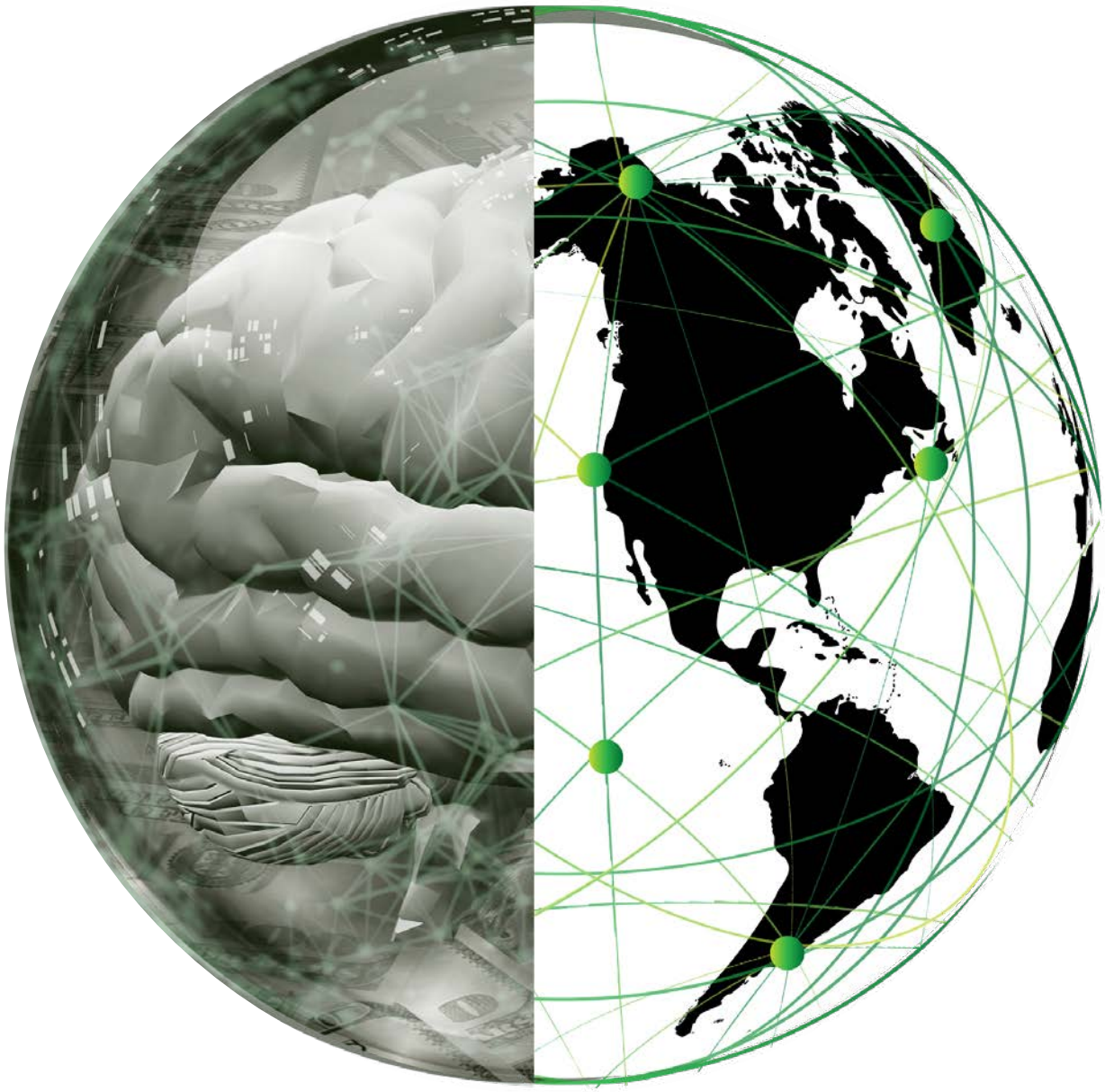
Deloitte.



2020 health care regulatory outlook

Get started

CENTER *for*
REGULATORY
STRATEGY
AMERICAS

Contents

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 likely have a significant impact on the market and our clients' businesses in 2020. 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 2020, we provide our regulatory perspectives on the following industries and sectors: banking; capital markets; insurance; investment management; energy, resources, and industrials; life sciences; and health care.

