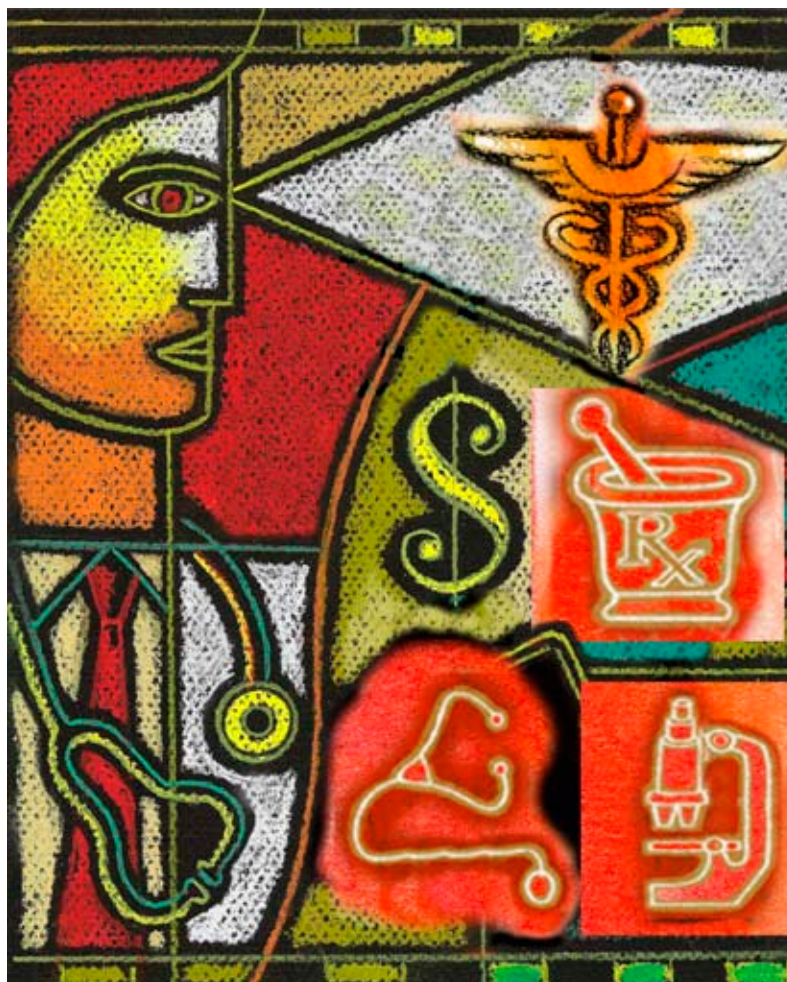




CALIFORNIA
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Innovating for the Health Care Safety Net: Sources of Funding

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Innovating for the Health Care Safety Net: Sources of Funding

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by

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About the Foundation

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Contents

2 I. Executive Summary

3 II. Introduction

4 III. Traditional Funding Sources for Medical Technology

Venture Capital

Corporate Investment

8 IV. Implications for Social Innovators

10 V. The Safety Net as a Market

12 VI. Venture Funding for Remote Monitoring

Venture Capitalists' Investment Criteria

18 VII. Strategies for Further Exploration

Driving Down Investment Costs

Minimizing Safety Net Risks

Augmenting Traditional Investment Models

21 VIII. Conclusion

22 IX. Case Studies

30 Appendix A: Glossary

31 Appendix B: Advantages and Disadvantages of Various Funding Sources

33 Endnotes

I. Executive Summary

MEDICAL TECHNOLOGIES WITH HIGH “SOCIAL value”—those that have the potential to reduce costs, improve health care, and improve access to care—can play an important role in helping safety-net providers use their resources more efficiently to better serve millions of patients. However, because the conventional wisdom among traditional investors is that the total market potential for such technologies is small relative to other, more immediate opportunities, many companies have struggled to secure capital to fund the development and commercialization of these innovations.

Venture capitalists are one of the most common sources of funding for medtech innovations. Typically, they screen their investment opportunities using criteria that place a high value on factors such as a proven business model, a large and accessible market, limited adoption risks, a clear reimbursement pathway, and a high return on investment. Venture capitalists use the same demanding criteria to evaluate all opportunities, including those with high social value, which can make it difficult for technologies that could benefit the safety net but pose greater investment risk to secure capital. Even if a technology meets these standard criteria, many venture capitalists remain skeptical; fundamentally, they do not believe that unbounded, profitable opportunities exist in low-resource environments.

Despite this perception, the safety net shows some promise as a market opportunity for commercial investors because:

- As financial circumstances across the health care industry worsen, cost-reducing technologies are sure to become more universally appealing;

- The lack of competition in the safety net represents a “white space” that could attract investment;
- The size of the underserved market is compelling, especially given that another 20 million people are expected to become eligible for Medicaid by 2014; and
- Low-resource environments outside the United States abound and could significantly increase the size of the market for innovations with high social value.

If one accepts the premise that innovations with high social value, such as remote monitoring technologies, are beneficial to the safety net, then foundations and other social investors could play an important role in overcoming the market failures that prevent these innovations from being funded. At least three key strategies are worth considering:

1. Early-stage investments, which would help drive down the mounting costs associated with addressing a product’s market and adoption risks;
2. Targeted grant-making, which could help reduce risks unique to the safety net that contribute to negative perceptions of it as a market for innovations; and
3. The creation of social venture funds to supplement traditional funding models for medtech innovations and thereby help technologies with high social value reach a point at which they are attractive to venture investors.

II. Introduction

IN THE CURRENT HEALTH CARE ENVIRONMENT, there is a significant need for new medical technologies that promise to expand access to important diagnostics, treatments, and specialty services by reducing costs, without sacrificing quality relative to prevailing standards of care or evidence-based guidelines. These technologies have high social value because of their potential to transform the way health care is delivered to underserved populations, but they may not necessarily generate the high financial returns expected by investors who typically fund the development and commercialization of new technologies.

This paper examines funding for new medical technologies, particularly traditional financing mechanisms and the barriers that commercial investment criteria create for medtech innovations with high social value but relatively low potential returns. It then proposes alternative funding solutions for important technologies that could benefit low-resource environments.

The targeted beneficiaries of technologies discussed in this report are underserved populations that receive care from “safety-net” providers. (See Appendix A: Glossary.) Such providers include “public hospitals and health systems, community health centers and clinics, and for-profit and not-for-profit healthcare organizations that provide free or discounted care,”¹ which often depend on tax dollars. Because of their mission and the socioeconomic status of the majority of patients they serve, safety-net providers face severe resource constraints. Medical technologies that have the potential to reduce costs, improve care, and improve access to care can play an important role in helping these

organizations use their resources more efficiently to better serve millions of patients. However, the conventional wisdom is that the total return to investors on technologies targeted to underserved populations is unproven relative to other investment opportunities. As a result, finding capital to develop and commercialize these technologies can be difficult.

III. Traditional Funding Sources for Medical Technology²

MEDTECH INNOVATORS HAVE TRADITIONALLY been able to pursue multiple sources of funding, including friends and family, angel investors, venture capitalists, corporate investors, customers, the government, and banks. These different types of investors have different priorities and distinct advantages and disadvantages that innovators must take into account (see Appendix B).

When innovators choose a financing strategy and investor(s) to approach, they must be explicit about what is most important to them. For example, must an investor be willing to make a long-term commitment and potentially contribute to multiple funding rounds? Or is it more important that it not restrict the company's strategic options by, for instance, taking a large ownership stake or majority voting rights that would make the company dependent on the investor's involvement in critical decisions? Different innovators will seek different levels of relevant experience and expertise on the part of investors, depending on the strength of their adviser base and/or their company's board of directors.

Innovators must also consider the types of investors they will realistically be able to attract. Each type uses different criteria to evaluate potential investments. For example, a bank may be willing to provide funding to a company that has sufficient cash flow to make monthly repayments and enough collateral to secure the loan. However, a young start-up without a product on the market cannot meet these criteria and, therefore, must pursue other funding options.

During a company's earliest stages, its worth to investors is low. The company has not yet proven

itself, so investors must assume significant risk. Thus, the cost of raising funds is high; the company should expect to give up a sizable portion of its ownership for a relatively small amount of money. As the company accomplishes its major milestones, the risk to investors declines and acquiring funds becomes less expensive.³ For this reason, a company may benefit from using different types of investors at different stages. For instance, innovators often turn to friends and family to finance early research and development work. Government grants are another option for meeting the relatively low capital requirements of early-stage work. Once a company is formed and activities expand to include product development, regulatory clearance, clinical testing, and other resource-intensive work, it needs significantly more money. At this point, innovators often turn to angel investors, venture capitalists, and/or corporate investors for financing. Venture capital is by far the largest source of funding in the medtech arena. In 2007, U.S. venture capitalists invested \$3.9 billion in 365 medical device start-ups.⁴

Venture Capital⁵

Venture capital, also referred to as venture financing, typically helps start-ups establish or sustain a business that appears to have high growth potential. A venture capital firm, represented by a venture capitalist (VC), makes the investment on behalf of one or more limited partners. In exchange, the VC and limited partners receive equity in the company. The expectation is that the investors will be able to realize a substantial return on their money through an "exit event" at some point in the future.

