Leading in times of change
Health care regulatory outlook 2019
United States
January 2019
This publication is part of the Deloitte Center for Regulatory Strategy, Americas cross-industry series on the year’s top regulatory trends. This annual series provides a forward look at some of the regulatory issues we anticipate will have a significant impact on the market and our clients’ businesses in 2019. The issues outlined in each of the reports provide a starting point for an important dialogue about future regulatory challenges and opportunities to help executives stay ahead of evolving requirements and trends. For 2019, we provide our regulatory perspectives on the following industries and sectors: banking; capital markets; insurance; investment management; energy, resources, & industrials; life sciences; and health care.

We hope you find this document to be helpful as you plan for 2019 and the regulatory changes it may bring. Please feel free to contact us with questions and feedback at CenterRegulatoryStrategyAmericas@deloitte.com.
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Introduction

Health care stakeholders can expect 2019 to be a year of significant regulatory activity as the Trump administration continues to use the rulemaking process to advance some of its key health care priorities. The flurry of regulatory activity from the administration in the final months of 2018 demonstrates the administration’s continued efforts aimed at driving greater adoption of value-based care, addressing rising prescription drug prices, and expanding health coverage options, especially in the individual health insurance markets.

Importantly, the administration is putting forward a variety of regulations and other guidance under each of these three key priority areas. As such, it will be critically important for leaders in the C-suite, as well as those engaged in strategic planning, compliance, and mergers and acquisitions functions, to stay current with the regulations and understand the potential implications for their organizations.

Given the central role of health care in the November 2018 elections, stakeholders could see targeted legislative efforts around health care where a bipartisan compromise could be reached, perhaps most notably around prescription drug pricing and continued expansion of Medicare reimbursement for telemedicine.

At the state level, the election of Democratic governors in Kansas and Wisconsin—states previously led by Republicans—could open the door to legislative negotiations related to Medicaid in states that have not expanded Medicaid under the Affordable Care Act (ACA). In light of the approval of ballot measures to expand Medicaid in Idaho, Nebraska, and Utah, health care stakeholders in other states could explore similar approaches to Medicaid expansion. The prospect of incorporating work requirements or other market-oriented waivers into any Medicaid expansion also could figure into the negotiations at the state level. States will also have a greater opportunity to reshape their individual insurance markets under recent guidance from the Department of Health and Human Services (HHS), including model waiver proposals that could permit ACA subsidies to be used to purchase insurance products like short-term, limited-duration insurance (STLDI) in some cases.

Importantly, health care stakeholders should keep in mind that there is strong bipartisan support for the move away from the fee-for-service reimbursement model and toward value-based payments via alternative payment models (APMs). The administration is poised to continue to roll out new payment models throughout 2019, potentially creating new opportunities for providers, payers, and other service providers to enter into new arrangements aimed at bolstering performance and supporting the administration of these new payment models.
Elections aside, the use of federal authorities to make a strong push for change in health care will continue. While requirements to report quality and other data continue to undergo careful scrutiny to assess whether administrative burdens outweigh their value—rulemakers have shown a dedication to information sharing and quality reporting—they will attempt to do so in as parsimonious a way as possible. The administration has shown an interest in testing new payment and delivery models on a voluntary basis, where possible, but is not averse to making such demonstrations mandatory where merited. At the same time, the Medicare Conditions of Participation and other key points of leverage have the potential to reshape price reporting, interoperability of electronic health records, and other areas of policy.

This outlook will examine at three key areas of interest to health care regulators:

1. Drug pricing
2. Payment models and other significant reimbursement changes
3. The individual insurance market

While regulatory activity in Washington, DC, will direct the approach to value-based care, efforts on drug pricing, and new health coverage options, health plans, providers, investors, and other stakeholders already are making strategic moves in hopes of securing competitive advantages as evolving regulations drive changes in the health care sector. Especially as nontraditional players enter the health care market and help drive further evolution of health care in the future, health plans, providers, and other stakeholders could face new pressure to reevaluate the way they interact with and provide services to their members and patients. Health care stakeholders would be well-advised to keep abreast of such market activity, even as they explore the potential opportunities and risks that the regulatory changes and shifting market dynamics present to their own organizations.
The administration is moving forward on multiple fronts with regulations to address drug prices, even as the leaders of the newly elected Democratic majority in the US House of Representatives and incoming Senate Finance Committee Chairman Chuck Grassley (R-IA) have raised the prospect of legislation on the subject.

