See Your Way Clear

Dan Mendelson
President

2018 will be a year that brings change from all quarters of the healthcare system. We have a market driven toward value-based purchasing and consolidation, a Congress eager to continue repealing the Affordable Care Act (ACA) and assessing the viability of major entitlement reform, and an Administration reaching for flexibilities under current law to enable state reforms. Momentum from political engagement, the tax bill, mergers and consolidations, and technological change will propel progress.

Drug affordability will remain a prominent political issue—one that the Administration has addressed to date through a focus on increasing the competitiveness of markets and the transparency of drug pricing in the supply chain. We expect Secretary Azar, when confirmed, to continue this focus and accelerate it through policy designed to improve the commercial diffusion of generics and biosimilars. Congress is also starting to look at drug purchasing in the entitlement programs, with an eye toward market-based solutions as opposed to government price controls.

Data reliability and accessibility will remain a major theme driving outcomes-based contracting, innovative network design, and transition toward alternative payment models. Real-world data is a key catalyst of market-based solutions. Specifically, the ability to capture and analyze data, create algorithms based on this information, and to field targeted interventions to improve patient care will be core to plan engagement as well as market change.

Consumers are increasingly a focus of strategy for all healthcare organizations. To date, consumers have felt change through modifications to benefit design, consolidations of healthcare organizations, protections under the ACA, and, for some, better availability of digital information. But more fundamental changes that are responsive to patient needs are urgently needed, and elusive to date.

Strategic and operational planning in this dynamic market requires an analytic focus. Providers and payers are coming closer together, and each needs to assess their posture around risk, outcomes, and collaborative engagement. Likewise, life sciences companies will continue to face pricing pressure and need to be prepared to engage on the outcomes that interest their buyers most. Avalere has built the tools to help you meet these imperatives, and we look forward to our engagement with you in 2018.

Some stakeholders will clearly benefit. Medicare Advantage plans will enjoy additional flexibilities to adjust their offerings to drive enrollment, and growth in these markets will also continue as providers consolidate and assume more risk. States seeking flexibility to change Medicaid will benefit from the Administration’s focus, as will Medicaid plans seeking to engage new markets. Outcomes-based contracting will favor cost-effective interventions that improve patient health.

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## New Approaches to Value-Based Payment /

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Medicare Advantage (MA) continues to play an increasing role in serving Medicare beneficiaries, with 32% of Medicare enrollees in the program, up from 20% in 2007. Existing and potential growth in MA attracts new players to the market each year.

In late 2017, CMS proposed to grant MA plans greater flexibility to tailor their benefit designs to increase access to services for individuals with certain conditions. Looking ahead, plans will continue to seek flexibility in the program, especially in ways that allow for innovative network design and coverage of non-medical services that help reduce total cost of care.

Evidence shows that tailoring benefits to meet the needs of specific beneficiary groups drives value for the MA program and beneficiaries. For example, an Avalere analysis finds that chronically ill beneficiaries in Special Needs Plans (SNPs) experience better outcomes than those in standard MA plans, including fewer hospitalizations and readmissions.

New rules propose to increase flexibility for plans in MA, including customizing benefits for some medical conditions.

As always, future policy stands to influence the opportunities available to stakeholders participating in the program, whether through increased flexibility, regulatory change, or debates about entitlement reforms and increasing eligibility for Medicare. Nonetheless, MA will remain a key growth opportunity for health plans and their partners, especially for those entities willing to invest in quality performance and operational excellence.

**Specialized Medicare Plans Improve Patient Outcomes**

**Beneficiary Outcomes in Special Needs Plans for Diabetes Compared with Standard Medicare Advantage Plans**

- **38%** Less likely to be admitted to a hospital
- **32%** Less likely to be readmitted to a hospital
- **22%** More likely to have a primary care visit
- **10%** More likely to have had a blood glucose test

Expert Perspective

Q: How might MA plans assert the flexibility granted in CMS’ proposal?
A: CMS’ proposal, if finalized, will open the door to more innovation on disease-tailored benefit designs. Data on enrollee experiences in SNPs suggest that outcomes improve when plans can tailor their benefits and services to specific conditions; until now, MA plans have not been able to tailor their services in this way. Also, MA plans will be able to provide a broader range of supplemental benefits to enhance care.