Venture capital is especially helpful to start-up companies that do not yet have an operating history, revenue, or significant collateral, and therefore lack access to other sources of capital, such as bank loans. VCs look for companies with a high probability of success and the capacity to generate better-than-average returns. However, because the investments are speculative and fraught with risk, VCs can be demanding about the amount of equity they expect and other terms of the deal. Estimates vary, but a major portion of a VC's deals may fail to earn a return on investment. Mudit Jain, a partner with Synergy Life Science Partners, explained the implications: "If roughly 20 to 40 percent of companies succeed, you need these 20 to 40 percent of companies to make up for the capital invested across the portfolio and generate a return for investors."⁶ Returns for VC-funded companies considered to have achieved a "successful" exit range from 300 percent to 1,000 percent, or "3x to 10x."⁷

How It Works⁸

On the surface, the process of venture capital funding seems rather simple. A VC raises money from a collection of limited partners (LPs), who are often institutional investors or endowments whose objective is to maximize the return on their investments. The money from the LPs is used to create a fund that the VC manages. Funds vary in size, but they typically range from \$50 million to \$2 billion. Each has a specific investment profile—for example, medical devices, biotechnology, or information technology.

The VC investigates companies that match the fund's profile and, before making any investments, performs due diligence by evaluating the business model, technical feasibility, management team, and other factors. After the VC chooses a company, any amount from about \$1 million to \$50 million

is transferred from the fund to the company in exchange for an equity stake. Then, the VC often takes a seat on the company's board of directors to supervise the investment. In this role, the VC also provides experience, expertise, and connections to help the emerging venture succeed. Money is returned to the LPs when the company achieves a successful "exit," most often through an initial public offering or acquisition by a larger enterprise.

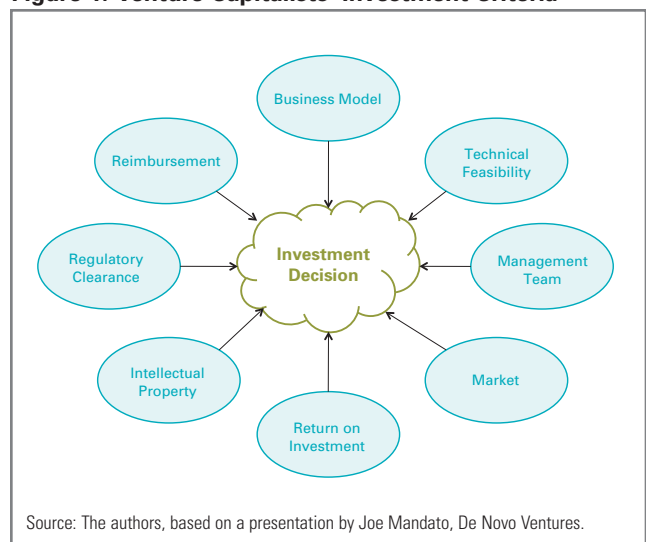
The VC's goal in this process is to maximize the return he or she delivers to the LPs within a reasonable period of time. The criteria VCs use to select companies for investment clearly reflect that goal.

Investment Criteria⁹

As Josh Makower, founder and CEO of device incubator ExploraMed, explained: "Investors are looking for unbounded upside with the least amount of risk possible." Toward this end, they use specific criteria to evaluate which investments enable them to balance the risk/reward equation.

At the top of the criteria list is the business model (Figure 1). This includes the extent to which

Figure 1. Venture Capitalists' Investment Criteria



the innovators have defined a clear, practical plan for making money. The opportunity also must be based on an idea that has reasonable technical feasibility. VCs are not interested in funding research that resembles a science experiment; they prefer technology that has been proven, at least through a working model and preliminary bench and/or animal tests. Additionally, the caliber and experience of the management team, along with its ability to execute the company's plan, are carefully evaluated.

The market is another major consideration. In the medtech field, VCs tend to favor technologies that correspond to a significant, validated clinical need. If the targeted audience is excited about and receptive to a solution, all the better. These potential customers also must be accessible: VCs may be less interested if the patients or physicians who would benefit from the solution are difficult to identify and/or reach through typical sales and marketing channels. Perhaps most importantly, VCs are usually interested in large market opportunities. "For medical devices, investors are typically aiming for market sizes that are north of the \$400 or \$500 million mark," said Jain, at Synergy Life Science Partners.

Smaller markets can attract VCs' interest under certain circumstances, but bigger tends to be better because a company often spends as much to penetrate a small market as it does to penetrate a large one, according to Jain. More specifically, VCs want markets in which fewer customers purchase higher priced devices and generate sales exceeding \$500 million. For example, a device that, per year, would sell for \$5,000 to 10,000 patients is more attractive than one that would sell for \$50 to 1 million patients. In the latter case, a company would have to sell to more physicians and patients, and thus need more capital to access these buyers. Finally, VCs consider the amount of competition in a market: crowded markets are less appealing than

those offering a better chance for a company to establish itself as a leader or, better yet, a first mover.

VCs also look realistically at the return on investment and the time necessary to reach a successful exit. They typically consider a potential 3x to 5x return to be acceptable, but 10x is the benchmark, and they hope to reach an exit within three to five years. However, as the external environment becomes more complex, due to factors such as higher regulatory and reimbursement hurdles, it is not uncommon for investments to span seven to nine years, which often makes the return less attractive. A study of medtech initial public offerings from 2004 to 2008 showed a mean time of seven years from round-one venture funding to an initial public offering, plus or minus four years.¹⁰

Ownership of intellectual property, regulatory approval of a product, and reimbursement for that product in the marketplace all have a profound effect on a company's ability to get an innovation to market and/or achieve an exit. VCs look favorably on companies that take a strategic approach to intellectual property and that own or have licensed critical patents. They want a straightforward regulatory pathway in which product approval is imminent. Devices that qualify for Food and Drug Administration clearance through the 510(k) review process, rather than the more costly, time-consuming, and inherently riskier premarket approval process, are of increasing interest to VCs.¹¹ In the past, reimbursement followed regulatory approval. But with the continuing increase in health care costs, innovators are under greater pressure to demonstrate not just the safety and efficacy of their products, but also the cost-effectiveness relative to other treatments. Companies and their investors can no longer assume that an innovation will readily qualify for reimbursement. New businesses that utilize established reimbursement codes have a distinct

advantage in investors' minds.¹² If no such codes exist, the company must have a clear, realistic strategy for establishing new ones or generating revenue by other means.

The terms of the deal are also important. VCs want clear, simple terms; input into a company's strategic decisions—for example, through a seat on the board; and a pre-investment valuation of the company, or “pre-money valuation,” that is realistic based on what it has achieved to date. In exchange for their investment, VCs typically seek an ownership stake of 10 percent to 20 percent. Although an equity investment larger than that is risky, they may take up to 25 percent ownership if they think a company has significant upside potential.

In simple terms, VCs use the above criteria to ensure that investment opportunities satisfy the following formula:

$$N \times (\text{price} - \text{cost}) / \text{invested capital} > X$$

N is the total number of potential customers, price is the amount a company can charge based on customers' ability and willingness to pay, and cost reflects the expense to make, sell, and distribute the product to the targeted audience. X is the return on investment the investors would like to realize. Because most ventures fail and none can expect to capture the full market, X is typically high: the rule of thumb for medtech in the venture investor community is at least 10.

Corporate Investment¹³

Another common funding source for medtech innovators is corporate investors. Large corporations, such as Johnson & Johnson and Medtronic, can help fund start-ups in two primary ways: by underwriting a specific research and development effort through a development partnership or by investing in the company as a traditional VC would.

Corporations use criteria similar to VCs' criteria when evaluating opportunities. For example, market size and accessibility, along with the potential return on investment, are important. However, there is another screening mechanism that can influence their willingness to commit funds. Unlike venture investors, corporate investors are looking for investments that will create synergies with other products in their portfolios or create new opportunities aligned with their growth strategy. Thus, if a new technology is strategically attractive, they may be slightly more flexible than VCs when evaluating it.

Corporate investment may appeal to innovators because it tends to be somewhat less expensive than VC funding. It also can bestow unique forms of leverage, such as access to established distribution channels and synergistic technology. Furthermore, association with a major corporation lends credibility to a young company.

On the downside, corporate investors may encourage the company to create a business suitable for acquisition rather than one that can remain independent. The two parties may also run into conflicting agendas as corporate investors look out for the corporation's best interests. In some cases, issues arise regarding the ownership of jointly developed intellectual property that may benefit both the start-up and the corporation. Additionally, corporate investments can be susceptible to changes in the economy and, consequently, may not be available as a source of follow-on funding. Finally, exiting a corporate investment can be complicated if there is more than one bidder for the venture but the corporation has “first rights” to acquire it. On the other hand, a strong, mutually beneficial relationship could lead to a smooth, high-value exit.

IV. Implications for Social Innovators

UNFORTUNATELY FOR “SOCIAL INNOVATORS,” or those who want to develop technologies of high social value for low-resource environments, VCs and corporate investors use the same demanding criteria to evaluate these technologies as they use to assess mainstream commercial opportunities. As Michael Goldberg, a partner with Mohr Davidow Ventures, put it:

The investors we represent don't look to us to do their humanitarian work. They look to our firm to generate a return on their investments in a way that's hopefully compatible with their humanitarian values. If we told them we were going to sacrifice investment returns in any material way in an effort to better serve the general welfare of the U.S. or world population, I think they would move their money as soon as they had the opportunity.

Jain underscored the same point: “Venture capitalists are measured by the capital they return to their investors.... It's a sheer dollars-in, dollars-out equation. While one would like to create social value, one doesn't get extra credit for creating it.”

Many venture capitalists who want to make a difference volunteer their own time and money to projects that benefit underserved populations in the United States or abroad. But Joe Mandato, managing director at De Novo Ventures, explained that as a volunteer, “I provide the same level of alleged expertise that I would provide to any of our portfolio companies but without any expectation that I'm going to generate a personal or a fund return. It's more of a pro bono or philanthropic interest than anything else.”