The Trump administration has undertaken a series of initiatives to address prescription drug costs since the May 2018 release of a policy report, *American patients first: The Trump administration blueprint to lower drug prices and reduce out-of-pocket costs.*1 The blueprint lays out four strategic areas for drug pricing reform: improved competition, better negotiation, incentives for lower list prices, and lowering out-of-pocket costs.

While a number of regulatory changes in drug pricing have been proposed in 2018, health care stakeholders should be prepared for further regulatory activity on drug pricing in 2019. Looking toward the near term, the administration is poised to release a proposed rule removing the existing anti-kickback safe harbor protection for rebates to plans or pharmacy benefits managers, involving prescription drugs and reformulating safe harbor protections under a new approach. The administration is intent on utilizing market forces wherever possible, especially around price transparency and competition. Prior discussions indicate that new Centers for Medicare and Medicaid Services (CMS) regulation may require explanations of benefits to note drug price increases and available alternatives. In an effort to increase market pressures, the Food and Drug Administration is undergoing a review of its regulatory body to bring new products to market in a shorter time frame and with fewer administrative burdens.

The following issues are already well underway and of particular interest.

**Price transparency in drug ads**

CMS in October 2018 released a proposed rule2 that would require pharmaceutical manufacturers to include the list price for drugs in direct-to-consumer television advertisements. The proposal is intended to reduce prescription drug spending in the federal Medicare and Medicaid programs and to provide consumers with more informed purchasing decisions by way of fostering greater price transparency.

The proposed transparency requirement would apply to all drug and biological products that are reimbursable in any way through Medicare or Medicaid. CMS proposes to exempt drugs that have a wholesale acquisition cost (WAC) of less than $35 for a 30-day supply from the price transparency requirement.

Advertisements would be required to include the list price for a 30-day supply or a typical course of treatment for such a drug.
For the purposes of this rule, the list price is defined as a drug’s WAC, which is set by manufacturers.

**International Pricing Index model**

On October 25, 2018, CMS issued an advance notice of proposed rulemaking (ANPRM) requesting public comment on a series of policies aimed at changing the way Medicare reimburses for Part B drugs, potentially through a proposed model that would more closely align Part B drug prices with an International Pricing Index (IPI) that CMS would develop.

CMS proposes to use the IPI model to test whether higher quality for Medicare beneficiaries and lower drug spending could be achieved in part by gradually reducing the Medicare payment amount for certain Part B drugs to align with international prices and creating a greater role for private sector vendors to negotiate prices for Part B drugs.

CMS estimates that the IPI model would reduce total Medicare spending by $16.3 billion between 2020 and 2025, while also reducing beneficiary cost sharing.

CMS is considering issuing a proposed rule in spring of 2019, with a goal of launching the IPI model in the spring of 2020. Recent statements by Secretary Azar suggest the Trump administration views this demonstration as a policy priority.

**Medicare Advantage, Part D**

In November 2018, CMS released a proposed rule aimed at providing new options for Medicare Advantage organizations and Part D plan sponsors to negotiate lower drug prices.

For example, the proposed rule would implement broader use of prior authorization (PA) and step therapy (ST) for drugs in the six protected classes (antidepressants, antipsychotics, anticonvulsants, immunosuppressants for treatment of transplant rejection, antiretrovirals, and antineoplastics). The proposed rule also would provide conditions under which plans could exclude a protected class drug from a formulary. These changes are intended to give Medicare Advantage and Part D plans greater room to negotiate with manufacturers on formulary placement more in line with standard commercial practices.

