Health Care Payment Is Shifting to Reward Value, but Can Information on Health Care's Value Be Shared?

DAN LEONARD (HTTPS://MORNINGCONSULT.COM/AUTHOR/DAN/) | AUGUST 1, 2016
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If you wanted to know the headlines in 1962, you watched the evening news, read the daily newspaper, or listened to the radio. Those were your only options.

But if you want to know the headlines today, the range of sources available to you is nearly limitless.

As news has evolved, we also have seen a rapid transformation in access to health care news and information. When the Food and Drug Administration began to regulate communications around the marketing of pharmaceuticals in 1962, neither the FDA nor Congress could have predicted the evolution of our health care system or the information explosion we have seen in the past 20 years.

When Congress enacted the Food and Drug Administration Modernization Act of 1997, which created a pathway through Section 114 for pharmaceutical companies to proactively communicate health economic information with specific stakeholders, health care looked dramatically different than it does today. We did not yet have biologics or personalized medicine. We got our information through paper health care records, not real-time feedback from mobile health devices, searchable electronic health records, and other data sources. We have revolutionized how we treat many conditions, and who pays for medications now includes Medicare Part D, exchanges, and consumer directed health plans.

Given these changes, broader exchange and communication of how treatments work in the "real-world," how they compare to alternatives, and their related impact on the total cost of care is needed. In fact, the ability to communicate valid, reliable information from many sources is critical to helping us achieve the common goal of delivering more efficient, high-quality health care.

Unfortunately, despite the best intentions of FDAMA Section 114, the exchange of information remains limited.

Ambiguities in the law's language, coupled with a continued lack of guidance about its scope, have led to a lack of information exchange (http://www.ncbi.nlm.nih.gov/pubmed/23048099) due to concerns from biopharmaceutical companies regarding the risk of penalties for violating standards.

As a result, the congressional intent of FDAMA 114 (http://www.ncbi.nlm.nih.gov/pubmed/26297097) has never been fully realized. And as stakeholders wrestle with how to deliver the right care to the right patient at the right time in the most appropriate setting, they do so without all the information they may need to make the best coverage and treatment decisions for patients.

To address these challenges, there are a number of potential paths forward that will provide the clarity and changes to ensure there is a better, more balanced sharing of valid and reliable information — including real-world evidence with payers and other stakeholders. Several proposals have recently been put forward, including new FDA guidance, congressional action on 21st Century Cures, and the Prescription Drug User Fee Act reauthorization negotiation. Additionally, interested groups have brought diverse stakeholders together to address this issue including the Duke-Margolis Center for Health Policy and the Academy of Managed Care Pharmacy. Regardless of which approach is fully considered, the following recommendations should be included:

1) Ensure changes we make today are sufficiently flexible for future health care evolution. Evidence sources and approaches have significantly evolved over time. As a result, we not only need to develop policies that work in 2016 — but policies that are flexible for the future of health care product and payment innovations.

2) Provide effectiveness (rather than just efficacy) information to health care decision-makers. Communicated product label information traditionally is based upon efficacy or "how well treatments can work" compared to placebo; however, today's stakeholders are also interested in effectiveness — meaning, "how treatments work in the real-world" and how these treatments will affect quality measures.

3) Ensure meaningful evidence is available to health care decision-makers both now and in the future. The range of stakeholders making population health decisions — affecting the care covered and delivered by everything from health exchanges to accountable care organizations and by providers reimbursed through bundled payments — did not exist just five years ago. As we look ahead, we need to ensure all decision-makers have the information they need to make the appropriate choices for patients and our health system.

4) Communicate early and often with payers. Health plans and those who bear financial risk for health care need to have information about new technologies 12-18 months in advance of launch. Early communication about new technologies allows health plans to incorporate these changes into future health insurance rate reviews and premium changes, which are reviewed by state insurance commissions. Creating a safe harbor to allow communication is needed.

5) Identify and allow trusted sources to educate and empower patients to be engaged and informed decision-makers about their treatments and the impact on their financial investment. Patients increasingly are responsible for premiums, deductibles, copays and prescription cost sharing. With the increase in consumer-directed health plans, they need to make informed decisions—assessing the benefits, risks, and costs of treatment. Trusted sources can aid in this shift.

The communication of health care information is now more important than ever. The products available to treat conditions, the ways in which health care is organized, delivered and reimbursed, and the available information sources and analytic processes have vastly evolved. Now is the time for communication laws, regulations, guidance, and/or policies to evolve in parallel.

Dan Leonard is the president of the National Pharmaceutical Council.