Q: How can plans succeed in the current MA market?
A: MA plans that are succeeding in the market are prioritizing operational excellence on issues like Medicare Star Ratings and risk adjustment. Given the strong financial incentives tied to the Medicare Star Ratings, plans that perform well on these measures receive higher payments, which can be invested in supplemental benefits that attract enrollment. Some large provider-sponsored plans have achieved particular success on Stars and all plan performance is improving, leading to topped-out measures that will be replaced with new metrics for plans.

Q: What is ahead for MA cost trends?
A: Medicare cost growth has been level at 2% annually for several years. However, costs are beginning to rise and could renew the focus on entitlement reforms.

“MA plans are prioritizing operational excellence to fuel financial and enrollment success in the market.”
Sean Creighton

Impact

Health Plans /
MA plans will have more room to innovate in how they deliver care if CMS’ proposed changes are finalized. These new flexibilities may also attract more insurers into the MA market, which could make the market more competitive for established players.

Providers /
As MA grows, there will be an emphasis on efficient provider networks, which may exclude some physicians who have traditionally served Medicare populations. Plans are looking for provider partners who can help realize quality improvements for beneficiaries and maintain efficiency.

Manufacturers /
MA will need to be a growing focus for manufacturers, particularly for Part B drugs. MA benefit designs for Part B drugs have been evolving to include more beneficiary cost sharing akin to the exchange and commercial markets.
States Seek to Increase Personal Responsibility in Medicaid

Throughout 2017, Congress repeatedly attempted and failed to repeal the Medicaid expansion and cap funding in the program. However, efforts to modernize Medicaid and control spending growth will continue for the foreseeable future. While Congress may try again to impose per capita caps on the program, the most immediate reforms will come from state-led waiver activity.

After failed attempts to reform Medicaid in Congress, action will shift to state waivers as a mechanism for change.

Over two-thirds of states have submitted comprehensive waivers since the start of the current Administration. The waivers focus on increasing beneficiary premiums and cost sharing, requiring able-bodied individuals to participate in job search programs, limiting the duration of coverage, and reducing the scope of benefits. Other states are expanding coverage for substance abuse treatments. The Secretary has broad authority to approve waivers and is likely to drive the program toward more commercial style benefits with greater personal responsibility requirements.

Meanwhile, with additional flexibility in the federal government and a changing political environment, more states may expand Medicaid for the lowest income individuals. Ballot initiatives supporting expansion could also gain traction. Together, if all remaining 19 states expanded Medicaid, they could receive $182B in additional federal funds over 10 years. Furthermore, 10M more people could be covered by Medicaid if all states expand.

**State and Federal Policymakers Are Pursuing a Range of Approaches to Transform Medicaid**

- **Work Requirements**: 7 States seeking enforceable work requirements
- **Cost Sharing**: 3 States want mandatory premiums <100% FPL
- **Drug Management**: 32M people access drugs through FFS
- **Expanding Medicaid**: 10M more people eligible, if all states expand
- **Per Capita Caps**: $164B less funding for states over 10 years

**State Led**
- **Work Requirements**: Make program eligibility contingent on job search or retraining
- **Cost Sharing**: Increase beneficiary premiums and cost sharing above statutory limits
- **Drug Management**: Limit scope of drug coverage and increase ability to negotiate supplemental rebates
- **Expanding Medicaid**: Grant broader federal flexibility, allowing 19 remaining states to expand
- **Per Capita Caps**: Enable states to combine Medicaid and ACA waivers for broader program reform

**Federally Led**

ACA: Affordable Care Act, FPL: federal poverty level, FFS: fee-for-service. As of December 15, 2017. Source: Avalere State Reform 360™
Health Plans / Medicaid continues to be one of the fastest-growing channels for private payers. While margins in this market are slim, insurers have an opportunity to expand their enrollment as more states shift fully to managed care and other states expand eligibility.

Providers / Stability in Medicaid coverage and potential expansion of Medicaid in additional states is a positive opportunity for providers, particularly hospitals, which have seen an uptick in volumes and a reduction in uncompensated care in expansion states.