Bringing formulary and pricing information to patients is another feature under the proposed rule. Part D plans would need to provide their members’ prescribers comprehensive, real-time, and patient-specific formulary and benefit (F&B) information. F&B information would include a drug’s cost, alternatives within the plan formulary, and any requirements related to utilization management in order to make informed care decisions. The requirement would take effect on January 1, 2020.

At the same time, regulators are aware of potential negative consequences of greater limitations on formularies in some instances. In response, other provisions of the proposed rule would add new consumer safeguards to plans’ use of step therapy for Part B drugs and seek further comment on a potential requirement for plans to administer rebates at the point of sale to members.
Payment models and other significant reimbursement changes

CMS is pushing ahead on multiple fronts in its effort to drive greater participation in value-based payment arrangements via APMs with Medicare, state Medicaid programs, and commercial payers, including Medicare Advantage organizations. This effort could gain momentum as CMS applies payment adjustments under the Medicare Access and CHIP Reauthorization Act (MACRA) for the first time in 2019, especially as leaders of CMS and the Center for Medicare & Medicaid Innovation (the Innovation Center) continue to roll out new APMs and make changes to existing APMs. The launch of additional payment models could present a greater array of opportunities for both plans and providers to define their preferred approach to value-based payment.

MACRA
As CMS moves forward with implementation of MACRA, the agency is raising the performance thresholds under the Merit-based Incentive Payment System (MIPS) for the 2019 performance year. As a result, a greater percentage of clinicians participating in MIPS will face larger negative payment adjustments in 2021, while a lesser percentage of clinicians will qualify for an additional positive payment adjustment for exceptional performance.

Figure 1. Payment updates under MACRA

MACRA offers two distinct incentive payment tracks within the Physician Fee Schedule (PFS): the Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Model (AAPM). Additionally MACRA fixes updates to PFS rates for all future years.

Advanced APMs
- Two-sided risk-based, care coordination models (i.e., Next Generation ACOs, Comprehensive Primary Care Polus (CPCs))
- For Qualifying Participants (QPs), temporary bonuses from 2019–2024 (5% of Medicare PFS payments)
- Use of All-Payer Combination Option to reach AAPM QP status begins in performance year 2019

MIPS
- Clinicians receive a composite score based on performance across four categories
- Budget-neutral payment adjustments are made based on clinician performance, with +/- 4% in 2019 increasing to +/- 9% in 2021
- For 2017, it is reported that approximately 91% of providers eligible for MIPS reported to the Qualified Payment Program (QPP)
The increase in the weight of the Cost measure in MIPS is poised to be an additional challenge for many clinicians. For the 2019 performance year, the MIPS Cost measure will account for 15 percent of the overall MIPS composite score, marking a steady increase toward the 30 percent weight of the MIPS composite score that the Cost measure is required to account for by the 2022 performance year. In addition, the MIPS Composite measure in 2019 will expand to include new episodes of care, meaning that providers will be assessed relative to other MIPS-eligible clinicians based on how efficiently they manage and deliver care for specific clinical episodes.

For other health care stakeholders, the higher performance standards under MIPS and the move away from fee-for-service reimbursement will present opportunities to partner with clinicians on efforts to more effectively monitor and improve performance in the cost and quality performance categories.

Medicare Shared Savings Program Accountable Care Organizations
Beyond implementation of MACRA, CMS is also restructuring the Medicare Shared Savings Program ("Shared Savings Program") to require Accountable Care Organizations (ACOs) to accept downside financial risk after two years, rather than six years. In addition, the final rule discontinues Tracks 1, 1+, and 2 under the Shared Savings Program and similarly discontinues the option for ACOs to renew participation under the old program tracks.

Instead, the Pathways for Success initiative restructures the Shared Savings Program into two tracks:

- **BASIC track**, which allows eligible ACOs to begin under a one-sided risk model and gradually increase to higher levels of financial risk. After two years, the BASIC track is modeled after the existing Shared Savings Program Track 1+.
- **ENHANCED track**, modeled after the existing Shared Savings Program Track 3, which offering additional tools and flexibility for ACOs that take on the highest level of risk and potential shared savings.

