed, prospectively determined amount of money for different episodes of care, based on formulas that take into consideration various factors, and principally backward-looking surveys of historical costs.

These prospective payment systems define a fixed payment for a bundled service. CMS establishes a set payment for treating a case that’s meant to cover all the costs of providing the service. These payment formulas are meant to encourage providers to operate efficiently by offering a financial incentive to provide a particular service for the lowest possible cost and less than the fixed reimbursement rate. But the approach also puts providers at significant risk for the higher costs associated with changes in technology because new technologies are typically introduced without adjustments to these fixed payment levels.

Instead, the rates that Medicare associates with different services can take years to adjust to the adoption of a new, better, but more costly technological approach to treating a particular condition. The Medicare program has tried to introduce various methods to account for the cost of new technology, but these approaches are unpredictable and, therefore, discounted by investors and entrepreneurs, who are typically reluctant to factor into their expectations any assurance of securing one of these payment adjustments. As a consequence, breakthrough medical technologies whose benefits are realized over a period of months or years can face significant obstacles, because adoption of the innovation might be in the public interest, but providers might incur the incremental cost, discouraging adoption.¹⁰ Without appropriate adjustments for the provider at the point of use, technologies that provide long-term value to patients and the health care system might not be available.

These highly regulated and backward-looking payment formulas are inconsistent with the way that many disruptive changes occur and, in turn, the biggest breakthroughs in technology and health care services are revealed. When innovation in life sciences, medical devices, and the organization of health care services needs to follow a growing menu of carefully arranged political and regulatory directives, it discourages a lot of useful advances. It makes paradigm-shifting change harder to achieve. It denies patients transformative breakthroughs. As I’ll set forth, there are data to suggest these obstacles now abound in Medicare.

When it comes to technology, investment is increasingly skewed by these regulatory considerations, with more money going to the areas of less regulation, even if those aren't the areas of greatest public health need. In health care services, it means that investors and entrepreneurs have backed away—almost entirely—from supporting new facilities-based or provider-based health care startups. Most of the investment capital going into health care services is allocated to endeavors that are not capital intensive, such as health care IT. At the same time, most of the capital flowing into facilities is aimed at consolidating existing structures rather than creating brand-new kinds of provider-based arrangements. When it comes to drugs and medical devices, the regulatory considerations create a paradoxical obstacle to new innovation. The areas of greatest spending or public health need are often those where Medicare seeks to apply more oversight and, in turn, regulation. That increased regulatory burden ultimately discourages entrepreneurship and capital investment for new innovations in those areas that could ultimately improve outcomes and reduce costs. So we get less innovation in the areas of highest spending and the most interest to the policymakers.

Today I want to talk about each of these aspects of health care innovation—health care services, biopharma, and medical devices. First, I'll briefly outline the state of investment and entrepreneurship in each of these domains. There's evidence that the capital flows are not as robust as we might perceive and that they have been skewed by the policy signals sent by Medicare. I'll show some data that I believe suggest that entrepreneurship and investment capital is being influenced by considerations of Medicare regulations and reimbursement policy.

I'll then turn my attention to the ways that I believe our policy and regulatory decisions are compelling us to forgo some potentially beneficial innovation across these different domains. Finally, I'll close with some thoughts on how I believe we can reform our regulatory approaches, especially as it relates to the Medicare program, to improve the incentives for new innovation in drugs, medical technology, and health care services.

Medicare is such a large purchaser, and has such a profound impact on the private markets, that its influences can have an outsized impact on total entrepreneurship and innovation.

Investment Trends and Entrepreneurship

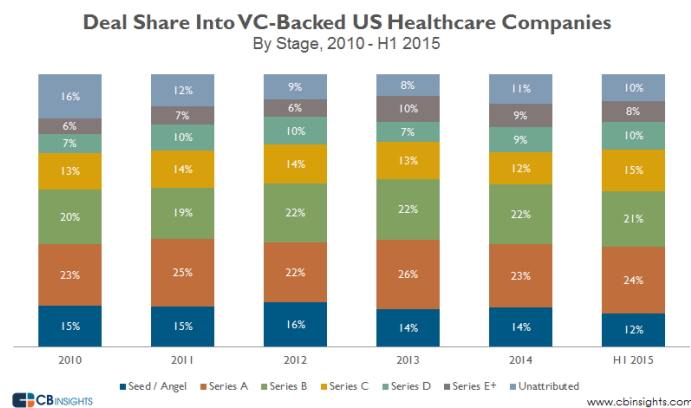
When it comes to medical innovation, there's a perception that we're in a "bull market" for biotechnology. It's true that we're in the middle of a genuine scientific renaissance. The enabling technologies developed during the late 1990s, principally through advances in genomics and proteomics, are now translating into novel ways to target the mechanism of disease. This creates more opportunity for transformative and even curative therapy for a broader range of maladies. These advances have attracted more investment capital into health care. This is especially true for the life science sector. But it's wrong to say that booming science is being fully met by commensurate investment in life science endeavors.

While the biotech sector has expanded over the last decade, and many companies have been able to tap larger pools of capital through initial public offerings, the truth is that overall venture investment in life sciences has actually declined in recent years as a percentage of total venture capital flows (Figure 2). A growing proportion of total venture capital is being allocated to other endeavors, such as media, and politically favored areas, such as green energy. A growing proportion of the venture money that's being invested is also going to a smaller number of larger biotech companies, rather than earlier startups and new company formation.

Moreover, the investment has been uneven when viewed from the prism of medical specialties, with a majority of the money chasing a relatively small number of therapeutic areas. This is even more pronounced when it comes to services and medical devices, where the numbers of venture firms willing to back new startups has declined. But it's also true when it comes to components of the life science sector and the development of new drugs.

All of this isn't to say that the biotech and medical device sectors haven't been strong in recent years, especially for late-stage companies and new public offerings in biotechnology. They've been buoyed along with a rising stock market and increasing overall flows of money into venture capital. But the health care trends mask rising investor caution, especially when it comes to new company formation and early-stage bets on certain very novel technology (Figure 1). In fact, the share of seed and angel stage investments in venture-backed health care companies has actually declined as a total percentage of venture capital flows into health care.