In 2010, the need for VCs to maximize returns was only growing more imperative. According to William Starling, managing director of Synergy Life Science Partners:

Since the recession hit nearly a year and a half ago, the whole venture community has been turned upside-down. There are two main problems that venture groups are having. One is that medtech returns, on average, have been dismal the past decade—below even the S&P 500 on average. Basically, only about 10 to 20 percent of recent vintage medtech venture groups are making good enough returns to keep them above water today. The vast majority of the medtech venture groups in this category are losing money for their LPs in this current environment. The other problem is that many limited partners have stopped investing in new venture funds, for the most part, and even in their own existing venture funds, to a certain extent. After the stock market cratered, there just wasn't much cash available for many alternative investment opportunities. So what you have is a situation where many limited partnerships are telling their venture funds, “Don't expect us to come forward in the next fund, and if we do it will be for a lesser amount.” They're also telling us to be very prudent and make sure that we have some liquidity events before we come back asking for more money in follow-on funds.

Because VCs face greater pressure to produce results and have less money to invest, securing venture capital is more difficult than ever. Unless innovators have technologies that can meet or exceed the established investment criteria in the

industry, there is little hope of getting traditional funding, even if the new offerings could potentially revolutionize health care in the safety net. When asked what advice he would give to innovators with technologies targeted to underserved populations and low-resource environments, Starling bluntly replied, “Avoid venture capitalists.” He added: “Venture capitalists are trying to survive. There’s just no way they’re going to put money into efforts that don’t meet the minimum bar for return on investment in the current climate.”

V. The Safety Net as a Market

EVEN WHEN TECHNOLOGIES THAT COULD benefit the safety net show promise in meeting venture investment criteria, many VCs are skeptical. They do not believe that big, unbounded, profitable opportunities are available in low-resource environments. Referring again to the simple investment formula, they doubt that the price a company can charge for a product in the safety net relative to the cost of making and selling it, the number of potential users, and the necessary investment capital will generate an acceptable return.

Because safety-net providers are fundamentally resource constrained, the perception is that in many cases they could not pay a price that would generate a sufficient profit margin. The small number of potential customers in the safety net relative to the broader health care market exacerbates this problem. As James Sweeney, founder of CaridoNet and chairman and CEO of PatientSafe Solutions, put it: “They tend to be looked at as orphaned opportunities, with investors asking, ‘Why would I want to fish in a small pond when I can go fishing in a big pond?’”

Moreover, gaining widespread access to the safety-net market can be difficult because many providers operate independently or in small clusters of hospitals and clinics. Another perception is that overburdened safety-net providers and their patients of low socioeconomic status are not willing or able to commit the time and resources necessary to effectively utilize or comply with new technologies.

However, as financial circumstances worsen across the rest of the health care industry, cost-reducing technologies that can achieve benefits in severely resource-constrained safety-net environments may

become more universally appealing. Products that show potential to cross over into more mainstream commercial settings would help establish the safety net as a preliminary market from which a company could expand.

The lack of competition in this arena, which makes it a so-called “white space,” also could help attract interest, as many investors are notoriously drawn to such spaces in the medical field. “[Underserved] markets might look unattractive and so people might not want to go there,” said Ed Manicka, CEO of Corventis, “but that’s also an advantage because you find very little high-quality competition when you get there, especially if you’re trying to use a technology-based solution to do the work that otherwise would have been a lot more expensive to get done.”

Additionally, while there is little that innovators can do on their own to increase margins in this space, the economics become more compelling if they can make a case for expanding into other low-resource environments abroad. Manicka explained:

If you can actually find a solution that makes sense in these resource-constrained environments, you may be able to enter the true growth markets of tomorrow. Specifically, India and China are demanding low-cost solutions that are technologically on par with what is available in the United States. Now, clearly, the margins are going to be lower, but the pure scale is mind-boggling. The scale allows you to rethink the business model in the context of the pricing on the margin.

Finally, the size of the underserved population, while small compared to the total U.S. market, is still

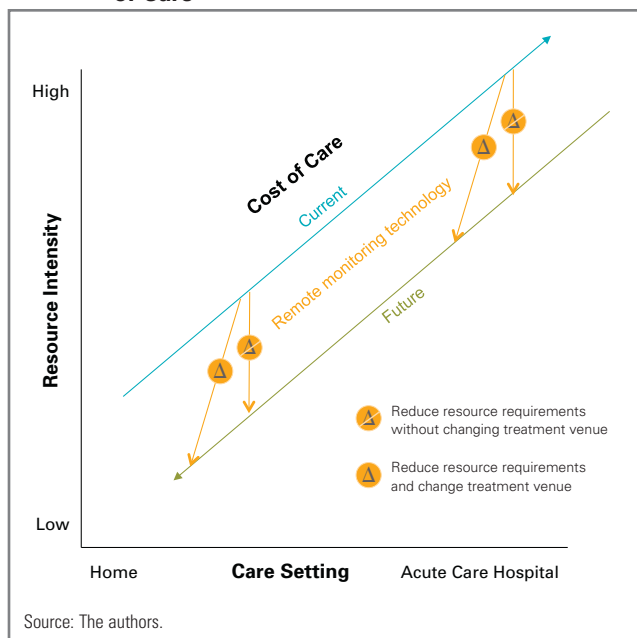
substantial. Medicaid covers roughly 44 million low-income families and another 14 million elderly and people with disabilities. Total Medicaid spending for fiscal 2009 was \$335 billion, a 7.8 percent increase over the previous year, and the budget was expected to continue growing.¹⁴ Although there are significant challenges associated with reaching and serving these patients and their providers, the population represents a sizable opportunity for innovators who can figure out how to serve it profitably by creating high-value, lower-cost solutions.

Hypothetically, the safety net could be an attractive market if companies can find ways for their innovations to cross over to the broader U.S. market, tap opportunities abroad, and/or reduce the cost of accessing and acquiring customers, such that $N \times (\text{price} - \text{cost})$ becomes more favorable.

VI. Venture Funding for Remote Monitoring

REMOTE-MONITORING AND INTERVENTION technologies, a specific class of products, illustrate the challenges and opportunities associated with seeking venture funding for innovations that have high social value. Although remote monitoring can potentially reduce costs, improve care, and increase underserved patients' access to specialty care, venture investment has been slow and somewhat inconsistent. These devices, such as blood pressure cuffs and glucose monitors, enable physicians and other care providers to supervise patients' physiological parameters and/or treat their conditions without being physically present. This lowers the cost of care by reducing the resource intensity of certain provider-patient interactions in a less expensive health-care or nonhealth-care setting, such as a clinic or the patient's home rather than a hospital (Figure 2, wherein the

Figure 2. Remote Monitoring and Its Effect on the Cost of Care



greatest potential savings come from moving down and to the left). Importantly, by keeping patients out of the hospital, these solutions can also significantly help improve their quality of life.

Venture Capitalists' Investment Criteria

When VCs and corporate investors evaluate remote monitoring technologies using their standard investment criteria, many innovations receive high marks in terms of technical feasibility. "Remote monitoring technologies are relatively low-tech in some ways—I mean, it's not like we're putting devices inside the body that are going to shock a patient's heart," said Suneel Ratan, a marketing, reimbursement, and government relations executive at Robert Bosch Healthcare. Most such products are based on fundamental technologies that have proved themselves in sensor, data-communications, or other arenas. What makes each one unique is its innovative application to a specific medical challenge. Algorithms for interpreting patient data, providing diagnoses, and offering decision support may be highly sophisticated and complex, but the underlying technology is relatively well understood. Moreover, because these devices are for external use, they pose few safety risks for patients, which means they often receive regulatory clearance through the FDA's faster 510(k) review process. Most investors favor 510(k) products over those that require premarket approval, and thus may be more attracted to remote monitoring innovations.

However, while the technical and regulatory risks are relatively low, several other investment criteria have proved to be problematic for many remote monitoring solutions (Table 1). Investors

Table 1. Major Remote-Monitoring Factors and Risks for Investors

FACTORS	RISKS
Market / Adoption	<ul style="list-style-type: none">• Physicians often resist technologies that disrupt the traditional care paradigm.• The fixed investment in facilities, staff, and equipment may amplify that resistance if the technology shifts the care venue.• A high burden of clinical proof is necessary to establish a new standard of care.• Providers may not want to build and manage the service infrastructure necessary to support the technology.• There are no incentives to help offset the additional liability physicians may face by using remote monitoring.
Business Models / Reimbursement	<ul style="list-style-type: none">• There are few proven business models as precedents.• The current reimbursement system creates disincentives for providers to adopt these technologies.
Return on Investment	<ul style="list-style-type: none">• Realistically, the size of the targeted market may not align with the capital necessary to overcome prevalent risks.• Prevalent risks extend the time to exit.• Exit options are limited.

Source: The authors.

frequently decide not to fund these due to the market and adoption risks and to issues regarding business models and reimbursement—factors that can affect both the price and cost components of the investment formula. Investors are also hesitant to commit resources because they perceive a low potential return on investment.

Market and Adoption Risks

When it comes to fundamentally changing the way health care is delivered, medtech innovators can expect to encounter some degree of resistance. Face-to-face interactions between providers and patients are a dominant standard of care; remote monitoring technologies dismantle this approach. Mark Blatt, director of global health care strategies in Intel’s Digital Health Group, explained how deeply current practices are entrenched in the medical establishment:

We have a practice model in health care that’s about 200 years old. Sir William Osler [who is widely regarded as the founder of modern medicine] would recognize it. If he came through the gates today, he would be surprised by the diagnostics and the therapeutics we use, but he would recognize the process. He designed it 200 years ago, and we still gallantly study it and teach it to our medical students, and ding them when they deviate from it.