Manufacturers / Recent state efforts to limit the scope of drug benefits and elicit deeper supplemental rebates threaten the traditional coverage protections for products that pay Medicaid rebates. This channel will become increasingly competitive with more limited access over time.

"Novel state approaches to waivers can start a trend among states and even lead to changes in federal program rules."

Caroline Pearson
Individual Market Sputters Along, but Major Threats Will Persist in 2018

The uncertainty surrounding the long-term future of the ACA has taken a toll on the individual market, resulting in higher premiums, fewer participating insurers, and lower enrollment overall for 2018. Passage of the tax bill, which repealed the individual mandate, will further stress the market and could lead to more plan exits. Together, these dynamics will spur more policy focus from some members of Congress on how to stabilize the market. Meanwhile, other policymakers have vowed to continue efforts to repeal and replace the ACA.

In order to improve affordability for consumers, there are several policies that could help lower premiums, including reinsurance, higher subsidies, and changes to rating rules. While these policies require new federal funding, they also reduce costs by limiting government premium subsidies. For instance, the federal government gets back 40 cents on every dollar it spends on reinsurance in the individual market. However, heated political dynamics will make bipartisan legislative efforts to improve the market difficult.

For every dollar spent on reinsurance, the federal government gets $0.40 back from lower premium subsidies.

Enrollment in federally-run insurance exchanges for 2018 fell 5% behind prior years due to a shorter sign-up period and political uncertainty about the ACA. Nonetheless, there continues to be a core group of enrollees—highly subsidized individuals and those with chronic health needs—who underpin the market. As insurers have gained more experience, they have been able to improve their financial performance by pricing products appropriately for the true health needs of the covered population.
Q: How have premiums changed in the individual market for 2018?
A: Silver plan premiums rose by 34% this year, driven largely by the termination of payments for the cost-sharing reductions. Interestingly, while this shift drove up premiums for silver products, it made gold and bronze plans more affordable for many subsidized consumers. Nonetheless, the shorter enrollment period led to slightly fewer people signing up for coverage compared to prior years.

Q: Has this instability affected plan participation in the individual market?
A: 2018 has seen a significant reduction in the number of plans selling products in the exchange. In more than half of counties, there is only one insurer offering coverage. However, all regions of the country do have at least one plan available.

Q: How are benefits changing among exchange plans?
A: Exchange plans continue to strive for low premiums that attract enrollment. As such, we consistently see an emphasis on closed-network HMO products with relatively high cost sharing. In 2018, average deductibles for silver plans will be nearly $4,000 with consumers paying more than one-third the cost of specialty drugs.

Health Plans /
The individual market continues to be a tumultuous environment for plans but those that remain may see improved financial outcomes as the enrollees’ medical needs are better understood. However, legislative changes will be needed to improve the market in a way that supports long-term growth.

Providers /
Narrow networks in individual market products remain a challenge for providers, especially academic centers that may be excluded based on cost. High cost-sharing requirements also place a burden on patients, which may reduce volumes and limit access to care.

Patients /
Rapid increases in premiums, a shorter open enrollment period, and no funding for outreach efforts all hampered participation in insurance exchanges in 2018. Still, subsidized coverage with a maximum out-of-pocket limit remains an important source of coverage for many consumers.

“Repeal of the mandate threatens the stability of ACA markets, which depend on having health plans that are willing to participate.”
Elizabeth Carpenter
While lawmakers have voiced concern about prescription drug costs, current policy efforts have shifted toward sharing price concessions with patients and government programs. As deductibles continue to rise rapidly across commercial insurance and coinsurance becomes the norm for specialty drugs, patients who use high-cost specialty products are increasingly exposed to their drug costs.

The policy focus on prescription drug prices is currently centered on limiting patient out-of-pocket costs.

When consumers pay for drugs at the pharmacy counter, they pay a portion of the list price, which does not reflect any rebates, discounts, or protections against price inflation the health plan or pharmacy benefit manager (PBM) may have negotiated with the manufacturer. Instead, those rebates are largely used to reduce premiums for all enrollees rather than to directly lower out-of-pocket costs for the consumers using the product. In the coming year, Medicare will pursue strategies to return a portion of those rebates to consumers at the point of sale and other payers may follow suit.