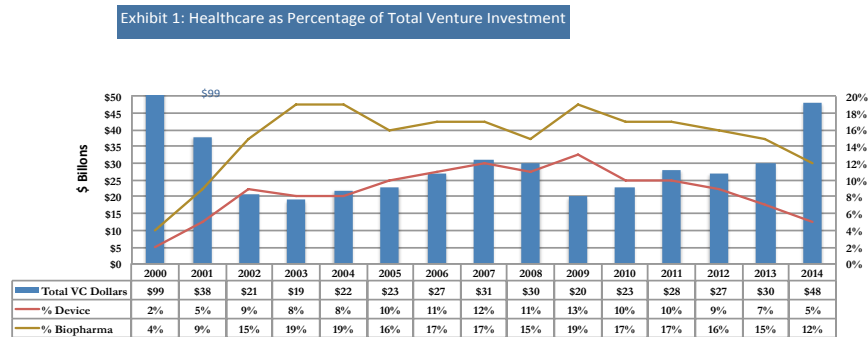
Figure 1



At the same time, the total amount of money going into health care has also declined, even while overall venture capital flows have expanded. After reaching a peak of nearly \$10 billion in 2007, health care venture capital financing has seen a significant correction, dropping by nearly 30 percent to \$7 billion in 2013. This drop is not simply a consequence of the 2008 financial crisis but represents a change in investor appetite for

the sector, as health care’s share of total venture capital financing fell from 31 percent to 24 percent between 2007 and 2013.¹¹ Investment grew to \$8.6 billion in 2014.¹² But these gains are against a backdrop of even larger flows into sectors outside of health care. In 2015 venture firms invested \$128.6 million globally, from \$89.4 million in 2014 and \$50.2 in 2013—a 44 percent increase between 2014 and 2015 and 78 percent increase from 2013 to 2014. These increases exceed the corresponding rise in health care flows.

Figure 2



Source: PricewaterhouseCoopers and SVB proprietary data

Growing policy uncertainty, and the lack of predictability around reimbursement and Medicare’s rate schedules, is a meaningful factor in fueling investor skittishness. In one large survey of venture capitalists who allocated money to health care, two-thirds of respondents said that increases in risk (including government reimbursement risk) would lead them to shift investments across health care sectors or reduce their health care investments altogether.¹³

This relative reduction in the capital that’s flowing into the health care space is reflected by the fact that venture firms have struggled to raise health-care-specific funds. According to a 2013 report by Silicon Valley Bank, between 2005 and 2008, there were 99 health-care-dedicated venture capital funds actively investing capital. From 2009 to 2012 the number dropped by 34 percent to 65 active funds. The numbers are even lower when it comes to firms dedicated to investing in medical devices or health care services. Many firms that were focused on these sectors shifted to biopharma or to later-stage growth equity or private equity—exiting venture capital entirely. Other firms exited the sector entirely, such as Salix Ventures,¹⁴ a once pioneering and celebrated venture investor in the health care services space.

While the absolute amount of capital invested in health care hasn’t kept pace with flows into other sectors, the challenge has also been exacerbated by highly uneven allocations

across different health care sub-sectors. The share of health care venture capital going to biotech has risen over the last five years from 58 percent of the total in 2008 to 65 percent in 2013. This reflects the successful IPOs and equity performance of biopharma companies. Medical devices, on the other hand, have seen a drop in capital, from 41 percent to 30 percent of the total invested over the same time period.¹⁵

Health care services have seen even more dramatic declines, with most of the venture investment going to services endeavors that require less capital, like health care IT. There's been almost no venture capital allocated to new facility-based and provider-based startups. Most of the investment capital being allocated to facility-based health care services is from private equity firms that are focused on buying and consolidating existing assets. Likewise, there's been very little new health plan formation, despite the opportunity ostensibly created by the Affordable Care Act. This stands in stark contrast to the experience after implementation of the Medicare Modernization Act, when so many new health plans entered the market that the refrain from critics was that consumers would be confused by all the new options.

Impact of Medicare Policy on Delivery Innovation

To drive efficiencies, improve outcomes and patient satisfaction, and deliver a modern benefit to senior citizens, we're going to need to innovate in how we deliver medical care.¹⁶ Yet there's been scant investment in new facility- and provider-based health care service ideas.

These are areas of health care services that once attracted the efforts of a large segment of health-care-focused entrepreneurs and venture capitalists. Now the market is virtually devoid of such efforts. In its place is a prevailing political view that a lot of improvement in the delivery of health care services will arise not from startups but from consolidated health systems that are able to take capitated risk and adopt technologies and practices that better coordinate care. It's often envisioned that hospitals will be at the hub of these arrangements. So new regulations have tried to steer the market toward this sort of consolidation.

The best hospitals have often been early adopters of new services innovations that helped improve the delivery of care. But the truth is that most of the greatest innovations in health care services – whether the advent of practice-management companies, home health care, outpatient dialysis, or the first for-profit HMO – typically have come from entrepreneurial firms, often backed by venture capital. Hospitals have adopted these new approaches after they became more tested and mainstream ideas.

Venture investment in these facilities-based and provider-based startups have been virtually eliminated, however. For one thing, Medicare has adopted a culture of punishing what it views as “excess” profitability in any service venture, which tends to be anything more than a 10 percent profit margin. This sort of price regulation doesn't allow for

returns on the risk and high capital costs needed to start new facilities-based and provider-based ventures.¹⁷

A large part of the problem is that health care services that earn above market returns can't even be sold to other health care businesses. Acquirers will worry that CMS will eventually punish the reported profitability by slashing rate schedules in order to compress a segment's profit margins. There is ample precedent for this sort of regulatory behavior.