Both the BASIC and ENHANCED tracks feature five-year participation agreements. ACOs currently participating in the Shared Savings Program voiced strong opposition to the proposal, but CMS and the Innovation Center policy makers opted to finalize the rule largely as proposed with minor changes that add some flexibility to the program design and time frames. The new Shared Savings Program will take effect July 1, 2019.
In the Medicare Part B final rule for 2019, CMS included a provision that gave Shared Savings Program ACOs with participation agreements that end on December 31, 2018, the option of extending their current participation agreements until June 30, 2019. The policy is intended to give such ACOs the opportunity to stay in the program without a break in participation.

New bundled payment models
Recognizing the limited APM options available for specialists, HHS Secretary Alex Azar in November 2018 said that the administration soon will announce new bundled payment models, potentially focused on cardiac and radiation oncology episodes.

“Real experimentation with episodic bundles requires a willingness to try mandatory models,” Azar said at a conference in Washington, DC, in November 2018. “We’re not going to stop there: We will use all avenues available to us—including mandatory and voluntary episode-based payment models.”

A leading indicator of the scope and nature of new models is the Physician-Focused Payment Model Technical Advisory Committee (PTAC). PTAC was formed under MACRA to make comments and recommendations to HHS on proposals for physician-focused payment models submitted by individuals and stakeholder entities, many of which represent medical specialists. To date, no PTAC models have emerged as APMs, but Congress and nongovernment stakeholders have shown particular interest in ensuring that PTAC models receive greater consideration by regulators. To keep ahead of the trends in new payment models, it is prudent to monitor developments from PTAC.9

Revisiting reimbursement
The administration is taking a new approach to several areas of government program reimbursement of particular interest to hospitals.

First, CMS elected to retain its policy to issue lower Medicare Part B payments for 340B-covered outpatient drugs administered by most hospitals from the standard rate of average sales price (ASP) plus 6 percent to ASP minus 22.5 percent for most hospital-affiliated providers. Changes to the classes of providers affected by this policy, as well as the amount of the payment reduction, may be reviewed in future years.

Second, site neutrality remains a prevalent regulatory theme. As a result of statutory changes, off-campus provider-based departments (PBDs) that were acquired by a hospital after November 1, 2015 (“nonexcepted” PBDs) are paid a modified Physician Fee Schedule. In prior rulemaking, CMS set that rate at roughly 40 percent of Hospital Outpatient Prospective Payment System rates. Additionally, for 2019, CMS will apply the reduced 340B reimbursement rates for this class of PBDs as well. Looking toward to future rulemaking, CMS indicated that it may revisit a proposed policy to restrict the grandfathered (“excepted”) PBDs to the families of clinical services they provided prior to the enactment of the site-neutrality policy in November 2015.

Last, while the Medicare Conditions of Participation have long required hospitals to make their standard charges public information, new conditions for 2019 will require hospitals to publish that information online and in a machine-readable format, so that CMS or third-party vendors can use that data for consumer comparison and research purposes. Requests for comment in recent rules suggest that CMS will pursue policies in the near future to make the information as useful as possible to consumers, such as requiring hospitals to post the average charges across all payers, or organizing the charges into common procedure categories.
A key policy objective of the Trump administration is to provide more options for health coverage in the individual market, particularly in making lower-premium options more readily available. The administration's efforts on this topic largely have been driven by an executive order that President Trump issued on October 12, 2017, directing the Departments of Health & Human Services, Labor, and the Treasury (collectively, “the Departments”) to issue regulations or guidance to expand the availability of other coverage options.

State regulators will be expected to play a greater role in many areas of health care regulation. Recent rulemaking encourages states to operate their own ACA Exchanges instead of defaulting to the federal platform, while states will have far greater latitude to define the specifics of essential health benefits covered by ACA-compliant plans. At the same time, states will play an important role in how federal tax credits and other subsidies under the ACA are allocated, while also determining whether or how new offerings such as Association Health Plans (AHPs) and STLDI are available to consumers in their markets.