For physician-administered drugs, Medicare is moving forward with a change to reduce its reimbursement of 340B drugs to safety-net hospitals, which will also reduce beneficiary cost sharing by more than $320M per year.

State efforts to increase transparency into drug development and supply chain costs will continue throughout the year, maintaining public focus on pricing and the role of PBMs, though similar legislation in Congress is unlikely.

Medicare Rebate Pass-Through Proposal Would Share Rebates with Patients

<table>
<thead>
<tr>
<th>Current Policy</th>
<th>Proposed Policy</th>
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<tbody>
<tr>
<td>List Price</td>
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<td>Rebate</td>
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<tr>
<td>Rebate Pass-Through</td>
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<td>Negotiated Price</td>
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<tr>
<td>Deductible</td>
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<tr>
<td>Coinsurance</td>
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<tr>
<td>Coverage Gap</td>
<td>$126</td>
</tr>
<tr>
<td>Catastrophic</td>
<td>$18</td>
</tr>
</tbody>
</table>

*Illustrative example. Assumes 50% of rebates will be passed through. CMS has not yet proposed a minimum percentage or finalized which price concessions will be included in the definition of rebate.
Q: What shifts have you seen take place across the drug supply chain?
A: We are seeing a push toward vertical integration within the supply chain, including consolidation between plans, PBMs, and pharmacies. Such consolidation gives payers more leverage over supply chain costs, better data across medical and pharmacy benefits, greater ability to manage members and utilization, and can lower transaction costs for negotiating price concessions with manufacturers.

Q: How will the drug supply chain evolve in the coming year?
A: In 2018, there will be further efforts to unpack costs within the supply chain. As these costs become more transparent and well understood, we will see new experimentation of alternative methods to lower transaction costs and deliver drugs to consumers more directly. New entities, like Amazon, may take advantage of this opportunity and seek to disrupt the traditional approach to pharmaceutical distribution.

Q: How do you expect the Administration to pursue additional policies aimed at reducing drug costs?
A: The Administration will assess the feasibility of new payment models to encourage value-based drug payments and shared savings with beneficiaries. To the extent possible it will take advantage of its broad demonstration authority, though other changes will require legislation.

“We are entering a period when experimentation across the supply chain will be encouraged and new entrants and models could disrupt the market.”
Rujul Desai

Health Plans & PBMs /
Efforts to implement rebate pass-through arrangements in Medicare Part D will create new demands on PBMs for reporting and real-time data transmission to pharmacies. If executed, such policies may increase premiums.

Manufacturers /
The shift in emphasis toward patient costs is positive for manufacturers and has the potential to improve access. Point-of-sale rebate pass-through enables patients to benefit from the net price of a product but will not eliminate concerns about overall drug costs. Details of how these policies are implemented are critical to protect access.

Patients /
While rebate pass-through and 340B changes do not impact overall drug spending, they redirect savings to consumers who use high-cost specialty medicines. In contrast, premiums may increase for all consumers as a result.
Under Active Commissioner, FDA Advances Broad Policy Agenda

Since being sworn in as the 23rd FDA commissioner in May 2017, Scott Gottlieb has emerged as one of the highest-profile commissioners in recent history. Gottlieb has been bold in unveiling a broad public strategy to encourage more competition in the drug market, and to support the development and approval of innovative drugs and medical devices.

Active FDA Commissioner elevates FDA as a major player in the pricing and value debate.

In his first remarks to FDA staff, Gottlieb broke from his predecessors by asserting a role for FDA in tackling the challenges of drug pricing. He followed these remarks with the announcement of a Drug Competition Action Plan under which FDA would advance policies to bring more competition into the drug market. Under the plan, FDA has already outlined a policy to expedite the review of generic drug applications and has issued draft guidance to support the development of complex generics. More elements of this Action Plan will be released in 2018.