It's the reality that a health care service business that earns above a 10 percent profit margin (and trades for more than 10–12 EBITDA¹⁸) will have its profits openly scrutinized by MEDPAC and CMS. Each institution will seek to reduce the sector's reimbursement to compress its profits to an "acceptable" level. There's a perception by CMS that profitability should be relatively uniform across different health care businesses. But there are many reasons why different businesses might need to trade at higher multiples or earn above market returns to attract the capital needed to compensate different degrees of risk and startup costs.¹⁹

This regulatory behavior discourages entrepreneurship that might improve services for beneficiaries or introduce genuine innovation in the way care is delivered. Many health care services businesses are forced to stay private, quite literally to conceal their profitability. But this denies them the chance to scale their efforts. These are often very capital-intensive businesses. This instinct to remain private just compounds the woes in sector. It denies firms the ability to raise capital—typically through initial public offerings—that could give them access to additional (and lower-cost) resources in order to expand.

The alternative to tapping equity for expanding a business is to tap debt. But it becomes very hard to add leverage to these businesses until they are generating sufficient EBITDA. It's impossible to generate EBITDA until they get to sufficient scale because of the high fixed costs in these businesses. They just don't become profitable until they are generating higher revenue when compared to other industries. The outward focus on their margins by CMS takes little accommodation of these business facts. As a consequence, most of the facilities-based investment in health care services is focused on consolidation and transforming existing lower-margin service businesses into conglomerates that can use their scale to offset the impulse of regulators to scrutinize and punish profit margins above some fixed norm. It's a recipe for turning the entire services space into a utility model, devoid of the sort of disruptive innovation that is going to give patients the chance to access novel services.

These are the reasons why venture capitalists are leaving this sector and the private equity firms are entering. Private equity is much different than venture capital. Private equity plays a very useful role in refashioning existing businesses and supporting them with capital. It brings efficiencies to the market. But it's not focused on taking outsized risks on very novel ideas. It modernizes existing concepts. With the absence of venture capital in health care services, in large measure a consequence of Medicare's policy culture,

there are few facility- and provider-based businesses being started. Any of the facility- or provider-based ideas that are being started are often focused more on the real estate aspects of these businesses and the ability to tap cheap debt to finance facilities that have low but stable income.

That's very different effort than novel business creation. These investment efforts aren't going to fully drive the efficiencies and innovation we seek in the delivery of medical care. The few provider-focused and facility-based startups that are getting done mostly sit outside the regulated payment model, and thus are not subject to the whimsical nature of government reimbursement. This same impulse, to stay out from a dependency on government reimbursement, is also driving the shift to investment in IT. Investors are drawn to the healthcare IT start-ups because they are less capital intensive. But it's also because they are generally facing providers and patients in these models and, therefore, aren't dependent on government reimbursement. Investors are turning away from service-based models that are mostly Medicare facing.

Yet healthcare IT is the fastest growing sub-sector of venture investing in recent years. It shows that there is significant investor interest in making investments in healthcare services. Investors recognize the magnitude of the opportunity to help bring new ideas and efficiencies to the delivery of healthcare. Only investors are appropriately skittish about placing bets on capital-intensive ideas that are subject to the highly uncertain reimbursement schedules maintained by Medicare. Investors who might have, one time, allocated capital to start new facility-based or provider-based healthcare delivery vehicles are now earmarking their capital towards healthcare IT focused start-ups.

To appreciate the opportunities and patient benefits that could be possible if we had more robust investment in these sorts of endeavors, consider some of the few new provider-based ventures being started. One provider-based concept attracting interest is home-based hospital services programs. These services use advanced monitoring and staffing models to deliver lower acuity but typically inpatient services to patients while they remain in their homes. It transforms what is typically an inpatient, hospital-based admissions to admissions fully administered in a patient's home. In other words, the inpatient services are brought to the home.

There are data to show that these approaches not only increase patient satisfaction and reduce readmissions but also improve outcomes. While this concept has mostly advanced in the private market outside of Medicare, CMS recently approved a demonstration through CMMI to test these same opportunities for Medicare beneficiaries.

Among some of the other few facilities-based concepts that have gained prominence in recent years, and offered certain conveniences and benefits to consumers, is the more widespread adoption of an old concept: urgent care clinics. These have gained popularity as patients find themselves out-of-pocket for more of their routine health care costs.

Another facilities-based concept that has been established by some Medicare Advantage plans is the creation of short-stay clinics that offer an alternative to hospital emergency

room visits for lower acuity episodes such as an exacerbation of heart failure. A patient might require short-term diuresis and monitoring that could span less than 24 hours, eliminating the need for a hospital admission or a long emergency room visit.

Skewing Innovation in Medical Devices

When it comes to medical devices and biotech, similar trends can be observed. There's evidence that policy and regulatory decisions have skewed the clinical areas where capital is being allocated. Even more revealing than examining the total amounts of capital going into these sectors is surveying the sub-sectors of medicine that money is being allocated to.

There's indication that investment in health care has been highly uneven when viewed according to the clinical sectors where capital is flowing. This irregularity can be correlated to areas of policy and political risk, with those clinical areas of highest risk getting the least investment. A disproportionate share of the investment is being allocated to areas of health care that are perceived as being more lightly regulated, or subject to more predictable political trends (like oncology). Government policies, and especially the impact of regulatory policies advanced by the Medicare program, are having an observable influence on entrepreneurship.

The unique incentives created by Medicare policy are most observable when it comes to medical devices. In the medical device, also referred to as the medtech space, the focus of entrepreneurship is directed as much if not more on lowering costs than improving outcomes. This is, in large measure, because of the bundled (and mostly static) rates that Medicare will pay for different episodes of care.

These rates are largely based on a system called Diagnosis Related Groups (DRGs)²⁰ for episodes of care delivered in the inpatient (Part A) setting and Ambulatory Payment Classifications (APCs) for episodes of care delivered in the hospital outpatient (Part B) setting.²¹ A DRG is a statistical system for classifying an inpatient stay into groups of related services for the purposes of assigning a bundled payment rate.