While the greatest potential savings from remote monitoring come from moving down and to the left on the graph in Figure 2, the adoption hurdles are likely to climb even higher for technologies that seek to change the traditional care setting and physician-patient interface. Ratan, the executive at Robert Bosch Healthcare, described the situation this way:

We’re talking about virtualizing the health care delivery system, which is not inconsequential. On the Stanford campus, for example, you’ve probably got at least \$2 billion dollars worth of fixed investment

for Stanford hospitals. So if you go to the Stanford hospitals and say, “We’d like to move you from a model of institutionally based care to one that’s more community-based,” some of the people there would be supportive. But others would say, “Wait, what about the billions of dollars I have invested in beds and equipment?”

Before health care providers and public and private insurers will agree to significantly alter the established care paradigm and/or shift the venue of care to accommodate an innovation, they demand substantial clinical data, which drives up the product’s cost. “If you don’t have clinical evidence, nobody’s going to buy your product,” said Manicka, the Corventis CEO. “They’re not just going to take your word for it.” As a result, many remote monitoring companies have been forced to launch clinical trials and demonstration projects that involve studying hundreds or even thousands of patients over multiple years. Goldberg, at Mohr Davidow Ventures, said: “This resistance creates a very high burden of proof for the technology developer, which means that the company has to spend enormous amounts of money developing the clinical evidence to persuade clinicians that a new standard of care is appropriate.” From an investor’s perspective, he added, “It’s discouraging when you have to spend so much capital to get the flywheel going in terms of adoption and market growth.” Jain concurred: “The time and money that’s required to establish the efficacy of these solutions is starting to test the boundaries of what venture capitalists can do.”

Large corporations are potentially better positioned to commit the funding necessary to conduct these extensive demonstrations. Interestingly, high-tech companies such as Intel and Cisco Systems have been most active in the telehealth field so far.

“The cost of the current health care system is unsustainable,” Intel’s Blatt explained. “The world

can no longer afford health care as it is, which is creating an unprecedented opportunity for change. [Information technology] can automate and lower cost and improve quality as it has in every other industry. It’s this unprecedented opportunity that’s driving big technology companies to get involved.”

With other sources of revenue from a diverse product portfolio, corporations can commit the long-term capital necessary to gather the clinical data to convince providers and payers that a change is warranted. As Ratan put it:

What this industry needs are the deep-pocketed corporations with a long-term planning horizon to come in and say, “This technology is transformational. We can do a lot of really good things for people and we can make a lot of money doing it eventually, but we understand it may not be tomorrow. We also understand that it may require significant amounts of incremental investment.”

Another issue that can hinder the adoption of remote monitoring solutions and drive up cost is that they encompass both a product and a service. The systems reduce demands on physician time but also require that other staff review and interpret the collected data and, if necessary, refer patients back to the physicians. “There’s a technical backbone to it,” noted Jain, “but these can be very service-oriented solutions. When it comes to building a large service capability, this can get beyond the means of what venture capitalists can afford to fund.”

One option for remote monitoring companies is to focus on building the technology, then have providers develop and manage the service component. While this approach may make the innovation more appealing to investors, given that it requires less capital, it could create another adoption hurdle: providers who may not want to build or expand their own service infrastructure.

Liability and physician incentives are other concerns. As Jain said: “In some cases, physicians don’t want access to 24-hour, real-time monitoring. It exposes them to uncompensated liabilities. At times, they are not paid for monitoring these patients—individual physician incentives don’t line up with these technologies. I think that’s one of the biggest issues to getting them into the marketplace.”

Business Models and Reimbursement Challenges

An even greater challenge for innovators is proving to investors they have a sound business model that will support a reasonable price for the product. Numerous high-value remote monitoring technologies have been developed and brought to market, but few have demonstrated they can make money in the current health care system.

Without exception, the biggest obstacle to making money in remote monitoring is reimbursement. As previously noted, technologies that can utilize existing codes for reimbursement purposes have an immediate advantage. An example is the low-cost, ambulatory, cardiac-rhythm monitoring device and analysis system from iRhythm that attracted venture funding partly for this reason. But in most cases, new remote monitoring technologies do not qualify for use of existing codes. More importantly, they can be fundamentally at odds with the established reimbursement system.

“The bottom line is that we’re trying to apply these technologies to a health care system and reimbursement models that were never set up to include them,” said Thomas Nesbitt, associate vice chancellor for strategic technologies and alliances at the University of California-Davis. “Providers get paid when patients come in for episodic visits, but this is meaningless for companies trying to set

up continuous physiologic monitoring systems to improve chronic disease management.”

Under the current reimbursement model, physicians and hospitals are rewarded for providing acute care to patients, not necessarily for keeping them healthy over the long term. As an article in *Time* explained:

A major problem with American health care today is what policy experts call “perverse incentives.” Doctors and hospitals bill insurers for every individual service—every office visit, MRI or hour of operating-room time—a “fee-for-service” model that drives health-care inflation by rewarding providers who order potentially unnecessary tests, perform potentially unnecessary surgeries and even make mistakes. A hospital readmission caused by avoidable complications just means more billable expenses.¹⁵

Incentives for providing care remotely—for example, to keep patients out of the hospital—largely do not exist. However, the Centers for Medicare & Medicaid Services is considering reimbursement penalties for certain hospital readmissions within 30 days of discharge of patients who have particular medical conditions. These pending changes could present an opportunity for remote monitoring technologies to demonstrate value and take hold.

Moreover, the way health care is reimbursed under fee-for-service tends to promote a short-term, transactional view of patient care among providers. It creates a focus on reactively treating problems as they arise rather than proactively managing patient health over the long term. This view can be even more pronounced in the safety-net environment, where decision-making and spending are tightly constrained by annual budget cycles. Uday N. Kumar, iRhythm’s founder and chief medical officer, elaborated:

Sometimes it is difficult for people who are in charge of resource-constrained environments to think about long-term perspectives regarding costs, since they are required to focus on the short-term annual budget they are given to work with every year. This means that focusing on and understanding how to model short-term costs of new technologies versus the long-term indirect costs of not implementing a new technology or providing a new service for a patient is often not prioritized and/or considered to the degree that it should. But it would make sense to be more proactive in these environments if the short-term solution is low-cost enough and the long-term outcome of inaction is expensive enough.

The growth of integrated health care delivery systems is helping to combat this short-term focus, to some extent. They bring together the health insurer, physician group, and hospital(s) to provide “a full continuum of services.”¹⁶ Because these “closed” systems are responsible for the end-to-end care of members, there is a greater focus on prevention and the cost of treatment over patients’ lifetime. Kaiser Permanente and the U.S. Department of Veterans Affairs (VA) are two of the largest, most well-known examples of integrated health care delivery systems in the United States. The same reimbursement rules apply to them, but their long-term view of patients creates other incentives for managing costs and perhaps investing in new technologies. Blatt said that when he markets remote monitoring devices or tries to launch demonstration studies on behalf of Intel, “I have a much easier time talking to the VA or Kaiser where they have a closed-loop health care system.” The same is true in other countries where health care has been nationalized.

Nevertheless, without reimbursement to help cover the cost, integrated health care delivery systems demand a strong business case for new technologies

they adopt. They also can be difficult to penetrate because established and aspiring companies looking to break into new markets bring thousands of new technologies to them every year.

In the absence of any meaningful reimbursement reform, some innovators believe that consumers might be willing to pay out-of-pocket for remote monitoring and other telehealth devices. Blatt shared this scenario as an example:

If everything stays the same—health care costs continue to skyrocket, Medicare cuts go through—the biggest customer for Intel’s remote monitoring product is going to be me, the guilty son, the baby boomer who wants to take care of his elderly parent but can’t be there in person. So I’m going to buy the Intel Health Guide [a remote health management solution] and put it in my mother’s home. I’ll pay for the cost so that she can be monitored and cared for at home and so she doesn’t have to end up in hospitals that will bankrupt her.

Although this model of care seems logical, there is a great deal of uncertainty about accessing consumer markets and getting individuals to pay out-of-pocket for medical goods and services. Fundamentally, because consumers are used to having health insurers pay for all or at least part of such expenses, motivating this kind of behavior change is not easy. And it can be expensive: consider, for example, the billions of dollars that pharmaceutical companies spend every year on direct-to-consumer advertising.

“A lot of times you’ll see venture guys shying away from consumer markets,” Jain said. “In a consumer-driven market, you can sink \$100 million into commercialization efforts to get \$5 million worth of revenue, and vice versa. It’s a risk that most medical device investors find difficult to get their arms around. There’s typically more predictability

in physician-driven markets with focused commercialization efforts.”

Public and private health plans show more immediate promise as potential customers for some remote monitoring companies. Because they pay for all medical care over members’ lifetime, health plans have a long-term perspective and a direct incentive to provide comparable or better care at lower cost. Some companies try selling to health plans using the traditional value proposition: their product will reduce overall costs. But others are experimenting with more innovative approaches.

For instance, Sweeney, the chairman and CEO of PatientSafe Solutions, is investigating the prospect of having payers give performance-based loans to providers that would enable them to adopt the company’s technology—tools to help improve workflow efficiency and patient safety at the point of care. “The health plans would loan an institution X number of dollars to fund a program like ours,” he explained. “And when those institutions are able to show reduced length of stay and other financial benefits to the health plans, then the health plans would forgive the loans.” As this example illustrates, the key to defining any new business model is ensuring that customers who pay for a new technology directly reap its benefits.