Gottlieb has voiced his commitment to encouraging the development of new products. 2017 saw the first US approvals of gene therapies, Kymriah™, Luxturna™ and Yescarta™. In 2018, FDA will continue to refine its policies to support further development and approval of gene therapies. FDA has also taken steps to encourage innovation in medical devices and plans to announce additional steps to support device innovation in 2018.

Scott Gottlieb’s Positioning of the FDA in the Public Policy Debate Generates Media Attention

Inflation Pressure for Greater Drug Competition / FDA

 Increased Pressure for Greater Drug Competition / FDA
Expert Perspective

Q: Are public perceptions of FDA changing?
A: Through his public statements and actions, Commissioner Gottlieb appears to be signaling that FDA will be part of the solution in addressing the challenges of our healthcare system, including the opioid crisis, drug pricing, and impediments to innovation.

Q: Have you noted any changes in how the FDA operates?
A: Attention is now being given to many of the innovative activities that had long been taking place at the agency but perhaps were underappreciated by the broader public. An example would be FDA's cultivation of adaptive trial designs to make the drug development process more efficient. FDA is also beginning to be responsive to public policy concerns, including on drug pricing, where it has not previously sought to have a role.

Q: Is this affecting how product sponsors engage with the agency?
A: Yes. FDA's prioritization of competition and innovation supports constructive engagement between product sponsors and the agency. FDA is also clarifying the role that real-world evidence can play in regulatory decision making. This establishes a basis for discussion between FDA and product sponsors on the potential applications of real-world evidence in product approval decisions.

“Commissioner Gottlieb’s early actions indicate his willingness to engage on issues related to value, pricing, and competition that FDA has traditionally avoided.”

Tom Kraus

Impact

Manufacturers / FDA’s priorities under Commissioner Gottlieb and the most recent user fee agreements may enhance opportunities for early and constructive engagement with FDA on product development. Evidence generation programs should also consider a role for real-world evidence, as FDA shows a greater willingness to consider evidence beyond that generated in clinical trials.

Health Plans / FDA reports that more than 550 active investigational new drug applications related to gene therapies have been granted. We will see more high-cost products as FDA and industry work to bring innovative therapies to market. Health plans will need to track the pipeline carefully to anticipate new product launches that may have substantial cost implications in the future.

Patients / FDA has signaled it is receptive to looking at new types of evidence, including patient preference information. Through public workshops and a newly established Office of Patient Affairs, patient groups will have opportunities to shape the ways the patient voice is integrated into FDA’s decision making.
Policies to Support Biosimilars Market Come into Focus

As of the close of 2017, eight biosimilars have been approved for marketing by FDA and three have launched. While none of these biosimilars have been designated as interchangeable, the first study to examine interchangeability in the US was initiated in 2017 for Cyltezo® (adalimumab-adbm).

Efforts to advance policy solutions to support a robust biosimilars market are gaining ground.

The biosimilars market has been slower to grow in the US than in Europe, where biosimilars are widely available. To help stimulate the US market, policymakers are deliberating on solutions to remove perceived barriers to competition. Some of these solutions may ultimately be promoted by policymakers to meet dual goals to support a biosimilars market and address the issue of drug costs.

CMS is taking steps to address differential reimbursement in the Medicare program that may be limiting biosimilar uptake. In 2017, CMS announced a change to its Part B reimbursement policy so that all biosimilars would receive unique billing codes. In 2018, Part D policies toward biosimilars will be debated.

Medicare Part D Patients & Plans Pay More for Biosimilars

Biosimilars are excluded from the Medicare Coverage Gap Discount Program, which results in Part D enrollees and plans assuming higher costs for a biosimilar than its reference product.

<table>
<thead>
<tr>
<th>Difference in Product Cost*</th>
<th>Patient Out-of-Pocket Cost</th>
<th>Health Plan Cost</th>
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<tbody>
<tr>
<td>Reference Product Price: $50,000</td>
<td>$1,630</td>
<td>$2,378</td>
</tr>
<tr>
<td>Biosimilar Price: $42,500</td>
<td>$7,500 (-15%)</td>
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</table>

Biosimilar Development Pipeline

- **23** Reference Products
- **68** Biosimilars in Development
- **8** Approved Biosimilars
- **3** Biosimilars Launched

*Illustrative example.
Manufacturers / 
As attention on drug prices continues, ways to promote a sustainable environment for biosimilars will continue to be an area of focus. By reversing its decision on biosimilar billing codes, CMS has shown that it is willing to effect policy changes that can better support the market.