Figure 2. The world according to the Congressional Budget Office (CBO): Will the world actually look like this in 2028?

Projected sources of health coverage, 2018 vs. 2028 (millions of Americans)

While the administration moves forward with regulations focused on rules governing insurance markets and coverage options, CMS also is laying the groundwork for states to seek waivers under Section 1332 of the ACA that would provide federal funds for new insurance coverage options that are not required to meet ACA insurance market reforms.13 Recent guidance on 1332 waivers grants states far greater latitude in the use of federal funds for alternative insurance products, reimbursement, or variations in benefit and subsidy structures.

Just as states will determine whether to seek such waivers from CMS, states also can adopt laws or other rules that restrict the availability of the new coverage options now available under federal regulations. This could result in a greater variety of insurance products being available from one state to another.

**Association Health Plans**

In June 2018, the administration in June 2018 finalized a rule13 that will make it possible for more small employers and their employees to join AHPs, which generally are considered large group health plans that are not subject to insurance market requirements for small-group and nongroup health insurance products that were enacted as part of the ACA. For example, AHPs will be exempt from requirements for small-group and individual market policies to cover the ACA’s 10 essential health benefits.

The final rule provided for all associations, new or existing, to be able to establish a fully insured AHP beginning September 1, 2018, while delaying the availability of self-insured AHPs. Existing associations that established an AHP on or before the publication date of the final rule (June 21, 2018) are permitted to establish a self-insured AHP beginning January 1, 2019, while all other associations will be permitted to establish a self-insured AHP beginning April 1, 2019.

The final rule cited a May 2018 Congressional Budget Office (CBO) report14 projecting that enrollment in AHPs will total 4 million by 2023. Of the 4 million, 400,000 enrollees otherwise would have been uninsured, and 3.6 million would have been enrolled in other types of coverage.

A lawsuit challenging the final rule has been filed by the attorneys general for 11 states and the District of Columbia. The American Medical Association and a group of nine House Democrats led by Nancy Pelosi (D-CA) have filed briefs in support of the legal challenge to the AHP rule.

**Short-term, limited-duration insurance**

A final rule15 issued in August 2018 lengthened the maximum period of STLDI coverage, allowing policy durations of up to 12 months, and provided options to renew such policies for up to 36 months. A 2016 rule had strictly limited STLDI coverage to fewer than three months. The rule took effect on October 4, 2018.

The Departments estimate that in 2019, STLDI enrollment will increase by 600,000, with Exchange enrollment decreasing by 200,000, and off-Exchange plan enrollment decreasing by 300,000. An additional 100,000 previously uninsured individuals are projected to acquire STLDI coverage.

Twenty states have existing rules limiting the duration or placing other limits to STLDI coverage. Duration limitations are typically in the range of 90 days to six months. Some of those states—Maryland, Oregon, Vermont, and Washington—recently restricted STLDI coverage to 90 days, while California, Massachusetts, New York, and New Jersey prohibit the sale of STLDI plans altogether.16

**Health reimbursement arrangements**

In October 2018, the Departments released a notice of proposed rulemaking (NPRM)17 aimed at expanding the availability of health reimbursement arrangements (HRAs), principally by permitting HRAs to be used to purchase health insurance on the individual market.

An HRA is an account-based group health plan funded entirely by employer contributions that reimburse an employee for medical care expenses incurred by the employee, their spouse, or dependents up to a maximum dollar amount for a coverage period. Similar to employer-sponsored coverage, HRA funds are exempt from federal taxes, placing them on equal footing with traditional coverage as an option for employers. The proposed changes to HRAs could have significant impacts on employer-sponsored coverage, allowing it to change from a defined benefit to a defined contribution model.

