PERSPECTIVE:
Health Care Consultant

Regulatory and Reimbursement Ripple Effects

Health care industry expert Randel Richner discusses the effect the Affordable Care Act could have on practices and device innovation, as well as the need for faster routes to approval and reimbursement in the United States.

Randel Richner is the Executive Vice President for Advanced Analytics at Intralign, a health care services firm specializing in intraoperative management solutions to help providers deliver the best possible care. She previously founded the Neocure Group after working for Boston Scientific Corporation as its Vice President of Global Government Affairs, Reimbursement, and Outcomes Planning, and she served as the first industry representative to the Executive Committee of the Medicare Coverage Advisory Committee. Intralign was formed in 2012, and Ms. Richner's Neocure Group joined the company soon after. The company is composed of health care entrepreneurs from various industry backgrounds who identify areas in which hospitals and physicians can improve efficiencies toward more effective and affordable outcomes.

How would you summarize the net effect of the Affordable Care Act (ACA) on vascular practices that treat patients who are primarily in the Medicare population?

The legislation is wide-ranging and will affect many disease areas, but changes in the ACA are largely directed toward high-cost, high-volume procedures. It will likely take a while before the impact of the new payment methodologies is felt in the vascular area. Overall, the quality metrics regarding functional status, improvement in productivity, and infection rates, etc, are all sensible, and they present some opportunities for efficient practices to benefit. The vascular interventions that make measurable differences, such as improving ambulatory status, functional status, and productivity, will likely present the best opportunities.

In my estimation, vascular practitioners as a group are sophisticated in their understanding of how to track and measure these elements in a meaningful way, which should help, as the new episodic payment methodologies are attached to quality metrics. But, it will require proving that benefit through data collection.

What would you say are the biggest drawbacks of the ACA as applied to vascular therapy?

One of the complicating issues for establishing fair payment for patients with multiple conditions, such as those with vascular disease, is trying to assign and track benefit of specific interventions within a defined time period. We know the benefit of a treatment for the patient's peripheral vascular disease will be affected by underlying conditions such as severe congestive heart failure or diabetes. The new episodic payment methodologies attempt to reward good clinical practice by increasing payment to the doctor and the hospital that deliver the best quality care with the fewest complications. This is complicated based on the severity, patient compliance in the care and, of course, the technical difficulty of the procedure. Implementation of these new payment incentives through the ACA will undergo a lot of refinement and debate to get the right (and fair) risk-sharing formula for hospitals, doctors, and payers.

Another challenge is related to patient referral pat-

terns. The construct of these new bundled payment methodologies is based on what is called a *medical home*, where the primary care physician is the first point of entry, and the patient is then referred to the specialist, and then back to the primary care physician. So, an understanding of the business arrangements of how your vascular practices are contracted with providers and primary care physicians is essential to understand in this new world of accountable care organizations (ACO) and episodic payments. On top of that, each payer has a different definition of the episode and how they will pay the primary care doctor, the specialist, the hospital event, and the services provided before and after. Of course, all of this depends on whether the vascular surgeon or interventionist is a staff physician in a hospital versus a contracted practice and whether the hospitals also have staff primary care doctors as part of the business model.

Vascular interventionists will have to understand these dynamics and how they will be compensated for their intervention along the pathway of care.

In what ways will physicians be expected to keep costs down?

Because the new mandates require long-term follow-up and measurement of outcomes, institutions will need to develop means of collecting and accurately reporting patient information. As a result, physicians will have a higher level of responsibility in that process, which is probably the last thing anyone wants to think about—more paperwork. But, it's added responsibility for the right reason: to show that outcomes are improved. I think payments will be relatively stable for a while without too much change in the short term, especially for vascular services. Vascular services have a unique advantage because much of the care can (and should) be delivered in the lower-cost outpatient and physician office settings.

Enlightened hospitals that have the ability to collect data, embrace vascular services, and encourage innovative techniques will win in the new, efficiency-driven payment world.

What are the specific forces driving health care providers to transition from volume-based to value-based delivery models?

The costly care of an aging population must be managed more effectively. Policymakers have designed the new episodic payment schemes to drive delivery of care more efficiently while protecting quality. It should be symbiotic—quality drives efficiency. The danger lies in artificially controlling costs by mandating volume reductions, services, and supplies. By looking at only supply costs without considering clinical benefit and impact, important products or procedures will never make it to the patient. In the vascular space, there are distinct, payment-driven opportunities for technologies and interventions that change how quickly patients recover and how adverse events are decreased by rehabilitating patients more quickly and delivering care in a less intensive site of service.

What is an example of services that might be affected?

Imaging tests that are currently part of standard care will be scrutinized. There is a debate over whether the amount of imaging going on is excessive. The current imaging standards are often built into hospital protocols, but the appropriateness of some testing and how these tests improve outcomes will be constantly challenged to justify the costs.

Is it likely that private insurance payments will follow similar trends to Medicare in the ACA era?

Absolutely. It's very obvious now, and there are many examples in which commercial insurers are embracing the new episodic models for payment. And, insurance companies may have government-mandated caps on how high they can raise their premiums, so they are pioneering episodic payments that are advantageous to them. Negotiations among physician practices, providers, and payers to make sure this is all managed properly and fairly will be tense.

In what ways do you think reimbursement potential will affect device innovation going forward?

It will be extremely important for the medical device community to understand the incentives in episodic payments. The interventions demonstrating improvement in outcomes, distinct from everything else that's being done to the patient, will see the best reimbursement. The collection and reporting of that information in a way that is recognized as beneficial by the hospital and the payers will be key.

How will this affect decisions to conduct clinical trials and the nature of those that are undertaken?

The traditional way to show that a device or procedure is different and better for patients is to conduct a randomized trial to demonstrate improvement in outcomes. There is no question you have to deliver evidence that your technology or intervention is going to make a difference. But, I believe that new, creative ways to deliv-

er that evidence have not been established. I encourage regulatory authorities to be creative in embracing different study designs allowing manufacturers to make devices available to patients sooner. Regulators should look at claims analysis and large data studies using retrospective designs and other novel study methodologies that are not so burdensome, satisfy safety concerns, and get products to the market faster.

Faster regulatory approvals outside the United States are now the norm, and we are losing innovation due to our extraordinary regulatory requirements. Everything, even incremental changes to existing, approved technology, must go through the traditional approach. I think that's arcane and a waste of resources. New methods for collecting information for quicker, reasonable approvals must be implemented.

How are these forces influencing venture capital investment?

Venture capitalists are looking to reduce risk, and they're reluctant to fund anything that requires an extensive regulatory process. If a technology makes it through the regulatory hurdles, but there is uncertainty on the payment side, there is even more reluctance for the venture capital community to commit funds. Investors are now very aware of the efforts it may take to get an optimal price for a new technology—and will accept the costs of doing the required economic studies needed to commercialize a product if the product is really game changing.

Smart investors will embrace products and companies like we've initiated at Intralign—procedures/products that have the potential for changing the cost curve delivered safely and effectively. The smart manufacturers that are thinking about delivering a service, not just a product, will be the winners. They will rise to the top, and investors will look to them as the place to play.

What is missing from the health care legislation, in your opinion?

The patients' responsibilities in their own care are not addressed effectively, and this issue will rise to the surface eventually. The patient has to assume some of the risk in terms of behavior and outcomes—it can't all fall on the physician practitioner. Another major concern in this construct is our current medicolegal environment. With more scrutiny on the appropriateness of testing and the protection-and-prevention approach to treatment, legal-driven medical practices must be reformed. ■

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