The DRG classification divides possible diagnoses into more than 20 major body systems and further subdivides these body systems into almost 500 groups, with each group assigned a different payment rate. A group will typically encompass an episode of care for a given condition, such as a hospital admission for an appendectomy. Factors used to determine the payment amount for each individual DRG include the diagnosis involved and the hospital resources necessary to treat the condition.²² In recent years, CMS is creating a much larger bundles for outpatient services under its outpatient prospective payment system, with no separate payment for additional items or services, making the APC process more akin to how the DRGs work.²³

Although CMS annually revises the DRGs using data from inpatient claims submitted for inpatient services rendered to Medicare beneficiaries, and the APCs using data from

outpatient claims, the classifications and weights are generally based on data from claims for services provided two fiscal years before the fiscal year in which they will be used. In the case of hospital inpatient services, for example, this can create a two-to-three-year delay between the initial introduction of a new technology and the recalibration of DRG weights to reflect its added cost. During this period, providers that adopt the new technology may experience a financial loss by using it.

This prospective payment approach can work reasonably well when the technology is a smaller component of the total procedure and the rate covers a lot of bundled services. But it works less well with narrow bundles, for which technology can represent a much larger share of the total payment. For example, a new scalpel may represent a small share of the payment for a surgical stay, but the costs of a new cancer drug could dominate payment for outpatient chemotherapy administration.²⁴

By using these approaches to cap what Medicare pays for the treatment of a particular condition, like an episode of heart failure or an admission for pneumonia, CMS can skew investment decisions. Entrepreneurs are reluctant to introduce superior but also potentially higher-cost technologies into these clinical settings for fear that adoption will be slowed and perhaps stymied altogether by these backward-focused payment arrangements—even if the technology can reduce long-term costs. If the new technology raises the immediate costs of treating the condition at issue, providers could be strained to bear the incremental cost.

CMS has certain tools that are meant to accommodate the cost of such disruptive innovations. But as I'll describe later, these mechanisms fail to achieve these purposes. As a result, new devices increasingly have to prove that they can either lower overall costs or deliver better or equivalent outcomes for lower costs in order to be used.

The result? Innovations that can deliver superior outcomes, but only at a higher (immediate) cost than the prevailing technologies, are very difficult to develop if the products are going to be largely Medicare reimbursed. This is principally because of the way that Medicare uses prospective payment to cap what it'll pay for the treatment of a given condition. As a result, the focus of new medical device innovation, across a growing number of clinical areas, has shifted to technology that “delivers an acceptable clinical outcome at a better price.”²⁵

This premise can be traced directly to an increasing insistence by Medicare and policymakers that “the benefits (and value) of new technology lie less in its ability to enhance existing technologies or procedures, than in its ability to provide adequate clinical solutions at a reduced cost.” It's a construct is sometimes referred to as “negative innovation.”²⁶ Hence the notion of technology that is “good enough” to achieve a clinical outcome, but not necessarily superior to devices currently on the market. Historical estimates indicate that this new segment of “good enough” devices is growing twice as fast as the device industry as a whole in some categories.²⁷

One interesting therapeutic area that reveals some of these challenges is ophthalmology. This is an area where payment has not been DRG based in some therapeutic areas, and as a result, there's been wider investment in, and adoption, of new technology. At the same time, this clinical area has been DRG based (and therefore affected by capped reimbursement) across other therapeutic needs, and we've seen less investment in these areas as a consequence.

One clinical area that straddles each of these considerations is the insertion of intra-ocular lenses. These procedures are typically subject to price caps through DRGs. Yet doctors still use some of the newer and costlier intra-ocular lenses, but only if the patient is able to pay the cost difference out-of-pocket for these presumably better lenses. The price points are still low enough that many patients are able to pay these differences in cost themselves, and the volumes are large enough that even a small percentage of patients who opt for the premium lenses still enable a large enough market to attract investment and new innovation.

Does this suggest that innovation for medical problems that are largely Medicare reimbursed will be increasingly dependent on patients' ability to pay the incremental cost of the newer innovation? In ophthalmology, that may still be affordable for many patients. This same requirement wouldn't be feasible in more acute areas of medicine, where the better technology may be very costly. It's in those settings that insurance is meant to protect patients against these costs.

The concept of cost-conscious innovation, where new technologies are focused less on improving outcomes than delivering equal outcomes at a lower cost, has an important role in helping to reduce health care costs. But a challenge arises when Medicare's payment rules establish a one-sized set of parameters for how innovation develops, and skew all investment toward only certain kinds of endeavors. It leaves little room for the kind of disruptive but perhaps costlier innovations that could yield paradigmatic changes in clinical outcomes.

While entrepreneurship in the medical device space has long been subject to these economic constraints, these considerations are becoming far more prominent. Moreover, these same policy rules are also beginning to constrain drug innovation as well, especially in Part A, where Medicare increasingly sets both a floor and ceiling on prices. Such is the case in dialysis, as well as the treatment of largely inpatient maladies such as acute heart failure.

The end result is that a lot of useful innovation doesn't get developed if it can merely improve outcomes, but at a higher immediate cost than Medicare's prevailing rate bundle. It's worth noting that, especially when it comes to medical devices, the cost of new innovations typically decline over time as technology improves. So a medical product that, at first, is costlier can become much cheaper as more people adopt the product and better ways of fabricating it emerge. This is the experience with certain cardiac defibrillators. These devices declined in cost over the period from their initial adoption in 1990s²⁸ to today, even while their functionality has noticeably improved.