Nevertheless, as Goldberg pointed out, VCs “may ultimately look to nontraditional business models, but that’s only after we exhaust the traditional ones.”

Return on Investment

In evaluating the potential return on remote monitoring innovations, investors cite several common problems closely linked to the above issues. First, the realistic size of the targeted market may not align with the amount of capital necessary to overcome market adoption risks, conduct large-scale demonstration studies, and/or build a service

capability to support the technology. Second, these factors extend the time to profitability and therefore can delay the exit for investors. Third, there are limited exit options for companies in this space; few successful initial public offerings have been completed, which leaves corporate acquisition as the primary exit strategy. However, corporations such as Intel and Cisco Systems have their own remote monitoring competencies, so it is uncertain to what extent they will rely on acquisition to fuel their growth. Finally, without a clear model for making money or a pathway to reimbursement, the fundamental business opportunity is risky. According to the investment formula, more risk requires higher returns, which many innovations have been unable to deliver.

The safety net could reap meaningful benefits from remote monitoring technologies, but without some sort of disruption to the prevalent funding models in the health care field, such innovations may never reach the safety net in a timely or significant manner.

Case Studies

See Section IX (starting on page 22) for examples of the challenges that four remote monitoring companies faced in attracting investment capital.

VII. Strategies for Further Exploration

IF ONE ACCEPTS THE PREMISE THAT NEW technologies with high social value could benefit the safety net, how can foundations and other social investors help? There are at least three key strategies for further exploration, all of which seek to realign price, cost, and margins in the safety net to make investment opportunities more favorable.

One is for them to drive down costs through financial support for worthwhile projects in the early stages of development to reduce the mounting expenses that companies bear in addressing market and adoption risks through clinical trials. Another is targeted grant-making by foundations and other social investors to minimize safety net-specific risks, which would help overcome factors that discourage investment in innovations of potential benefit to this sector. The third is for foundations and other social investors to create social venture funds that would supplement traditional funding models, enabling technologies with high social value to reach a point where they are attractive to traditional venture investors.

Driving Down Investment Costs

After identifying the most promising technologies that have high social value, foundations and other social investors could help innovations succeed by underwriting or facilitating compelling pilot studies or even clinical trials, complete with control arms and publishable results. This would ease the burden of clinical proof on companies and their prospective investors, and directly reduce the cost of bringing promising innovations to market. However, to get good value for their funding dollars and increase the likelihood that a new technology will take hold

within and beyond the safety net, foundations must think strategically about what to test, how to test it, and what data should be generated. They must also make funding contingent upon a well-developed and viable commercialization plan. Finally, requiring a rigorous economic evaluation of the technology would strengthen its appeal.

Minimizing Safety Net Risks

One of the most prevalent operational risks in the safety net is patient compliance. Perceptions persist that safety-net patients are less likely than others to comply with the care regimens—including the use of technology—prescribed by their providers. Foundations and other social investors can help mitigate such risks through the pilot studies they fund. Rigorous studies with results that stand up to peer review may be able to demonstrate that underserved populations are no less compliant than other market segments. If a particular population continues to have compliance difficulties, social investors might support innovations that minimize patient noncompliance issues—for example, by shifting the burden of treatment or testing from the patient to the provider and/or making patient requirements more fail-safe.

In parallel, social investors can help mitigate reimbursement-related risks by urging the Centers for Medicare & Medicaid Services and federal lawmakers to realign incentives in the current reimbursement system to support the use of technologies that reduce costs, improve care, and increase access, even if this means shifting the venue and/or disrupting the traditional model of care.

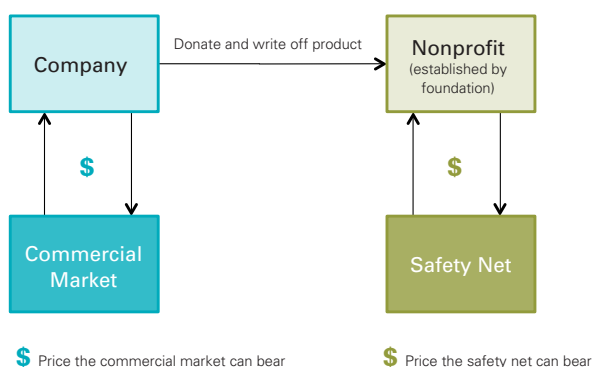
A Role for Differential Pricing?

If an important new technology could potentially cross over to a sizable commercial market, differential pricing might stimulate the process. For example, if an innovation would cost \$200 in a commercial market but data indicate that the safety net can only bear \$100, new funding mechanisms could make up the difference while costs are reduced or other funding streams are established. The differential or subsidized pricing arrangement would help the company attract investment and compile a track record of compelling results it could later use to springboard into the commercial market. Success in this market might then provide adequate volume to enable the company to sustain operations over the long term and allow for technology and services to be offered to safety-net customers at reduced cost.

Some companies have their own charitable care policies. iRhythm, for example, has considered implementing a program in which hospitals, such as San Francisco General, that serve many underserved patients could write off charges for patients who cannot pay for the technology. The goal would be to give all patients equal access to the technology, but this could also increase utilization of iRhythm's devices. If foundations and other social investors initiate and/or participate in similar programs, their efforts could significantly expand the number of technologies available to deserving individuals unable to pay for them.

In some cases, a hybrid model may make sense. Initially, a social investor might provide subsidies to establish a beachhead in the safety net and stimulate commercial sales of a company's product. Once the company has gained traction in the commercial market, it could set up a nonprofit entity, then donate its products to that entity and take a tax write-off; the nonprofit would sell those products to safety-net providers at a price they could afford (Figure 3).

Figure 3. A Nonprofit Model for Differential Pricing



Source: The authors.

Incentives for “closed” safety-net providers, such as managed care organizations and those receiving capitated payments, to adopt innovations may be adequate as long as sizable, long-term capital investments are unnecessary. However, direct reimbursement would certainly strengthen their motivation. It would also make the technologies more appealing to safety-net providers who still serve fee-for-service Medicaid patients.

Furthermore, creating incentives that encourage fee-for-service providers outside the safety net to adopt the technologies would increase their cross-over potential. This is important because subsidized

business models are rarely sustainable, which gives foundations and other social investors a vested interest in seeing that technologies that have a beachhead in the safety net cross over to commercial markets.

Augmenting Traditional Investment Models

At an even a higher level, foundations and other social investors can disrupt traditional funding models for health care innovations by creating social venture funds. The purpose of these funds would be to help technologies with high social value reach

a point at which they are attractive to traditional investors.

Ideally, venture investors would participate early on by helping to identify important criteria for selecting social investment projects. These criteria might include the magnitude of effect a technology could have on the safety net and the likelihood of attracting downstream investment from traditional investors after specific risks have been mitigated or retired.

VCs would be motivated to contribute to such a model because they would not bear an up-front risk yet gain an additional avenue for sourcing high-quality deals. As costs continue to escalate throughout the health care system, cost-reducing technologies have become increasingly important in all market segments, and this model would expose VCs early on to relevant innovations. Moreover, because the recently enacted Accountable Care Act, or health care reform law, is expected to make another 20 million Americans eligible for Medicaid by 2014, VCs would have an inside track on products targeted to this growing population.¹⁷

To take advantage of such opportunities, foundations and other social investors focused on the domestic health care market would have to build new capabilities for effectively establishing funds, selecting investments, and advising companies about how to eliminate the risks of early-stage market failure. The housing and community development fields, where social investing has a long history, provide strong examples. If successfully executed in the health care arena, the impact of this work could be far-reaching.

“Financial Aid” for Providers

A risk for safety-net providers is that they often cannot afford technologies that may save them money in the long run. Foundations and other social investors could offer “financial aid” to compensate companies for the difference between the price large commercial markets can pay and what safety-net providers can afford. In addition to traditional grants, financing mechanisms such as low-interest loans or “share of savings” models might be used to align incentives and promote program sustainability.

VIII. Conclusion

INNOVATIONS IN HEALTH CARE — AND THE investment capital that fuels them— have delivered important advances in medical technologies and services. Unfortunately, there have been few incentives for innovators to develop care paradigms that reduce costs for underserved populations. This gap exists primarily because the technologies and business models that enable lower-cost care are not rewarded in the current reimbursement system. Moreover, traditional investors believe these opportunities will generate suboptimal returns.

However, in an era when nearly all health care stakeholders believe that gaining better control of rising health care costs is crucial, there is growing interest in innovations that enable more efficient and cost-effective care. Traditional investors appear more open to funding such projects, as long as they can generate adequate financial returns. Foundations and other social investors can play an important role in this movement by identifying opportunities to work alongside or in partnership with traditional investors to provide flexible, long-term capital in areas where the risks of innovation have previously created gaps in funding for bold, potentially market-transforming ideas.

IX. Case Studies

THE FOLLOWING CASE STUDIES EXAMINE THE experiences of four remote monitoring companies, evaluate the funding challenges they encountered, and reflect on their results to date. Although none of these companies have technologies designed specifically for the safety net, this market segment could potentially reap substantial benefits from their offerings.