The NPRM would remove the current prohibitions against integrating an HRA with individual health insurance coverage and would set forth the conditions under which employers could offer HRAs that could be integrated with individual health insurance either via an ACA Exchange or off the Exchange in the individual market of a state. Of note, HRAs integrated with individual coverage would be available only for the purchase of individual coverage meeting ACA standards, meaning that such funds could not be used to purchase STLDI.
Under the NPRM, employers would be permitted to offer HRAs that could be integrated with individual health coverage to employees so long as the HRA was offered to all employees in the same employee class. Importantly, the NPRM would prohibit an employer from offering a class of employees both a traditional group health plan and an HRA integrated with individual health insurance coverage in order to reduce adverse selection.

Employees would be required to demonstrate that they have purchased ACA-compliant individual coverage as a condition of participation in an HRA integrated with individual coverage.

The NPRM also outlines conditions for employers to offer HRAs as excepted benefits alongside traditional employer-sponsored group coverage. Employer contributions to HRAs used for excepted benefits would be limited to $1,800 annually under the proposal.

If finalized, the proposed changes would take effect for plan years beginning on or after January 1, 2020. The Departments estimate that about 1 million individuals would receive an HRA integrated with individual coverage in 2020 and roughly 800,000 employers would provide HRAs covering 10.7 million individuals by 2028. Enrollment in group health coverage is projected to fall by about 0.4 percent in 2020 and by 4.5 percent by 2028 if the proposals are finalized.

**State relief and empowerment waivers**

In October 2018, the Departments provided updated guidance in the context of changes in the individual insurance markets since 2015 and as part of a larger effort to provide greater flexibility to the states. The guidance is applicable beginning October 22, 2018. CMS followed up in November 2018 with the release of a set of waiver concepts to give examples of how states can take advantage of waivers and to spur further state innovations. The four waiver concepts outlined in the guidance are:

- **Account-based subsidies**, which would allow states to direct public subsidies into a defined contribution, consumer-directed account that an individual uses to pay for health insurance premiums or other health care expenses

- **State-specific premium assistance**, which would allow states to create a new, state-administered subsidy program in place of federally run premium assistance tax credits

- **Adjusted plan options**, which would permit states to provide financial assistance for different types of health insurance plans, including nonqualified health plans

- **Risk stabilization strategies**, which give states more flexibility to implement reinsurance programs or high-risk pools

It will be important for health care stakeholders to closely monitor state decisions related to new coverage options or about pursuing new waivers, both in terms of implications for existing operations and potential opportunities for new products or business opportunities.
Conclusion

The Trump administration is moving forward with a health care regulatory agenda aimed at achieving greater price transparency, expanding consumer choice, and driving regulatory decisions to the state level. Below are implications for industry.

**Drug pricing**

**Providers**

Direct-to-consumer advertising and Part D and Medicare Advantage explanations of benefits with price information will require providers at all levels to be better prepared to discuss the prices of the therapies they prescribe. Increased use of formulary placement and step therapy for Part D and Medicare Advantage plans will mean that providers will also need to become more familiar with patients’ benefits as they make prescribing decisions. The IPI proposal would require Part B prescribers to seek out third-party vendors instead of directly billing Medicare.

**Life sciences**

Although many of the implications of the administration’s regulatory push around drug pricing are intuitive, certain secondary effects may be less so. For example, drug manufacturers will need to take a new look at the product usage patterns for Part D and Medicare Advantage beneficiaries with added scrutiny in order to ascertain which of the products they market are likely to be subject to utilization restrictions such as prior authorization, step therapy, and formulary placement.

The Trump administration has expressed particular interest in Part B drugs, suggesting an expanded role for pharmacy benefits management and other intermediaries in price negotiations. Competitive bidding for Part B drugs appears to be part of the program’s future, however the details are worked out.

From a wider view, pricing will no longer be simply between the drug manufacturer and the payer, but will increasingly be subject to consumer scrutiny, as well as more accessible information on a drug’s therapeutic equivalents or alternatives within a particular class.