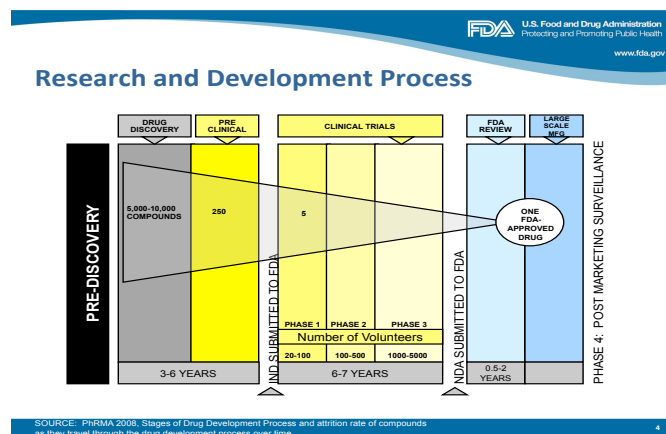
Similar Influences on New Drug Innovation

Similar influences can be observed when it comes to drugs targeting certain clinical settings, where data show investment shifting away from these areas of high Medicare regulation. Drug development is already a typically much longer and costlier endeavor than device development (Figure 3). Once again, some of the clinical areas of drug development that Medicare regulates most closely are episodes of care that occur largely in an inpatient (hospitalized) setting and therefore fall under diagnostic related group (DRGs).

Similar to the experience with medical devices, the problem is the static (and backward-looking) nature of the payments rates that are assigned to different episodes of care. They typically do not keep pace with cost of new drug innovations that might improve outcomes (and lower long-term costs) but perhaps raise the short-term cost of an episode of care. If a drug technology can improve outcomes, but at a higher cost than the current standard of care and it also targets an inpatient condition, then it faces a big hurdle in gaining adoption.

To illustrate the impact that Medicare has on drug innovation, I'll consider a clinical condition that falls largely in the hospitalized setting—acute heart failure. Relative to other clinical areas, there has been a marked underinvestment in treatments for heart failure, and the total capital allocated actually declined even as overall venture capital in health care rose. Investment in companies developing products for treating the heart slid under \$1 billion in 2012 for the first time since 1999, falling to \$922.85 million from \$1.18 billion in 2011, according to Dow Jones Venture Source. The decline continued in 2013, when the \$647.78 million spread across 73 financings was the lowest yearly total since the \$635.55 deployed in 1999.²⁹ These totals include all investment in cardiac conditions, not just heart failure, and also incorporate money spent not just on drugs but also medical devices. So these figures almost certainly understate the magnitude of underinvestment for in-patient cardiac conditions.

Figure 3



To take another example, consider investment in products related to dialysis. When people reach end-stage renal disease and require hemodialysis, Medicare will eventually cover their costs. CMS now pays a bundled payment for all of their dialysis-related care.

Yet once again, this fixed reimbursement formula doesn't easily accommodate the higher costs of new and disruptive innovation. In part, and as a consequence, we've seen little investment in treatments related to end-stage renal disease, and little innovation in the care of dialysis patients. In 2015, there were 18 venture deals for technologies related to the kidney, and almost all were for technologies that fell outside the dialysis bundle, for conditions like kidney stones and acute renal injury. By contrast, there were 60 venture deals for technologies related to immune disorder and 93 deals related to treatments for the brain.³⁰

Regulating Volume, as Well as Price

Even in settings where a new technology can deliver improved benefits for lower costs—meeting Medicare's dual criteria—the agency has still expressed reservations (and sought to slow or “stage” clinical adoption) largely to smooth out the cost of rollout. In the process, the agency has denied access to eligible patients and established precedents that ultimately discourage future investment. The Medicare program is focused on trying to engineer predictable and steady increases in spending. So it views transformative but costly innovations that could produce boluses of spending with skepticism.

Such was the case when a device came along four years ago that allowed older patients to repair failing aortic heart valves without undergoing risky open-heart surgery. As people age, the main valve carrying blood out of the heart becomes brittle and narrows, causing heart failure and even death. The new device allowed that valve to be repaired using a tiny catheter that introduces a replacement valve through an artery in the leg. The total cost of the new and noninvasive procedure wasn't much different than the open-heart surgery that it sought to replace. But Medicare's actuaries feared that the new replacement valve's low risks and easier administration would mean that many more elderly patients would seek to fix their failing heart valves, creating a bolus of higher spending.³¹

So regulators created coverage rules to sharply limit which patients could get one of the new valves, based on a set of medical criteria that always seemed dissolutely contrived. The criteria placed deliberate burdens on patients, limiting the number that would see the new treatment. It was a budget prerogative framed into a clinical rationale.

Landmark new data released recently at the annual meeting of the American College of Cardiology in Chicago make clear just how questionable the original rules were. This is hardly the first instance when CMS developed up its own fiscally driven interpretation of clinical medicine that subsequent science ultimately refuted. Take Medicare's tortured decisions concerning the use of implantable defibrillators that jump-start stopped hearts

during cardiac arrest. In 2003 Medicare adopted a highly novel theory, based on certain readings made off a person's electrocardiogram (called "wide QRS"), to expand coverage to some people, but not everyone, who needed one. Years later, another study firmly debunked the theories.³²

In the case of the aortic valve device, among other things, Medicare required that two cardiac surgeons first certify that a patient wasn't a candidate for the open-heart repair. CMS also required that a cardiothoracic surgeon and an interventional cardiologist were both present in the operating room when the procedure was performed. Medicare's regulators argued that if the procedure got botched (which is extremely rare) you'd need both doctors on site to help rescue the patient. In reality, this costly and redundant requirement was a not-so-veiled way to ensure that there wouldn't be "competition" between the two different medical specialties to widen use of the procedures.

Medicare also confined the procedure to a small number of mostly large academic medical centers. It's now obvious that many more patients should get the devices. But don't expect medical practice to change quickly as a result of the new data. It will take four months or longer for the FDA to update the product labels to reflect the new results, and only then, another six months or more for a hesitant Medicare to conform its payment rules to the new standard of medical care.

A Prescription for Reform

Medicare regulators are well intended and recognize the role for innovation in advancing health and improving the delivery of medical care. They're just responding to the political rules that they're obliged to follow and the budget prerogatives that they're asked to pursue.