HEALTH HERO NETWORK, PALO ALTO, CA
www.healthbuddy.com

At the time Health Hero Network was established in 1998, its primary product was the Health Buddy System for monitoring and improving the health of high-risk, high-cost patients—primarily the elderly and disabled—with one or more chronic conditions. The system comprised monitoring technologies, clinical information databases, Internet-enabled decision-support tools, health management programs, and content development software tools.¹⁸ The patient interface was simple: a four-button device with a screen that each day led patients through interactive sessions of 6 to 10 questions customized for the individual’s condition. Primary care physicians and specialists prescribed Health Buddy to (1) teach patients how to better understand their conditions, (2) help them change their behavior, (3) enable the early detection of health risks before they escalated to acute crises and/or hospital admissions, and (4) provide reassurance to patients that their health was being monitored.¹⁹ Health Hero Network supplied the technology and training for users; the health care provider set up the basic infrastructure for receiving, interpreting, and acting upon data transmitted from patients’ homes.

This entailed hiring roughly one “care manager” for every 125 to 150 patients using the Health Buddy system.

After Health Hero Network developed the technology, it conducted a series of demonstration studies to prove the system’s value. A small early study with the health plan PacifiCare showed a 50 percent reduction in hospital readmissions for heart failure patients who used Health Buddy, according to Suneel Ratan, a marketing, reimbursement, and government relations executive at Robert Bosch Healthcare, which ultimately acquired Health Hero Network. However, “PacifiCare didn’t go with us,” Ratan said. “They wanted a provider who could do all the disease management services, not just the technology. So they decided to outsource it.”

Shortly thereafter, in 2000, Health Hero Network launched a pilot with the Veterans Affairs (VA) in Florida. This study of 900 patients found a 63 percent reduction in hospital readmissions and an 88 percent decline in nursing home days.²⁰ The VA “liked the results,” Ratan said, “so in 2003, 2004, they decided to make the program national, and we got the first national contract.” The agency agreed to directly fund the purchase and use of Health Buddy technology and related services.

Health Hero Network then approached the Centers for Medicare & Medicaid Services (CMS) about securing reimbursement for its product. “The largest and most expensive group of patients we can go after globally are the folks on Medicare,” Ratan explained. “We had a desire to prove that health care management interventions with the Health Buddy would generate a similar result in a fee-for-service system.” The company submitted a proposal

to CMS and got approval to launch a three-year demonstration study in 2006, the results of which have not been officially released.

Robert Bosch Healthcare acquired Health Hero Network in late 2007, when more than 20,000 people with chronic conditions were using Health Buddy.²¹ (The company’s annual sales were not disclosed.) The total known investment in Health Hero Network was \$72.44 million.²² Bosch acquired the company for \$116.1 million,²³ which yielded a roughly 1.5x investment multiple at the time of the sale. Organizations that participated in Health Hero Network’s second round of funding on January 7, 2000, received a 3.1 percent internal rate of return on their investments (Table 2).

Reflecting on Health Hero Network’s funding experience, Ratan said: “A lot of time and money went into this company prior to its acquisition ... and, at the end, everyone realized it was going to take even more time and money.” In other words,

the cost of making and selling the product was high relative to the size of the market at that time. Lack of reimbursement for the product also affected potential customers’ willingness to pay for Health Buddy. Adoption was relatively slow and limited primarily to integrated health care providers, like the VA, that could benefit from the longer-term, system-level savings associated with improvements such as fewer hospital admissions. Ratan elaborated:

The U.S. Department of Health and Human Services estimates that roughly 75 percent of the nation’s health care burden is managing chronic disease. The premise of the Health Buddy system is chronic care. It’s continuous, supportive, and designed to build an individual’s capability to take better care of himself. But the health care system is engineered for acute care—the incentives are structured largely to wait until someone’s in crisis. So the incentives and infrastructure necessary to do

Table 2. Investor Funding for Health Hero Network

ROUND	DATE	KNOWN AMOUNTS RAISED	INVESTORS
1	October 1, 1998	\$18M	Oracle Strategic Partners, Psilos Group Ventures
2	January 7, 2000	\$29M	Oracle Strategic Partners, Psilos Group Ventures, Graham Partners Investments, J.P. Morgan Partners, Merlin Fund, Carousel Capital Partners, InvestCare Partners, Advent Capital, undisclosed funds
3	June 30, 2000	Not available	Advent International Corporation, undisclosed funds
4	March 1, 2006	\$9.44M	Oracle Strategic Partners, Psilos Group Ventures, Draupnir
5	August 24, 2006	\$2.065M	Oracle Strategic Partners, Psilos Group Ventures, Draupnir
6	November 16, 2006	\$13.935M	Oracle Strategic Partners, Psilos Group Ventures, California Technology Ventures, Shoreline Venture Partners, Boston Scientific Corporation, undisclosed funds
Total		\$72.44M	

Internal rate of return to round 2 investors = 3.1%

Source: Statistics & Data Corporation, March 17, 2010.

this kind of proactive health management of people outside an environment like the VA, they just don't exist.

Unofficial results from the three-year CMS pilot were “jaw-dropping,” according to Ratan, and the Health Buddy demonstration project was extended in 2009. Nevertheless, CMS has not yet decided whether to grant reimbursement for the technology and the intervention it supports. One potential issue: the success of Health Buddy’s technology depends on patient compliance.

ALERE MEDICAL, ATLANTA, GA

www.alere.com

Alere Medical, founded in 1996, entered the remote monitoring field by focusing on heart failure patients. It developed a technology for home use that could collect biometric and symptomatic information and exchange it with caregivers. Patients initiated the process twice a day by standing on the DayLink monitor, otherwise known as the “Talking Scale” because it also asked patients a series of simple questions about their health and took their weight and other measurements. Data were automatically transmitted by phone—and, later, via the Internet—to specially trained cardiac nurses. However, unlike the Health Hero Network solution, these nurses were part of the “Alere Network,” a collection of call centers the company staffed and managed by way of providing end-to-end disease management services (not just monitoring technology) to customers. Alere employees analyzed trends in patient data that could reveal a change in patients’ health status, then initiated interventions and/or notified their physicians as appropriate.²⁴ Over time, Alere expanded its disease management services to include conditions such as chronic

obstructive pulmonary disease, asthma, coronary artery disease, and diabetes.

Alere chose not to seek traditional reimbursement for its products. Instead, the company built its customer base by aggressively pursuing contracts with health insurance plans that sought cost savings and improved outcomes through their own disease management programs. It landed several large contracts to take over disease management programs in certain specialties, including a 2005 deal with PacifiCare. In 2006, Alere secured expanded long-term contracts with Health Net’s Medicare Advantage health plan members in Arizona and with Blue Shield’s Medicare Advantage members in California.²⁵ In all, Alere covered more than 20 million commercially insured and 2 million Medicare insured patients in 2007 and had 84,000 active enrollees.²⁶ Its revenue grew from \$16.6 million in 2003 to \$61.7 million in 2006.²⁷

By 2007, the company had a reasonable track record and had retired a significant amount of the risk associated with its offerings. Customer adoption of its technology showed that the price was workable and that the targeted market was willing to pay. Alere had also demonstrated that the cost of proving and delivering the technology and services was manageable. Based on these results, TA Associates, a private equity firm, partnered with Alere managers to buy out the company in April 2007 for \$175 million.²⁸ Total known venture investment in the company up to that point was \$42.7 million and Alere had taken on \$11.4 million in debt.²⁹ This yielded an investment multiple of 3.2x at the time of the sale.

One possible reason for the buyout was that Alere needed additional funding, but venture investors were unable or unwilling to commit more capital. The management team may have then turned to private equity funding as an alternative way to meet

the company's financing needs. Interestingly, just six months later, in October 2007, Inverness Medical Innovations announced that it would acquire Alere for \$302 million.³⁰ The sale closed in early 2008, resulting in a 1.73x return to TA Associates in less than a year.³¹

BEWELL MOBILE, SAN FRANCISCO, CA
www.bewellmobile.com

BeWell Mobile, founded in 2004, also sought to improve the outcomes of patients with chronic diseases. Its primary solution was a cell phone-based product that regularly collected biometric, symptomatic, environmental, and behavioral data from patients for monitoring by their caregivers, and provided coaching and feedback. The company generally deployed care management applications via common consumer network devices, including interactive voice response, the Web, and/or cell phones.

“What we've found is that when patients have access to each of these various modes, they use the cell phone-based applications 5.5 times to 1,” said Gregory Seiler, BeWell Mobile's vice president and general manager.

BeWell Mobile believed that its solution would have an advantage over competing products, such as Health Buddy, because of people's preference for, and the high penetration of, mobile phones. However, the two companies seemed to be addressing different segments of the same general market. In Seiler's view, Health Buddy was a fixed, hardware-dependent tool that primarily targeted seriously at-risk individuals who had chronic conditions and were often identified after an acute care crisis. He explained:

We see that as a potential target market for us, too, but our solution is fundamentally designed to cost-effectively serve the majority of individuals with chronic conditions, at each stage of their lives, who

tend to be more mobile. And what that means to me is that this person gets up in the morning, goes to school or an office, travels to see relatives, goes on vacations, and does a variety of other things where care needs to be delivered somewhere aside from the bedside table. So we see our applications as being much more expansive and accessible to the majority of the individuals out there who are diagnosed with chronic conditions.

The remote monitoring solution was delivered via BeWell Mobile's specialized software for consumer-provided network devices, including cell phones; caregivers had to provide case management. “[Alere] provides case management through their call centers,” Seiler said. “Bosch, on the other hand, relies on clinicians or disease management companies for case management. We have deployed in a manner that is much more like Bosch than Alere.”