We hope you find this document to be helpful as you plan for 2020 and the regulatory changes it may bring. Please feel free to contact us with questions and feedback at CenterRegulatoryStrategyAmericas@deloitte.com.

Introduction

With the increasing prevalence of technology around the globe, the status quo is no longer an option. To keep up with the pace of change, the health care industry should continue evolving its approach to keep up with the myriad of challenges that it is facing, and more importantly, the opportunities that it can take advantage of in this fourth industrial revolution. Regulatory, legal, and compliance functions are being asked to do more with less while grappling with new and emerging challenges that stem from the near-ubiquitous use of advanced technologies to meet the increasing cost pressures and need to deliver value beyond the limitations of traditional approaches to testing, monitoring, analysis, and supervision.

In this digital world, new threats are emerging along with new laws and regulations to help protect consumers and the markets. Regulators, both domestic and foreign, are focused on data privacy protections to mitigate the risks that result from improper collection, handling, storage, and use of data. Cyber threats continue to become more sophisticated and more damaging, putting even more urgency around developing protections from bad actors, both external and internal.

Against this backdrop, health care companies should continue to modernize and rationalize their regulatory, legal, and compliance functions and their practices. Health care organizations that take a broad view of regulatory risk management can find efficiencies that lead to streamlined and rationalized programs. A modernized compliance function can help achieve compliance as efficiently and effectively as possible by "thinking forward" and then harnessing leading compliance practices and technologies to comply with current and future regulatory requirements. Some companies are even looking at their regulatory and compliance risk management programs as a competitive differentiator that enables them to be more nimble in the marketplace.

Regardless of how the changes promulgated by lawmakers and regulators affect health care organizations, it is imperative that they continue to modernize and rationalize their regulatory, legal, and compliance risk management programs so that they can meet applicable laws, regulations, and oversight and monitoring expectations in a sustainable, efficient, and cost-effective way.

Changes to drug pricing from the health care industry perspective

Over the past decade, regulators and the market have pushed health care payers and providers to look at the total cost of care through value-based payment arrangements, but have largely left drugs out of the equation.

With the growing understanding that a sizeable proportion of overall health care costs are attributable to drugs, several forces are beginning to challenge the old paradigm that maintained a distance between drug pricing and other aspects of health care finance and delivery. Over the coming years, drug pricing is likely to undergo changes, along with a redistribution of risk that will have significant implications for health care payers and providers alike.

With payers and providers experiencing greater regulatory pressure to more attentively consider limits on price increases for drugs in the transition away from fee-for-service (FFS), intermediaries along the pharmaceutical supply chain, such as pharmacy benefit managers (PBMs), may have a unique opportunity to recharacterize their relationships with payers and providers. The introduction of value-based payment to drug pricing means that PBMs in particular will need to demonstrate their capabilities to negotiate in terms of clinical value, not simply price concessions, therefore assuring their position as an essential part of a changing health care ecosystem focused both on managing drug prices and delivering high-quality care.

The demand for change

Since 2000, the contribution of drugs to overall health spending in the United States has held fairly constant, fluctuating between 11 and 12 percent; but with health care costs outstripping other growth measures, drug spending has grown from 1.5 percent of gross domestic product to more than 2 percent over the same time period, with per capita spending growing from about $540 in 2000 to $1,220 in 2017.[1]

New drug and biologic therapies are increasingly focused on breakthroughs affecting an ever-smaller proportion of the population, meaning that their development expenses and revenue expectations are spread over a smaller group of individuals. The narrow focus has generated a revolution in cancer and immunological treatments, in addition to many other disease categories, but it has come with an added strain on consumers, while the addition of a high-cost drug to the care they underwrite increases uncertainty in actuarial planning for payers. If viewed as a stand-alone cost, many new drugs are not only expensive, but their costs are also front-loaded. If the drug cures a disease or otherwise improves patient lives, it can be shown to be worth the cost, both financially and personally, when viewed holistically. For these reasons, the value proposition for drugs is increasingly viewed by payers and providers in the context of an overall treatment plan.