Health Plans / 
Policy changes that support a more competitive environment for biosimilars will be positive for plans by removing financial disincentives to covering biosimilars.

Patients & Providers / 
Patients and providers will be the targets of education campaigns that seek to broaden their understanding of the safety and efficacy of biosimilars. Greater patient and provider experience with the three biosimilars on the market today will be critical to driving acceptance.

Q: How will the shift to individual codes in Part B affect the market?
A: The shift to unique codes will allow biosimilar manufacturers to behave more like brands when making pricing decisions and differentiating their products. Some expect unique codes to limit price erosion, but it is likely that biosimilar manufacturers will still need to compete on price or pursue other contracting strategies such as portfolio agreements to gain market share.

Q: Where do providers and patients stand on biosimilars today?
A: In 2018, public understanding of biosimilars will continue to grow. FDA launched an educational program in the Fall of 2017 to help further patient and provider understanding of biosimilars and the standards by which FDA approves them. More fundamental change in prescribing patterns among physicians is contingent on key opinion leader support and information on patient experiences with Zarxio®, Inflectra®, and Renflexis™, the three biosimilars on the market today.

Q: How will biosimilars coverage policy continue to evolve?
A: CMS will need to establish consistency across public programs on whether biosimilars should be treated as single source or multisource products, which will affect pricing policy. Meanwhile, some large private payers have been more aggressive in using their formularies to promote biosimilar use over the reference products.

“2018 will be a decisive year in which policy focus on biosimilars could translate to a competitive market.”

Kathy Hughes
Real-World Data Becomes Core to Commercial Strategies

New ways to collect data, advanced analytic capabilities, and accessibility of a growing number of data sources are revitalizing efforts to translate real-world data into evidence that can inform policy and clinical practice. There is also renewed interest in using real-world data and evidence in areas that had previously been discounted. For example, FDA’s mandate in 21st Century Cures to create a framework for evaluating real-world evidence has opened the door to broader applications of this data in the regulatory setting.

More widespread availability of real-world data will enable new entities to leverage analytics and insight to benefit patients and their providers.

The path to deploying real-world evidence in decision making has been well paved by health plans, which leverage data on the healthcare experiences of their members to manage plan risk, develop member engagement strategies, and design provider networks. Real-world data is bringing together plans and manufacturers to focus on improving outcomes and lowering costs in targeted disease areas. In 2017, Amgen and Humana announced a collaboration that encompasses a range of serious conditions, and additional partnerships are likely to be forged in the coming year. Avalere has also supported over a dozen outcomes-based contracts using real-world evidence.

In 2018, acceptance of real-world data and evidence to support decision making will continue to grow as payers, manufacturers, and providers begin to generate insights that position them to deliver better value to their customers.

Real-World Data Encompasses Broader Patient Population than Clinical Trials

Mean Age for MS Patients in Commercial Plans Compared to Clinical Trial Participants

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<th>Commercial Plans</th>
<th>Clinical Trials</th>
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<tr>
<td>Mean Age</td>
<td>Age 47.5</td>
<td>Age 47.5</td>
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</table>

The average age of MS patients in commercial plans is 10 years older than those in clinical trials.

Based on sample of three large commercial plans in MORE® Registry® 2011-2017. Source: Avalere analysis of the Inovalon MORE® Registry® and reported clinical trial data in drug label. MS: Multiple Sclerosis
Expert Perspective

Q: How is the use of real-world data changing?
A: The availability of robust data sources is changing how organizations make decisions. Plans and providers, for example, are not only using real-world data to demonstrate superior outcomes to their customers, but they are also looking to real-world data to inform their internal decisions regarding how they can expand market share or build stronger networks.

Q: What steps are organizations taking to leverage the opportunities presented by real-world data?
A: Organizations are deploying expertise, such as data scientists, to understand real-world data sources and the questions they are capable of answering. In addition, we have seen some organizations create a role for Chief Digital Officer, whose responsibilities include improving the way the organization uses data to inform its decision making.

