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By Rebecca Shanahan

The amount of disruption — both positive and negative — taking place in health care over the past decade has been unprecedented. It's not an exaggeration to say that the only constant in the health care industry right now is change. A dynamic regulatory environment, along with other factors like new technology, have already enabled new models of care delivery, greater integration and alternative types of care reimbursement.

Most experts expect that 2017 will be no different in that respect. Internal and external forces will continue to reshape health care in the next 12 months, including the transfer of power in the political arena. The specialty pharmacy industry is not immune to these changes and will likely feel repercussions both directly and indirectly.

As an association representing hundreds of specialty pharmacies and thousands of stakeholders across the nation, NASP has a broad perspective of not just the specialty pharmacy niche but the industry as a whole. Based on this knowledge, below are a few of the key drivers that we believe will transform the specialty pharmacy space next year.

Affordable Care Act's uncertain future

Perhaps the biggest issue on the mind of everyone in the health care industry is what is going to happen to the Affordable Care Act — and, equally important, how quickly it will happen. The impact of any changes to this legislation will be significant for all health care entities, but especially for insurers. Any move to eliminate or alter ACA provisions could have a significant impact on their bottom line.

For example, if insurance subsidies are eliminated, most insurers — many of whom are already leaving ACA insurance exchanges — will likely exit the individual market altogether. Quite a few experts believe

that this scenario is not only likely, it will also happen early in 2017, perhaps in the first quarter.

While insurers anxiously await potential changes to health reform, specialty pharmacies should also be contemplating the downstream impact of these changes on their business models. The ACA has significantly increased the number of insured consumers. These segments include many individuals with preexisting conditions who require costly drug interventions, an area which ties directly to revenue within the specialty pharmacy space.

Oncology drug pipeline will keep growing in 2017.

While 2017 will undoubtedly bring changes to the foundational aspects of the ACA, certain strategies enabled by health care reform will probably stay in place regardless of what happens in Washington. Specifically, health care organizations will continue to look for ways to meet the ACA's triple aim — improving quality, reducing costs and increasing patient satisfaction. Payers and providers have invested substantial time and effort in value-based care and quality improvement programs, and they have also incurred direct costs in areas such as new technologies.

As a result, specialty pharmacies should continue to look for ways to provide value within these new models, whether that means collecting and tracking quality data or employing clinical best practices that are consistent with these measures.

Other potential issues on legislative front

Although most of the conversation around legislation right now is centered on the ACA, and for good reason, there are other new measures on the ho-

rizon as well. Many represent both good news and bad news for the industry.

Take the 21st Century Cures Act. This legislation aims to speed FDA approvals for drug and medical devices, especially for orphan drugs. Experts say it will likely increase the number of drugs in the pipeline for 2017 and beyond. That would be a welcome change for manufacturers and pharmacies, as the number of Food and Drug Administration approvals for new drugs dropped to just 19 in 2016 (as of mid-December).

However, one specific section of this legislation could have a negative impact on one important segment of our industry — infusion drug providers. A provision of the act essentially eliminates a provider's ability to charge for the professional services provided along with infusion drugs for the next four years.

Another move by Congress to put the squeeze on drug spending could have an even greater reach across the entire pharmacy sector. The Senate is currently considering changes to the Medicare fee schedule for 34 Part B drugs, which would shave \$500 million off Medicare's prescription spend. Yet to do so, specialty pharmacies would no longer be reimbursed for all of the valuable services they offer patients — from education and support to adherence and financial assistance programs.

In an industry where margins are already razor thin, this move could have wide-reaching implications, especially if the Centers for Medicare and Medicaid Services (CMS) continues to consider similar efforts to curb spending in 2017.

New technologies to bring greater connectivity

The adoption of electronic medical records (EMR), health information exchange systems and advanced analytics is helping the health care industry finally "catch up" with other sectors on the technology front.

Experts expect that the next wave of technology-enabled initiatives in 2017 will take this one step farther, especially for specialty pharmacies. For example, today many specialty pharmacies have web-based portals that supply one-way data to providers about medication adherence, patient outcomes, etc. The next step in this process might be to directly interface with a provider's EMR, providing two-way, seamless data exchange that offers a real-time view into a patient's treatment, prescription adherence and health status.

Mobile apps continue to be adopted in the specialty pharmacy space, and some of the most interesting provide clinical decision support for providers in selecting appropriate drug options. Finally, telemedicine continues to grow as health systems and providers look for ways to improve convenient access to care, and better serve patients in more rural areas. While most specialty pharmacies haven't yet adopted telemedicine as a means for patient outreach, this may be a logical next step in their efforts to improve patient engagement and education.

Oncology to dominate specialty pipeline

Hepatitis C drugs and oncology drugs put specialty in the spotlight throughout 2016, for the good (outcomes) and for the bad (pricing).

In particular, the oncology pipeline in 2017 shows no sign of this growth slowing. According to QuintilesIMS, annual global growth in the oncology drug market is expected to be 7.5% to 10.5% through 2020, reaching \$150 billion. This specialty will also benefit from trends toward oral delivery options as well as a higher portion of new therapies focused on niche patient populations.

Tightening revenue and industry consolidation

While drug prices and price sensitivity rose in 2016, most specialty pharmacies aren't feeling improvements to their bottom line as a result. With pressures like greater competition and increased DIR fees as the new normal, these organizations will continue to feel the squeeze in 2017.

Biosimilars and generics will continue to play a role in the competitive landscape for specialty pharmacies. But for many smaller pharmacies, industry consolidation may also make it more difficult to compete. Most analysts agree that the pharmacy sector remains priced for



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horizontal and vertical integration in 2017.

In fact, a high valuation for specialty pharmacies right now indicates that investors and other organizations are willing to pay a high price for the value these companies can offer.

Countering negative, misleading media coverage

In general, 2016 was a troubling year for our sector on the media front, especially in the general business press. Negative articles about pharmacy and pharmaceutical relationships as well as inappropriate reimbursement dominated many headlines.

Yet the media cast a wide net, misrepresenting certain organizations accused of fraud and inappropriate financial dealings as specialty pharmacies. However, these entities in no way meet NASP's definition of a specialty pharmacy, which consists of accredited organizations providing drugs for serious, complex health conditions alongside extensive patient education and support.

These stories may well continue on into next year, which means that as an industry we must seek to promote education and awareness of this important sector of the health care industry.

In fact, one of NASP's critical aims for 2017 is to promote greater awareness about the true role and impact of specialty pharmacies, helping to ensure that the improper practices of certain mail order pharmacies and other entities don't tarnish the reputation our member organizations have earned.

Our intent is that the entire industry also sees this as a call to action — to promote accurate information about the true drivers of pricing, the nature of industry relationships and many of the positive things we're all doing to drive better outcomes and manage costs in this sector.