Seiler said his company's primary customers were “organizations that are financially at-risk or disease management companies”—mostly insurance plans and other payers, including self-insured employers. BeWell Mobile charged for its software on either a per-member, per-month or per-participant, per month basis. “Most insurance carriers already have case managers or disease management organizations under contract that are being compensated by the insurance carriers to lower the overall cost and improve quality of care for a particular population,” he said. “We simply change the cost structure and effectiveness of their workflow.... We improve their utilization management.”

An early challenge for a young company like BeWell Mobile was figuring out how to penetrate this customer segment, particularly in light of the proliferation of new technologies seeking to address similar needs. BeWell Mobile had contemplated marketing directly to physicians and other providers.

But, according to Seiler, that model did not make sense, at least not yet:

The reason we don't market to individual physicians is that they currently lack a mechanism for reimbursement for telehealth solutions and rarely have economic incentives to improve the health outcomes of their patient population. Without the hope of reimbursement or some other form of offsetting economic incentive, it would be like asking physicians to pay for their patients' prescription medication just because it will improve the health of the patients. Without compensation, physicians would spend unreimbursed time they could be devoting to revenue-generating office visits or procedures, thereby earning less money in the same amount of time by using our system today. By focusing on payers, we work to remove financial barriers for clinicians who choose to coordinate care with their patients using BeWell Mobile care management applications. This helps align benefit across payers, clinicians, and patients.

A pilot study with the San Mateo County Medical Center underscored this point. In the study, funded by the California Healthcare Foundation, BeWell Mobile provided cell phones containing its customized disease management software to urban, uninsured youth who had severe, persistent asthma. Over eight months, 50 bilingual teens and adolescents recorded their symptoms on the phones at least once a day by answering 20 physician-authorized questions. Monitoring, real-time feedback, reminders, and other interventions caused patients' drug compliance to more than double, to 85 percent from 40 percent. Their need for rescue medications dropped by 53 percent. Emergency room visits also decreased: in the entire study population, there were just five unscheduled physician or ER visits for asthma-related conditions,

compared with three to five unscheduled visits per year by typical youth who have chronic asthma. Finally, participants in the study missed an average of 0.38 school days per year due to asthma-related complications, versus an average of 3.7 days in comparable, nonstudy populations.³²

Despite these encouraging results, said Seiler, "The issue is that it requires clinician time to review the records and make sure things are going appropriately. CMS doesn't have a line item for billing for a service like this so the doctors can get reimbursed for a clinic visit. But if they're keeping patients out of the clinic, they're not going to get paid." In effect, Medicaid accrued the benefits of keeping these patients healthier and reducing the overall cost of their care, while the physicians or San Mateo County Medical Center did the work but did not share any of the benefits.

In addition to this challenge, Seiler noted, "The pilot was not defined by the sponsor in a way to have a scientific paper written. Even though the results are so significant, without peer-reviewed, published results, it is more challenging to motivate career administrators and bureaucrats to change policies."

Scientific evidence makes it easier to convince health plans and other potential customers to adopt—or at least try—a technology. Scientists with a track record of publishing in medical journals and serving as principal investigators in university research studies funded by the National Institutes of Health participated in the project, but the necessary steps for more formal publication of the results were not documented before the study began. The most valuable pilot studies, Seiler said, are structured and funded in a way that would more directly support a market development pathway. In BeWell Mobile's case, an effective pilot would have included publishable results, an economic evaluation of the

technology, and a realistic chance for the technology to be adopted by the types of users who tested it.

Seiler said that as of mid-2010, BeWell Mobile had raised “in excess of \$5 million” through customer contracts and personal investments made by the management team. To date, the company has not taken any venture funding. “Our experience with venture investors has been more at the investigative level—seeing what our options are and what the climate is,” he said. “We’ve gone out and talked to some venture investors at different stages, but we made a strategic decision to pursue other alternatives.”

Instead, the company has focused on expanding its customer contracts. “It would be at least as much or more work to secure venture investment as it would be to secure recurring revenues from customers,” said Seiler. “And customer contracts are required by venture investors anyway, so we simply focused on customers to begin with.”

BeWell Mobile’s goal is to secure one or more major customer contracts, thereby demonstrating that it can align the price and cost of its product to realize an attractive profit margin and market scale. “We looked at the case study of Alere and how they grew,” Seiler said. “After they landed PacificCare as their first big customer, venture investors jumped in and invested. Our focus on customers continues to serve our long-term objectives very well.”

VISICU, BALTIMORE, MD
www.healthcare.philips.com

Although it operates in another area of the remote monitoring field, VISICU’s story is also instructive. It was founded in 1998 by two intensivists—doctors specially trained to care for critically ill patients, typically in an intensive care unit (ICU). Recognizing the growing shortage of intensivists, they set out to develop a solution to make high-quality intensive

care available to everyone.³³ The result was *eICU*, a care model that used a centralized team of intensivists and ICU nurses, along with remote monitoring tools, to enable small or under-resourced hospitals to have ICU beds without the need to maintain a complete ICU infrastructure on site. According to company materials, the team “works in concert with onsite ICU clinicians. The *eICU* facility does not house patients or replace the hospital ICU. It operates like an air traffic control center staffed 24/7 with experienced specialty physicians and seasoned critical care nurses who are networked to multiple ICU patients across a health system by voice, video, and data.”³⁴ Specialized work-flow and decision-support software enables the *eICU* team and physicians at the bedside to optimize patient care and thus reduce mortality and improve efficiency—for example, by reducing length of stay and streamlining the use of ancillary services.

ICU services are billed to Medicare, Medicaid, and private insurers using diagnosis-related group codes. When a hospital contracts with VISICU, its standard billing methods and reimbursement levels do not change. However, because services can be delivered more cost-effectively with the help of *eICU*, the hospital can improve its margins. Importantly, hospitals directly accrue the benefits of their investment in the VISICU solution. It also enables rural hospitals, other low-resource environments, and institutions that lack an ICU or experienced intensivists to effectively serve their patients and retain the admission-related revenue, instead of transferring patients to other facilities.

VISICU reached profitability in 2005, earning \$10 million in profits on \$18 million in revenues that year.³⁵ Soon after, in April 2006, it executed an initial public offering, raising an additional \$96 million and realizing a post-money valuation of \$557.73 million.³⁶ Previously, VISICU had raised

\$25.34 million through three rounds of financing (Table 3). The internal rate of return to investors at the time of the initial public offering ranged from 47.5 percent to 100 percent and the investment multiple was 14.4x to 20.3x.³⁷

Part of VISICU’s success may be attributable to good timing. The company completed its initial public offering near the height of the market, realizing a valuation of more than 25x revenue. (In April 2006, the company had revenues of \$21.5 million and earnings of less than \$1 million before interest, tax, depreciation, and amortization.)³⁸ Other factors that contributed to a successful exit for investors included:

Cash flow visibility. Customers paid license and implementation fees soon after the *eICU* program was implemented and made support-service payments throughout the term of the three-year service agreement. These long-term contracts enabled forecasting as well as cash flow visibility;

A well-defined market need. The shortage of intensivists at the time was severe—there were only

enough to cover one-fourth of ICU beds.³⁹ Hospitals had to resolve this growing problem regardless of what reimbursement incentives were in place;

A clearly visible value proposition. One intensivist could typically monitor 10 to 12 hospital patients. With *eICU*, one intensivist and two ICU nurses making virtual rounds could effectively monitor up to 100 ICU beds.⁴⁰ Additionally, studies showed that increased, intensivist-directed ICU care reduced hospital mortality by roughly 30 percent.⁴¹ In a VISICU study of one customer, the *eICU* program led to a 27 percent reduction in mortality, a 16 percent reduction in length of stay, a 25 percent decline in average cost per case, and a 56 percent increase in per-case profitability.⁴² Such results made it easy for customers to understand the benefits of *eICU* and justify their investment in it;

Patient compliance not an issue. *eICU* keeps compliance in physicians’ rather than patients’ hands, contributing to the solution’s effectiveness; and

Fast growth. The first *eICU* program was implemented in June 2000, just two years after

Table 3. Funding for VISICU

ROUND	DATE	KNOWN AMOUNTS RAISED	INVESTORS	INTERNAL RATE OF RETURN AT IPO	INVESTMENT MULTIPLE AT IPO
1	June 30, 1998	\$3.50M	Cardinal Health Partners, The Abell Foundation	47.5%	20.3x
2	May 31, 2000	\$15.00M	Cardinal Health Partners, The Abell Foundation, Envest Private Equity, HLM Management, Pacific Life Insurance, Pacific Venture Group, Partech International, Sterling Venture Partners	63.2%	14.8x
3	January 14, 2002	\$6.84M	Cardinal Health Partners, The Abell Foundation, Envest Private Equity, Pacific Venture Group, Partech International, Sterling Venture Partners	100%	14.4x
Total Before IPO		\$25.34M			

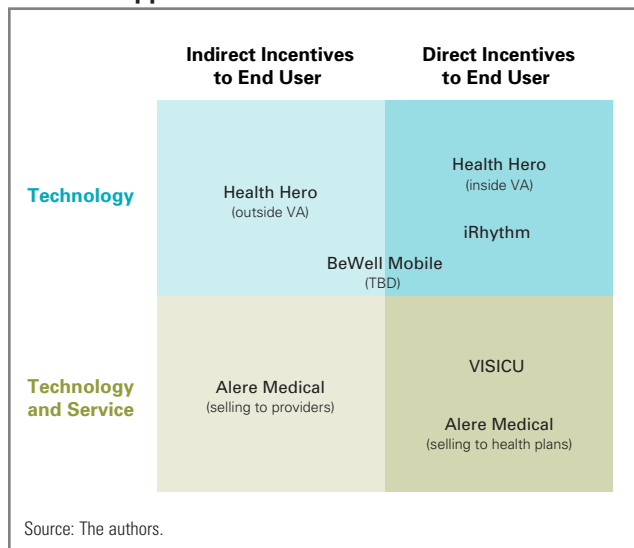
Source: VISICU company profile. VentureSource, February 2008.

the company's inception. Subsequently, VISICU grew rapidly—from six ICUs in December 2003 to 27 activated ICUs in December 2005, despite a seven- to nine-month implementation time for new customers.⁴³

VISICU secured venture funding and achieved a solid IPO because it cleared traditional investment hurdles with a price and cost structure for its offering that supported a desirable return.