For all the clinical successes that have emerged from the biopharmaceutical industry in recent years, there are many more conditions for which effective treatments have not yet been discovered, while at the same time, each new discovery comes at a high price. Out of this tension has emerged a virtual consensus among policy makers that incentives for new drug discoveries are needed, along with ways to manage the costs of those discoveries. The challenge to balance these goals will fall not only on life sciences companies, but also equally on health care payers, providers and PBMs, and others in the distribution channel. Just as FFS care loses clout, the old "fee-for-pill" pricing structure likely will as well. Payers will need to become better arbiters of value, while providers will need to include drugs as part of their own value propositions for an episode of care. With all the political uncertainty in play, one trend is clear: Value-based contracting (VBC) is coming to drugs, and with it will come far greater involvement on the part of payers and providers, as well as manufacturers.

A range of legislative possibilities

The US House and Senate are considering bills that have wide-reaching effects, both with significant impacts for Medicare Parts B and D. For most new drugs that use wholesale acquisition cost (WAC) as the benchmark for pricing, the proposed changes to the bill[2] lower the WAC add-on payments and place a cap on the total amount, though biosimilars would receive an added five-year incentive payment. Overall price increases for Medicare drugs would be limited to inflation. The House bill[3] uses an inflation cap as well, but makes it retroactive to 2016. Both bills make changes to

Part D, lowering the government's responsibility for drug coverage in the catastrophic phase and placing a large proportion of that responsibility on the Part D plans.

Regarding general changes to pricing, the Senate bill would establish new price transparency requirements around price increases, while the House bill would implement direct price negotiations for Medicare and require that manufacturers offer the same rates to commercial plans.

The Senate bill also addresses Medicaid outpatient drugs, with new federal audits for manufacturers and wholesalers, as well as eliminating "spread pricing" arrangements that allow PBMs and other intermediaries to charge a health plan a different amount than the price they negotiated from the manufacturer.

The range of legislative possibilities is considerable, and the common ground across the aisle shows the potential for a comprehensive bill with meaningful impacts on payers and providers. Nevertheless,

Table 1. Proposed drug pricing legislation

	Senate: Prescription Drug Pricing Reduction Act (PDPRA) of 2019	**House: H.R.3:** To establish a fair price negotiation program
Medicare Part B	• Average sales price includes value of coupons in calculation • Lower wholesale acquisition cost (WAC) add-on +3%, max of $1,000 in all cases • WAC +8% for biosimilars for five years, other incentives • Rebates to Medicare for drug increases above inflation (CPI-U)	• Part B and D inflation-based rebates back to government, retroactive to 2016 • Consider redirecting federal savings to vision, hearing, dental benefits, and improvements for low-income beneficiaries
Medicare Part D	• $415 enrollee deductible, then 25% enrollee cost sharing to catastrophic threshold of $3,100, then manufacturer pays 20%, plan pays 60%, Medicare pays 20%. • Publication of rebate data and price disclosures • Insurer audits of PBM-manufacturer contracts, reporting of findings • Rebates for brand-name list price increase above inflation (CPI-U)	• Manufacturers pay 10% before catastrophic phase • Catastrophic threshold of $2,000 • In the catastrophic phase: – Government reinsurance from 80% to 20% – Plan responsibility from 20% to 50% – Manufacturer responsibility from 0% to 30%
Commercial/ general	• Reporting and justification of WAC price increases, public posting • Strengthening of exclusions of sanctioned persons or entities from federal programs	• 250 drugs without price competition identified, minimum of 25 subject to negotiation • Maximum fair price of 120% of weighted average prices from Australia, Canada, France, Germany, Japan, and United Kingdom • Quarterly increasing penalties for manufacturers that do not negotiate, up to 95% of annual gross sales • Would apply to MA, Part D, and required to be offered to commercial market
Medicaid	• New program requirements around state of pharmacy and therapeutics committees, limits of conflicts of interest for members of drug use review boards • Federal audits of price and product information for manufacturers and wholesalers • Pass-through pricing for all Medicaid outpatient drugs, eliminating spread pricing • Increase maximum rebate amounts to 125% of average manufacturer price (AMP). Rebates extended to drugs in bundled payment	• No specific provisions

today's political environment is complex, somewhat clouding the outlook for major legislation on drug prices in the near term.

Even with all the uncertainty around whether drug pricing legislation will be signed into law, enough changes are afoot among regulators and within the market itself to bring drug prices closer to other areas of health care finance and delivery. Health care payers and providers should carefully consider how drugs and drug pricing fit into their overall business strategies.