The alternative is to break up the monopoly over these decisions and leave them to a more fragmented market of decision makers who compete to offer consumers good prices and timelier access to the most beneficial services. This is much more akin to the private model that guided the creation of the Part D benefit and the Medicare Advantage programs, and underpins the concept of "premium support," where Medicare would be modernized into a defined contribution, similar to the way coverage is administered in other parts of the market, with beneficiaries free to select and own their own health plans.

With Part D and Medicare Advantage, the rules afforded health plans the flexibility to experiment with different coverage models and didn't seek to claw back all of a plan's profitability above some arbitrary metric. The incentive was to entice entrepreneurs to establish new plans, on the premise that robust competition would compel plans to offer the best set of benefits for the lowest price in order to attract consumers. This is precisely what happened, enabling vigorous competition. As a result, net federal spending on Part D in 2013 was 50 percent less in fiscal year 2013 than the original Congressional Budget Office projections. Over the past decade, Part D has continually performed better than projected in federal budget estimates.

Yet even in Part D, mounting regulation is impeding the ability of new plans to get started, or existing plans to invest in the types of services that might lead to innovation and improvement in delivering benefits. Each year, stand-alone PDPs are subject to similarly complex and increasingly expensive compliance processes as Medicare Advantage plans, even though the MA plans generate more revenue to help offset these costs.

Furthermore, PDPs are subject to CMS's MLR regulation that a minimum of 85 percent of premium revenue be used to cover claim costs. Given the low top-line revenue for PDP plans, the remaining 15 percent—minus the cost of compliance and administration—leaves very little room for profit. Plans that offer an integrated Medicare Advantage and Part D drug plan may have some ability to share the administrative cost burdens across both membership populations. However, plans that offer only a stand-alone Part D plan do not have the same types of synergy.³³ It is a symptom of how continued innovation in services can atrophy as a program becomes entrenched in the Medicare sphere and subject to creeping and increasingly costly regulation over time.

To foster disruptive innovation that can lead to improvements in outcomes through better technology and better ways of delivering care, we need to be willing to compensate the capital, risk, and uncertainty that goes into these endeavors. We need to resist the impulse to try and carefully engineer choices, price, and outcomes. That means allowing prices to be subject to the constraints of market competition rather than the backward-looking and relatively fixed rate setting that prevails in many corners of Medicare. It also means ending the practice of scrutinizing new services based solely on their margins as a way to establish rate schedules and price reductions. Finally, it means taking into more careful consideration the returns needed to reward entrepreneurship and the different levels of risk taking and capital costs that characterize different health care business endeavors.

We are so far down the road with a scheme that uses regulatory tools to affix codes and politically determined reimbursement rates to every conceivable aspect of medical care that it may seem hard to conceive of a system in which these rates are left to be determined by private plans competing to offer these services rather than a system in which the rest of the private market prices its own payments off of Medicare's rate setting. There's a chicken-and-egg problem. But such a market-based pricing system is possible, especially with more private actors taking risk and administering Medicare services. The competition between private health plans for Medicare services can be used to glean the appropriate price rather than have CMS dictate these same terms.

We also need to be willing to pay a premium for disruptive innovation that can meaningfully improve outcomes, even if these technologies raise the short-term, direct costs for treating a particular condition. The implementation of bundled payment rates and prospective payment all serve to cap the compensation for treating a particular condition, and punish providers for adopting costlier technologies. It focuses innovation foremost on lowering treatment costs, with the goal of improving outcomes as secondary.

This focus on cost reduction has obvious virtue, but not when it comes at the trade-off of investment in new innovations that can meaningfully change the standard of medical care and provide the sort of clinical progress that can help improve beneficiary outcomes, while leading to more durable cost savings through improved productivity over time.

How can we improve the climate for innovation and better outcomes in Medicare?

1. Reform and expand the process for New Technology Add On Payments. The creation of new technology add on payments (NTAPs) was supposed to address some of the negative consequences from the reimbursement caps created by constructs like DRG-based pricing. The intent of the additional payments was to bridge the recalibration delay inherent in the prospective payment system that CMS uses to reimburse for inpatient services.

NTAPs provide a mechanism for granting a temporary payment boost when providers use a new technology—in addition to the DRG payment amount the hospital would otherwise receive. The NTAPs are supposed to be provided until the CMS has enough claims data to recalculate the DRG and can reflect the added costs in a new DRG calculation.³⁴

But the NTAPs are offered too infrequently. Their approval cycle, which is on an annual schedule, can leave gaps between a product's launch and the NTAPs' ability to influence its adoption.³⁵ The amount of money they offer is also typically too low to fully offset the higher costs of a new technology. Providers still often take a loss by adopting a costly innovation that qualifies for an NTAP.³⁶ As of 2015, CMS had approved only about a third of the applications for NTAPs since 2001 (19 of 53 applications).

The biggest drawback to this program, though, appears to be the process for persuading Medicare officials that a new drug or medical device offers a true advantage to existing treatments.³⁷ These criteria are not defined well enough to create a reasonable expectation that any particular technology will qualify. That means that innovators largely won't factor these payments into their assumptions around development costs and returns. So the NTAP has far less influence on entrepreneurship than it might otherwise offer.

Another factor limiting their utility is the often-byzantine process for qualifying for one of these payments. For one thing, the hurdle that new technologies must reach is very high. Not only does the new innovation need to provide a substantial clinical improvement over existing technologies, but also beneficiaries must largely lack access to whatever treatment or service the new technology offers. This means that a new technology that's a significant improvement over a treatment that beneficiaries already receive might not qualify for one of these payments, if beneficiaries already have access to the particular service that's at issue.

This program can be reimagined and reinvigorated to apply to a broader range of technologies, to be administratively less burdensome, and to provide more robust incentives. The House Energy and Commerce Committee included a proposal addressing

NTAP appeals in a discussion draft of its so-called Cures bill. Congress might consider other reforms in addition to these changes.