Figure 4, derived from the four case studies above, illustrates that remote monitoring technologies are most likely to be adopted if the end user—namely, the purchaser—is the entity that directly accrues a technology's benefits.

Figure 4. Assessment of Remote Monitoring Opportunities



Appendix A: Glossary

Access. A patient's ability to get necessary medical care and services.

Beneficiary. A person who has health insurance through a particular program and receives services from health care providers covered by that program.

Benefits. Money or services provided by an insurance policy. In a health plan, benefits are the health care provided to beneficiaries.

Capitation. A specified amount of money paid to a health plan or doctor to cover the cost of a health plan member's health care services for a certain length of time.

Covered benefit. A health service or item included in a health plan, and for which the plan partially or fully pays.

Covered charges. Services or benefits for which a health plan partially or fully pays.

Demonstrations. Projects and pilots that enable health plans and/or health care providers to test various or specific attributes, such as payment methodologies, types of preventive care, and new technologies. Demonstrations are used to evaluate the effects of various health care initiatives and the cost implications.

Eligibility. The process for determining if an individual is qualified for health care insurance coverage under a particular program. Each state determines eligibility for its Medicaid program.

Fee for service. Payments to health care providers from insurers based on each service rendered, rather than on a bundle of services.

Health maintenance organization. A type of managed care organization in which a group of doctors, hospitals, and other providers agree to care for eligible beneficiaries for a set amount of money each month.

Managed care organizations (MCOs). Health plans that provide health services on a prepayment basis. The prepayments are based on cost or risk, depending on the type of contract an MCO has with Medicaid. The term generally includes HMOs, preferred provider organizations, and point-of-service plans. Other organizations, such as federally qualified health centers, integrated delivery systems, and public health clinics, may set up managed care programs to participate in Medicaid managed care.

Medicaid. A federally and state-funded health program for people with low income and limited resources. Medicaid programs vary among states, which administer them and set their own guidelines. To qualify, potential beneficiaries must meet a number of eligibility requirements.

Medicare. A federal health insurance program for people 65 years old or older, for certain younger people with disabilities, and for people with end-stage kidney disease.

Outpatient care. Health care that does not include an overnight hospital stay.

Payer. Any entity that assumes the risk of paying for health care. Payers include public and private health insurers, HMOs, self-insured employers, and uninsured patients who pay out of pocket.

Payment rate. The total reimbursement that a health care provider receives for delivering services to beneficiaries.

Pilots. See demonstrations.

Prospective payment system. A system for reimbursing health care providers for services rendered, based on predetermined, fixed amounts. Systems vary depending on the type of provider. Reimbursements under *inpatient prospective payment* are made on a per-diem or per-discharge basis, depending on the hospital's Medicaid contract. Reimbursements under *outpatient prospective payment* are generally based on the fee-for-service approach.

Provider. Any organization, institution, or individual that provides health care services to beneficiaries. Physicians, hospitals, ambulatory surgical centers, and outpatient clinics are common providers.

Safety net. Health care providers of health services more than half of whose patients are uninsured or covered by public insurance programs, such as Medicaid and/or Medicare.

Technology assessment. A multidisciplinary form of analysis in which the medical, social, ethical, and economic implications of the development, diffusion, and use of technologies are examined. Such assessments often focus on safety, efficacy, and cost effectiveness.

Telemedicine. Services remotely delivered by a health care professional to a patient through an interactive telecommunications system. Telemedicine also includes provider-to-provider consultations.

Source: "Glossary." Centers for Medicare and Medicaid Services, November 13, 2009 (www.cms.gov).

Appendix B: Advantages and Disadvantages of Various Funding Sources

	DESCRIPTION	ADVANTAGES	DISADVANTAGES
Friends and Family	Members of an innovator’s personal network who have adequate means to make an investment in the company.	<ul style="list-style-type: none"> • Least expensive funding source. • A flexible alternative for early-stage funding. 	<ul style="list-style-type: none"> • Funding typically comes with limited expertise that can benefit the young company. • May not understand the level of inherent risk. • May not be able to participate in subsequent rounds of funding.
Angels	Experienced investors who use their own wealth to invest in areas in which they have a personal interest.	<ul style="list-style-type: none"> • A moderately priced, early-stage funding source. • May be willing to take on considerable risk. • Typically exercise less control than VCs and corporate investors, but they may want a board position. • May be able to act more quickly than VCs. 	<ul style="list-style-type: none"> • May or may not have expertise that benefits the company. • May or may not be able to invest in subsequent rounds. • Angels’ increasing sophistication improves value-added but negatively affects terms and level of control from the company’s perspective. • Multiple angels may be necessary to meet funding needs; managing many individual investors can become complex.
Venture Capitalists	Professional investment managers who specialize in investing in companies with the potential for high returns. ⁴⁴	<ul style="list-style-type: none"> • Typically are sophisticated investors with valuable experience to share with innovators and young companies. • Can provide access to a vast network of contacts. • Often willing and able to take on considerable risk. • Able to participate in multiple rounds of funding. 	<ul style="list-style-type: none"> • May seek to exercise considerable control over the venture’s direction, management, and exit; almost always insist on a board position. • Often require a considerable share of ownership in exchange for investment. • Expect high returns and other terms that the company may not perceive as flexible or as favorable to it.
Corporate Investors	Representatives of large corporations who invest directly or may fund specific R&D efforts through development partnerships.	<ul style="list-style-type: none"> • Can lead to meaningful product/project synergies. • Can provide access to valuable resources (e.g., technologies, and sales and distribution channels). • May be less expensive than VC funding. • May add to young company’s credibility. • May give the company a “built-in” exit strategy. 	<ul style="list-style-type: none"> • Inventors and founders may: <ul style="list-style-type: none"> • Receive limited value in return for building the business. • Encounter conflicts as corporate investors look out for their own best interests. • Encounter issues related to ownership of intellectual property. • Follow-on funding may be put at risk by changes in a corporate investor’s financial position. • A corporate investor may complicate or limit the value of an exit strategy if it has the “right of first refusal.”

	DESCRIPTION	ADVANTAGES	DISADVANTAGES
Customers	End-users of a potential product who invest in its design and/ or development. Examples: physicians who invest in a new device that meets a need in their field, or a manufacturer that invests in a technology company working on an important new component.	<ul style="list-style-type: none"> • Usually one of the least expensive funding options. • May enhance a young company's credibility. • Can provide valuable market-based insights that are relevant to product development. 	<ul style="list-style-type: none"> • May lead to conflicts if the company seeks to sell its innovation to one of the customer's competitors. • Customer may seek to limit the ways in which the innovation is marketed, consistent with its own best interests.
Federal Government	Research grants from entities such as the U.S. Department of Defense, the National Science Foundation, and the National Institutes of Health.	<ul style="list-style-type: none"> • An inexpensive option that does not require the founders to relinquish any equity in the company. • Government does not influence any business decisions. • May strengthen a young company's credibility. 	<ul style="list-style-type: none"> • Grants are highly competitive. • High expectations regarding the rigorousness of research. • Funding review cycles can be lengthy. • Funding capped at less than \$1 million per project.
Banks	Institutions that provide financial services, including loans, to individuals and businesses.	<ul style="list-style-type: none"> • Access to funds generally does not require the company to share ownership. • Loans can be secured relatively quickly and used to help bridge short-term financing gaps. • The bank does not influence any business decisions. • Interest payments are tax deductible. 	<ul style="list-style-type: none"> • Business assets must be used as collateral. • Loans require positive cash flow, as the borrower must make regular payments on the principal and interest. • Start-ups pay a premium for loans due to the associated risk. • Start-ups may have difficulty getting loans if they lack revenue or any tradable assets. • Too much debt may affect a company's credit rating.

Source: Zenios, S., J. Makower, and P. Yock (Eds.). *Biodesign: The Process of Innovating Medical Technologies*. New York: Cambridge University Press, 2009.

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11. The FDA's 510(k) review process applies to devices of moderate risk that have some similarity to a technology already in use. In this process, devices are cleared for market if they can demonstrate "substantial equivalence" to (a) one or more devices marketed before the Medical Device Amendments Act took effect in 1976; (b) other devices cleared via 510(k) after 1976; or (c) devices exempt from U.S. regulation. The process has traditionally been faster, less expensive, and less risky than the premarket approval pathway, primarily because the requirements for clinical data are significantly lower. Premarket approval is necessary for all devices that pose a significant risk to patients and that must always be supported by clinical evidence demonstrating their safety and effectiveness.
12. The Centers for Medicare & Medicaid Services (CMS) maintains most reimbursement codes. A notable exception is the American Medical Association, which maintains Common Procedural Terminology (CPT) codes on behalf of CMS. CPT codes describe medical, surgical, and diagnostic procedures performed by health care providers, thus standardizing claims processing and data analysis.
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