State-level policy

States are emerging as the drivers behind ongoing deliberations and changes to drug pricing rules. State price transparency reporting legislation generally focuses on delivering specific commercial or statutory prices to the state in a prescribed manner and timing. Each new law will require documentation, processes, and controls to enable reliable and consistent price reporting and may trigger state oversight in certain circumstances.

While many of these laws' most direct impacts are on drug manufacturers, a number of states have enacted laws that require disclosures of rebate and other contractual agreements between PBMs, plans, providers, pharmacies, and other stakeholders in health care. State-level drug pricing laws that bring transparency to the relationships along the biopharmaceutical supply chain will have significant impacts, most notably for provider relationships with manufacturers and payer relationships with manufacturers and PBMs.

For example, California recently passed laws requiring public disclosures of price increases, adding drug prices as a separate factor in insurance plan rate review and also requiring pharmacies to offer the lesser of the retail price for a drug or the plan's negotiated price. Likewise, California's elimination of drug discount coupons brings an entirely new set of considerations for health plan formulary decisions.[4] More drug pricing bills are now under consideration in statehouses across the country. Each state will likely take a different approach to its interventions on drug pricing, and each will require different strategies on the part of payers, providers, PBMs, and others involved in health care finance and delivery.

Regulatory changes

Over the past two years, the administration has made a concerted effort to address the growth of drug prices; for example, 2018 rulemaking[5] granted new latitude for Part D plan sponsors to negotiate with drug manufacturers for formulary placement. In 2019, the Centers for Medicare & Medicaid Services (CMS) began to allow for "step therapy" for Part B drugs, albeit with a somewhat more limited scope than what was initially proposed.[6]

In some instances, the administration has reconsidered its stance based on comments, as illustrated in its decision to retract a proposed rule to remove safe harbors for most PBM rebate arrangements. The decision was based in large part on the policy's potential impacts on Part D premiums, which many commenters projected to increase as a result of the policy while reducing out-of-pocket costs for a smaller subset of beneficiaries that spend more on drugs.[7] Beyond this particular proposal, any change to rebates would have major impacts on the reimbursement model for drugs, with reimbursement incentives pointed more heavily toward outcomes and value-based generation.

Reference pricing

Despite an incrementalistic regulatory approach, bigger regulatory changes are possible in the near future. In 2018, CMS issued an Advanced Notice of Proposed Rulemaking (ANPRM)[8] establishing a demonstration project to set an International Pricing Index (IPI) for Part B drugs across 50 percent of the country, which indicates a willingness among CMS officials to take bold steps. In view of IPI or other reference pricing models emerging in both regulation and legislation, it is advisable to remain aware that this major change has several viable paths to taking effect.

Value-based contracting (VBC)

Of all changes underway, the advent of VBC for drugs has the greatest impact on payers and providers. At the same time, current regulation promulgated under the anti-kickback statute (AKS) limits such arrangements between payers and drug manufacturers, but federal regulators are currently considering changes that would allow for broader implementation of VBC.[9] It is unclear exactly how such a plan will take shape, but in the interim, Medicaid State Plans offer a good test case for how VBC for can become a part of the bigger picture of outcomes-based reimbursement.

Oklahoma was one of the first states to receive approval from CMS to enter into VBC payment arrangements with drug manufacturers. Under the Oklahoma State Plan Amendment (SPA), manufacturers can agree to pay added rebates to the state if patients are hospitalized for the condition their product is intended to treat, or if a drug does not meet established clinical benchmarks.[10] Since the Oklahoma approval, Michigan[11] and Colorado[12] have had similar SPA language approved by CMS, with other states showing interest. Drug manufacturers are usually only willing to enter into a VBC with clinical benchmarks if they can have some guarantee that the patients will be treated according to their specifications. For that reason, Medicaid programs are becoming increasingly involved in ensuring that drugs are administered correctly, with follow-on impact on their relationships with providers.

Louisiana's[13] and Washington state's[14] subscription-based capped financing model for hepatitis C drugs gives the states significant negotiating power by entering into a bidding process with competing manufacturers. Of greater importance to providers is that a capped financing model gives states (or other payers) clear incentives to ensure adherence to drug regimens that have a high cure rate when used correctly. Under these arrangements, Medicaid managed care organizations can face their own incentives to ensure adherence, put in place by the state and the manufacturers themselves.