Q: What do you see as an area of innovation in this space?
A: The ability to link traditional claims data with consumer behavior and social determinants of health data is a potential area of innovation. This type of innovation would help us understand additional drivers of health status, which can inform more targeted care and better outcomes.

“Cutting-edge organizations are using real-world data to define their competitive advantage in the marketplace.”
Michael Johnsrud

Impact

Health Plans /
To optimize quality and cost savings, plans are deploying real-world data to develop high-performing provider networks, map members’ utilization patterns to develop care management programs, manage risk-based programs, and support value-based contracts.

Manufacturers /
Manufacturers see the potential for real-world data to support product label expansions, refine aspects of their clinical development programs, and support innovative contracting arrangements. Expanded access to Medicare data will help companies target approaches to addressing unmet needs.

Providers /
Providers are looking at the possibilities of real-world data for multiple purposes. As providers take on more risk, managing the cost and quality of care of their patient population will require more complete information on their patients’ journeys, which today’s real-world data sources can provide. Real-world data can also provide valuable insight into local market dynamics.
Value-Based Contracts for Drugs Increase in Sophistication

As the urgency to achieve higher value in the healthcare system intensifies, health plans and drug manufacturers are recognizing the potential merits of value-based contracts. In the US, the number of value-based contracts—broadly defined as arrangements that link the price of a drug to specified indicators of value—have increased in recent years. Outcomes-based contracts are a well-known type of value-based contract, but new contracting models based on indication-specific pricing are also emerging as an area of interest.

New technology solutions are enabling the deployment of value-based contracts across a wider array of health plans.

Value-based contracts are not new but how health plans and manufacturers think about them has evolved, prompted by advances in how data are collected, reported, and analyzed. In earlier contracts, performance was assessed at the end of the contract period—generally by the health plan—using claims data. Today’s technology solutions enable plans and manufacturers to monitor individual patient outcomes data in near real-time. In addition, advances in analytic capabilities allow plans and manufacturers to determine what interventions would optimize patient outcomes throughout the contract term.

Under most value-based contracts announced to date, manufacturers are the ones taking on the risk. As plan and manufacturer experience grows, value-based contracts of the future may involve two-sided risk, under which both parties bear risk and have specific targets to drive value.

Critical Steps to Implementing Value-Based Contracts

- **Data Integration**: Create holistic view of patients’ experience across medical, pharmacy & lab
- **Advanced Analytics**: Identify target patient populations & outcomes for measurement
- **Patient Interventions**: Direct patient outreach to improve results, including medication adherence
- **Real-Time Monitoring**: Track ongoing patient outcomes for contract adjudication

70% of surveyed payers report favorable attitudes toward value-based contracts for drugs

80% of surveyed payers view assurance of product value as top benefit of value-based contracts

Q: Where is the industry with value-based contracts?
A: Especially for newer drugs, more manufacturers are willing to take risk for their products and experienced health plans are more receptive to collaboration. That said, technology platforms are enabling manufacturers to engage with less-experienced plans. Because most value-based contracts are never announced publicly, there is more activity taking place than most people realize.

Q: What is the future of value-based contracts in public programs?
A: The announcement between Novartis and CMS for Kymriah™ affirms CMS’ willingness to pursue new payment models for new treatments. More of these models are likely given the Administration’s support, growing experience among manufacturers and payers, and the launch of more high-cost products in public programs.

Q: Is the objective of value-based contracts to reduce drug spending?
A: There is a common misconception that lowering drug costs is the only goal of a value-based contract. Many contracts are designed to increase drug spending but decrease overall medical spending and healthcare utilization. Our research also suggests plans are finding significant value in the insights into improvement in patient management made possible through the data-sharing element of value-based contracts.

“Value-based contracts facilitate trusted relationships between plans and manufacturers that can be the basis for future collaboration.”

John E. Linnehan

Health Plans / 
The availability of new technology solutions to help integrate and analyze data, which can support the development of targeted interventions, has the potential to reduce the administrative burden of value-based contracts, provide better insights into the effectiveness of drugs, and result in additional payments or discounts.