**Payment models and other significant reimbursement changes**

**Providers**

MACRA is at a midpoint in its rollout, with payment adjustments increasing to plus or minus 7 percent for the 2019 performance year, and Physician Fee Schedule increases held flat for several years to come. MIPS payment adjustments from the 2017 performance year will be applied to 2019 payments, giving a new sense of urgency to MACRA’s quality and other reporting requirements.

On balance, alternative payment models that require providers to take on risk may look like a better bet, especially as participation thresholds become easier to meet with the introduction of other payer APMs from the commercial and Medicaid sectors.

At the same time, the Medicare Shared Savings Program, which oversees many qualifying APMs, will require a shorter timeline for provider groups like ACOs to take on meaningful levels of risk. For specialist providers, new payment models that target their practices may become available in the near future, increasing their options for how to respond to MACRA’s incentives.

Site neutrality and pressures on 340B revenue will pose challenges to many hospitals and hospital-affiliated providers’ revenue strategies. Without the old incentives for hospitals to acquire independent practices, the payment environment will still require deeper integration, suggesting a trend away from mergers and acquisitions and toward collaborative ventures and agreements between hospitals and nonhospital providers.

**Insurers**

Commercial insurance is set to play an important role in realizing the ultimate vision of MACRA, where the vast majority of both public and private reimbursement occurs under risk-bearing arrangements. Many providers will look to a commercial counterpart to meet the APM thresholds through commercial, Medicaid Managed Care, and Medicare Advantage payments. Insurance plans can differentiate their offerings to providers by standing ready to help them meet their growing needs.
to report data or engage with alternative payments under MACRA.

**Life sciences**
Moving away from fee-for-service and toward risk-bearing alternative payment models will place a far greater emphasis on the total cost of care for both payers and providers. Life sciences entities should be ready to join in discussions around patient attribution, performance measures, and shared risk, offering solutions to help payers and providers to assess their products’ value and their relative contribution to clinical outcomes.

**Individual insurance market**

**Providers**
As more patients present with a greater array of insurance coverage, including STLDI, various health savings account arrangements, and direct self-pay, accounts receivable operations will grow in complexity, with revenue optimization strategies becoming even more important than they are today.

**Insurers**
The availability of new plan options such as STLDI, AHPs, and HRAs will make for challenging decisions around the viability of state and local individual insurance markets. On one hand, new flexibilities in plan design and underwriting should allow insurers to more carefully tailor their products to local demand. On the other hand, the ACA’s individual plans may see more enrollment from individuals whose employer opted to establish HRAs in lieu of offering coverage directly. Even for insurance carriers with more extensive exposure to the employer-sponsored market, new options for employers will require a strategic response when it comes time to renegotiate for open enrollment.

The open-ended nature of the new ACA Section 1332 waiver guidance means that states may take new and surprising directions in reformulating their individual insurance markets. Federal subsidies may take on a new form, as may benefits structures and the types of coverage receiving those subsidies. Likewise, reinsurance may make risk in the community-rated individual insurance markets more manageable in a greater number of states. All of these changes would occur with more federal money in play due to the administration’s inclusion of IRS and other federal expenses in the pool of money available to states in designing a waiver.

In the end, insurance plans would be well advised to watch state and employer decisions in regard to what products will be available for sale, and the risk and demographic makeup of new entrants to the individual insurance market.

**Life sciences**
The rise of consumer choice both within the individual insurance market and elsewhere will add a new dimension to life sciences entities’ marketing and education efforts. Consumers with high deductibles, health savings accounts, and highly variable forms of coverage will be more discerning than before. The combination of patient responsibility and price transparency means that life sciences entities will now need to demonstrate their value not only to payers and providers, but also to the end user.

As always, regulation in health care remains a balancing act between the voluntary and mandatory, the granting of greater and lesser flexibility to industry, and in maintaining adequate reporting without adding too greatly to administrative duties. Taken with administration themes of transparency, choice, state control, and judicious use of federal authority, a coherent picture for health care is emerging.
Endnotes


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