For example, if the criteria were more objectively defined, perhaps allowing technologies to automatically qualify if they meet certain outcomes that can be reasonably demonstrated in advance—with clinical data—there might be more opportunity for entrepreneurs to factor these payments into their return assumptions. Under such an opportunity, the NTAPs would then become a more useful and viable tool for actually creating incentives for investment in better technology for Medicare patients.³⁸

Of course, this would require CMS to give up some control over the individual decisions about which technologies get the payments. But the more that the process can be objectively defined, and automatically attach when technologies meet certain advance criteria, the more influence this program will have in creating incentives for the development of the sorts of advances that benefit patients.

2. Expand the period of time that technologies are eligible for pass-through status and make the criteria for obtaining pass-through more transparent and predictable.

The current payment unit that Medicare uses under the outpatient prospective payment system is the ambulatory payment classification (APC). Hospitals and other providers are paid a flat rate based on the individual outpatient services they bill, which are assigned to APCs. Like the inpatient approach, this outpatient scheme incorporates a mechanism to help offset the high costs associated with the introduction of new technologies in the outpatient setting. This concept is the “pass-through” payments for procedures delivered under the hospital outpatient prospective payment system. But like the inpatient approach, it falls short of all its goals.

Under the outpatient approach, CMS will pay for new devices, drugs, biologics, and radiopharmaceuticals while the agency collects data to incorporate the cost of innovative products into its bundled payment rates. These transitional pass-through payments cover technologies that are an input to an existing service. For medical devices, the pass-through payment is based on 100 percent of charges reduced to costs through the use of a hospital-specific cost-to-charge ratio. For drugs or biologics, it’s based on 95 percent of average wholesale price.

Currently, CMS provides transitional pass-through payments for two to three years, but the exact length of time varies depending on when during the year a product is approved. Pass-through status is determined on a quarterly basis but expires at the end of the calendar year once CMS has made at least two years of pass-through payments. This time period is too short in many cases to give entrepreneurs adequate time to penetrate markets and demonstrate the full utility of new technologies. CMS is proposing to provide three full years of pass-through payments to eligible products, and to align the expiration of pass-through status on a quarterly basis. The new scheme would begin in calendar year 2017.

That period of time may be sufficient for some new technologies but not others and may be more appropriate for some technologies than others, which have a different adoption cycle. Similar to the challenges with the NTAPs, entrepreneurs still face the added uncertainty of not knowing if they will qualify for pass-through status until well after they have taken on substantial risk and investment costs. As a consequence and similar to the experience with NTAPs, the pass-through process has a diminished impact on investment and new product development as a result of the uncertainty over which technologies will qualify for the status.

The complex if not highly contrived process for accommodating new technologies under the pass-through program has shortcomings similar to NTAPs. It is not predictable enough to be a significant factor in the decision for entrepreneurs to pursue a new technology. Therefore, it fails to serve as robust an incentive for innovation that Medicare might find useful for its beneficiaries and be willing to support and reward.

A far better alternative would be for Medicare to spell out objective criteria for when pass-through payments would attach (as well as NTAPs) and allow innovators to meet these conditions through clinical data that could be gathered as part of the approval process. If Medicare disengaged itself from a long and unpredictable review process, and made the attachment of these payments more automatic based on achieving certain reasonable and objective data milestones, all of these programs could become more useful in providing an incentive for the sort of innovation that can benefit patients.

3. Expand the pass-through concept to the determination of bundled payment rates.

In the outpatient setting we're moving toward wholesale forms of capitation as the preferred payment model. But the way that Medicare codes for individual services still skews the way care can be delivered and, ultimately, investment decisions in new arrangements. Moreover, the bundled rates are likely to suffer from the same challenges that plague DRGs and APCs—they will be backward looking, and won't adjust for the adoption of new innovation.

It seems that, in the long run, CMS is likely to adopt payment bundles as its preferred form of "alternative payment models" and capitation. The bundles are the most expedient way for CMS to achieve its goal of quickly transitioning payment to alternative models. They're also the administratively easiest form of capitation to administer. But bundling will put the same kind of pressure on the development and adoption of new technology as the DRGs.

We need to make the same accommodations that we've considered in the setting of the prospective payment system. Only here, we have the chance to make sure that these accommodations actually achieve all of their goals—including the goal of fostering the development and adoption of transformative innovations that can improve patient care. When it comes to bundling, we have the most experience with the bundled rate that's used to compensate providers for providing care to patients obligated to long-term

dialysis. And there's evidence that the dialysis bundle discourages the adoption of new technology in the treatment of these patients.

Like the experience with DRGs and APCs, anytime a costlier but superior technology comes along for the treatment of a given condition that's reimbursed under a bundle, it pushes the total cost of a treatment episode beyond the rate affixed to a particular payment bundle. Providers will lose money by using a costly new technology in the treatment of these conditions. They will be reluctant to adopt these new innovations.

To the degree that this disincentive exists, it will discourage entrepreneurs from developing these new products in the first place, again denying Medicare recipients such progress. We should make a deliberate effort to allow beneficial new technologies to initially pass through these bundles so entrepreneurs have an incentive to invest in them and providers have the ability to adopt them.

4. End a culture of punishing profits when it comes to disruptive health care services. We also need to allow for similar accommodations when it comes to new health care services. When Part D launched, there were thousands of new plans, and they showed a wide dispersion of profitability, with some plans earning significant margins and equal numbers losing money. Over time, this wide dispersion evolved to a very tight mean, with margins among Part D plans ranging around 3 percent, well below the initial target that Medicare estimated of around 4–5 percent. While Medicare Advantage is a more profitable line of business, and also one with higher risk and capital requirements, here too the market has consolidated over time, and profitability has been reduced to a more narrow range of around 5–6 percent.³⁹

We need to allow new services to enter the market in a competitive framework in which we can rely on market competition to establish an appropriate price equilibrium, and not rely on rate schedules that set arbitrary reimbursement based on measures of profitability rather than clinical utility and value to beneficiaries. We need to allow new segments to run at higher profit margins in some cases, so that entrepreneurs can earn more predictable, market-based returns, with confidence that competitive aspects of these services will work over time to reduce costs and prices.