Manufacturers / 
Manufacturers are increasingly recognizing the potential for value-based contracts to demonstrate the value of their products. As acceptance and experience grows, contracts are becoming more complex, making it important for less-experienced life sciences companies to grow their sophistication in this area.

Patients / 
As plans and manufacturers gain experience with value-based contracts, contracts will seek to integrate patient interventions (e.g., adherence solutions, member-facing communications) or enable patients to share in the value attained as part of the contract.
Providers Respond to Alternative Payment Model Incentives; More Change on the Way

Despite political transitions and revisions to Medicare bundled payment programs, the US healthcare system’s transition to alternative payment models (APMs) has remained steady. In 2017, some of the largest commercial plans reported they are running nearly 50% of their medical spend through APMs, with goals to go higher. Even as the Trump Administration shifts away from large-scale mandatory models, the Center for Medicare and Medicaid Innovation (CMMI) is designing new models that will incorporate drugs and Medicare Advantage.

Providers will continue to face pressure to manage costs as more physician reimbursements are paid through APMs. Medicare will push physicians to better manage both cost and quality via the payment penalties included in the Quality Payment Program (QPP). In 2018, these penalties will stiffen with providers being paid based on cost performance for the first time in the program. However, physicians can opt out of MIPS and earn a 5% payment if they participate in an advanced APM. An Avalere simulation found that based on prior performance, non-risk bearing accountable care organizations (ACOs) would stand to earn almost $1 billion in additional payments if they assumed two-sided risk and received the 5% bonus.

CMS is exploring broad options for what counts as an advanced APM, including MA and other bundled payment models. In 2018, the Physician-Focused Payment Model Technical Advisory Committee will continue to recommend physician-designed models to CMS for further implementation, some of which may eventually qualify as an advanced APM.

AAPM Bonus Payment Encourages Providers to Take on Greater Financial Risk

90% of MSSP Track 1 ACOs (372) in 2016 would have benefited from taking financial risk by switching to Track 1 Plus and earning an AAPM bonus.

Net Increase in Payments

- $263M (Shared Losses)
- $30M (Shared Savings)
+ $1.2B (Bonus Payment)

$966M

Avalere simulation of how non-risk bearing Track 1 ACOs in the Medicare Shared Savings Program (MSSP) would have performed if they were to take on risk in the Track 1+ arrangement and were eligible for the advanced alternative payment model (AAPM) bonus payment. Source: Avalere simulation based on MSSP ACO performance data in 2016.
Q: **How should providers get ready for the Quality Payment Program?**
A: CMS is taking a slow, cautious approach to implementation of the Quality Payment Program as they try to give providers time to prepare. CMS is providing clinicians with significant flexibility, but it is clear that providers will need to invest in their IT infrastructure, staffing, and quality-reporting capabilities to succeed in the second year of the Quality Payment Program and beyond.

Q: **What are key areas to watch in 2018?**
A: We expect CMS will continue to develop and expand the set of advanced APMs that will provide clinicians, and particularly specialists, with options to excel. Also, we will be watching how Medicaid programs take advantage of new program flexibilities to implement value-based programs.

Q: **Will shifting CMS priorities affect the move to value-based payment?**
A: It varies by region. In many markets, the momentum in the private sector will keep up the pressure toward value-based payment. In other areas, some organizations will maintain a wait-and-see approach.

“Overall, providers and plans continue to face pressure to move toward value-based payment, though the pace of change may vary by region.”

Josh Seidman

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**Providers /**
Success in APMs will require providers to create better infrastructure for proactive care management, data analytics, and timely integration of disparate data. Provider success will increasingly require care redesign. Mergers, affiliations, partnerships, and joint ventures will also be common.

**Health Plans /**
As value-based payment models grow, the payment environment is becoming more complex for providers. Plans must make it more attractive to providers to accept risk. Plans that support providers in population health management, data reporting, and analytics will have a competitive advantage.

**Manufacturers /**
Manufacturers must focus on selling their products as platform-enabled with associated value-based guarantees. Solutions that can help hospitals avoid complications and readmissions will be of higher value than products that address only one part of the care continuum.
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