This is especially true as we migrate toward payment arrangements that transfer risk to providers through capitation, and rely on consolidated health systems to be the stewards of how dollars are directed in the care of beneficiaries. As we do, we should also use this occasion to get Medicare out of the rate-setting business for so many services.

If we're going to rely on provider entities like large, capitated health systems to make decisions about how money is best allocated across different services to achieve the best outcomes, then we should also rely on them and empower them to negotiate with different health care service providers based on delivering the best services for seniors at the lowest possible cost. If we are going to put providers in control of how money is

allocated through capitation, we ought to also look for ways to get Medicare out of the rate setting business for services.

5. Make new technology promotion an explicit part of Medicare’s mission. Finally, it’s generally accepted that the goal of promoting biomedical innovation has never been an explicit objective in the strategic plan for the Medicare program. The agency’s former Chief Medical Officer also made this point during testimony before the Senate, an accomplished physician who had a long and distinguished career at CMS.⁴⁰ The agency’s currently stated mission, displayed on the Medicare website, is “to ensure effective, up-to-date health care coverage and to promote quality care for beneficiaries.”

FDA, by comparison, has made the promotion of new drug and device innovation an explicit part of its mission. The FDA has frequently reflected on ways that its policies impact innovation, investment, and entrepreneurship. Even if the FDA were sometimes criticized for promoting policies that make entrepreneurship more costly and complex, it would be unfair to argue that FDA doesn’t make consideration of these challenges and trade-offs a part of its culture.

The culture at Medicare is quite different in this regard. New technology is more likely to be viewed as a challenge than an opportunity. Even transformative innovations like TAVR are frequently viewed with skepticism. Medicare could be directed to consider the impact of its policies on entrepreneurship and innovation as a more integral part of its policymaking.

Just such an effort, to provide an assessment of specific Medicare policies that could promote innovation, was taken on by the National Venture Capital Association (NVCA) in a report published in 2007 titled “Proposal for a Reimbursement Critical Path for CMS.”⁴¹ It could offer a useful template for not only how Medicare might contemplate a similar process but also some of the specific areas that the CMS might seek to address.

The report offered eight separate recommendations. Among them that CMS should develop a clearer process through which new technologies could achieve coding, coverage, and payment; the establishment of specific timelines for all phases of the reimbursement process; clarification of evidence requirements necessary to obtain new technology add-on payments and to qualify for a separate Medicare billing code; and undertaking a thorough review of the overly complex process through which new CPT codes are assigned to new technologies.

These recommendations have been echoed over more than two decades, even while CMS has made multiple attempts through guidance and other measures to address these concerns. Yet these areas remain challenges for entrepreneurs and obstacles to new innovations. Even as CMS has recognized these criticisms, it has largely fallen short in meaningfully resolving the underlying challenges. As part of an agenda to reduce the obstacles that Medicare policy poses to the development and adoption of technology that can improve the health of seniors, all of these areas remain important areas for CMS to focus its policy reforms.

Conclusion

The only way we are going to solve our long-term fiscal challenges with programs like Medicare, and make sure future beneficiaries have access to high-quality medical care, is to make sure that we continue to get more health care outcomes for every dollar of GDP that we spend on these endeavors. The only way to achieve these productivity gains in medical care is through innovation, not only in the technology, such as drugs and medical devices, but also the service providers that organize the delivery of this care. And the only reliable way that we're going to realize these improvements is through the work of entrepreneurs who allocate capital toward the development of novel products and innovative services that can advance the delivery of medical care and improve outcomes.

Yet increasingly, Medicare's regulatory practices and its growing lists of rules are setting both a floor and ceiling on reimbursement levels for different sectors and different therapeutic settings and, in turn, the profits that can accrue to compensate entrepreneurs for risk taking. This is leading to an environment where innovation is increasingly being contrived to fit within a narrow set of parameters set out by policy prerogatives, rather than the opportunities offered by science, and the clinical aspirations of patients.

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Notes

¹ The five-year relative survival rate for people with stage I colon cancer is about 92 percent. For people with stage IIA colon cancer, the five-year relative survival rate is about 87 percent. For stage IIB cancer, the survival rate is about 63 percent. The five-year relative survival rate for stage IIIA colon cancers is about 89 percent. For stage IIIB cancers the survival rate is about 69 percent, and for stage IIC cancers the survival rate is about 53 percent. American Cancer Society, "Colorectal Cancer," January 20, 2016, <http://www.cancer.org/cancer/colonandrectumcancer/detailedguide/colorectal-cancer-survival-rates>.

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- ¹⁸ Earnings before income, taxes, depreciation, and amortization (EBITDA) is an indicator of a company’s financial performance. EBITDA is essentially net income with interest, taxes, depreciation, and amortization added back to it, and it can be used to analyze and compare profitability between companies and industries because it eliminates the effects of financing and accounting decisions.
- ¹⁹ This experience is, in part, why psychiatry-based facilities and provider businesses are one bright spot in the investment landscape for early-stage and venture investors. There is a perception in the investment community that the recent mental-health-focused legislation has provided some stability to the Medicare reimbursement in this segment. That perception of at least five years of rate certainty gives some investors enough time to make longer-term bets on their capital in this therapeutic space.
- ²⁰ The DRG system provides for a broad patient classification, encompassing all routine nursing, support service, and ancillary costs incurred in patients’ stays. Most technologies are bundled into the DRG payment.
- ²¹ Effective January 1, 2015, CMS established comprehensive APCs to provide all-inclusive payments for certain procedures. This policy packages payment for all items and services typically packaged under the OPSS. It also packages payment for other items and services that are not typically packaged under the OPSS. The single payment for a comprehensive APC excludes services that cannot be covered Outpatient Department (OPD) services or cannot by statute be paid under the OPSS. Office of Inspector General, “Medicare Hospital Prospective Payment System: How DRG Rates Are Calculated and Updated,” August 2001, <https://oig.hhs.gov/oei/reports/oei-09-00-00200.pdf>.
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