Figure 1. Stakeholder implications for reference pricing proposals

Payer
Commercial peg would be significant in reducing costs

PBM
Less value and margin potential due to broader controls on price

Provider
Accelerate shift of drug administration to hospital outpatient facilities

Patient
Potential to significantly reduce prices paid by consumers, though indirect costs (such as lower innovation) obscured

Stakeholder implications for VBC

A clear trend among the states is that policy makers are no longer settling for the mandated rebates under the Medicaid Drug Rebate Program and are choosing to enter into their own agreements with drug manufacturers themselves. Drug manufacturers will be required to stand behind the value propositions of their products, but in order to do so, they will require downstream payers and providers to be more closely involved in their products' administration.

Value-based care (VBC) incentivizes payers and providers to consider drug costs and efficacy to improve results by way of adjusting actuarial pricing models and driving positive health outcomes. By rethinking their business model, PBMs can transform their relationships with payers and providers to more closely align with their mutual interests. For example, PBMs can leverage population health data to perform assessments and design highly tailored formularies that most effectively treat specific populations at the most appropriate cost. If approached strategically and with a willingness to offer novel approaches focused on population-customized, cost-effective, and patient-oriented formularies, PBMs could repurpose their relationships with payers and providers and enable systemwide success in value-based care.

Bundled payments

Payers offering advanced alternative payment methods and providers organizing into accountable care organizations (ACOs) are growing interested in including drug costs as part of their outcomes-based payment structures. The CMS Center for Medicare and Medicaid Innovation's (CMMI) Oncology Care Model[15] has focused on episodes of care surrounding chemotherapy treatments, but contains clinical benchmarks that encourage full adherence to treatment protocols.

Regulators are focused on Part B drugs as a target for innovative payment methods. The IPI proposal discussed above establishes an international reference price, but perhaps more importantly, it establishes a vendor bidding arrangement that could lead to shared savings arrangements similar to what is seen in nondrug accountable care arrangements. For Part D, the 2019 overhaul of the Medicare Shared Savings Program's ACO models encourages beneficiary incentives for drug adherence and contains a request for information on how Part D plans can more closely align with Medicare ACOs.

Figure 2. Stakeholder implications for VBC

Payer
Increased leverage to reduce prices on select drugs

PBM
Fee models may need to evolve, but impact may be limited

Provider
Impact most prominent where outcomes are included in payment models (for example, cardiovascular and diabetes)

Patient
Improved outcomes and appropriate costs

Figure 3. Stakeholder implications for bundled payments in Part B

Payer
Slightly reduced burden for government payers, though restricted in scope to Part B expenditures

PBM
Moderating effect to pricing and margins, but may not be applicable depending on plan design (medical coverage only)

Provider
Reduces reimbursement and margin potential and thus decreased incentive to prescribe highest-price options

Patient
Reduced prices for those facing cost share, but limited impact due to medical benefit coverage

Preparing for the future

In health care, value-based contracting and bundled payments create dependencies among actors that have traditionally operated independently of, or even in competition with, one another. Changes in the payment incentive structures for drug pricing mean that many players along the drug supply chain, from manufacturers to PBMs to plans, providers, and the patients themselves, will see a strategic shift.

With federal programs such as ACA exchange and Medicare, as well as state Medicaid programs, all moving past accepting a rebate price for a drug, other payers are likely to follow suit, provided that regulators make the necessary changes. If a demonstrated track record of success among public payers becomes apparent, there may be a quick and decisive push toward replicating these efforts in the commercial environment. All this means that PBMs' traditional roles in negotiating rebates on behalf of a payer may undergo a sector-wide change as well, likely shifting toward flat bona fide service fees and eventually involving PBMs in the care management decisions at the root of VBC arrangements.

Let's talk

Tom Delegram
Managing Director
Deloitte Risk & Financial Advisory
Deloitte & Touche LLP
tdelegram@deloitte.com

Andy Hollinden
Manager
Deloitte Risk & Financial Advisory
Deloitte & Touche LLP
ahollinden@deloitte.com

Jim Recupero
Manager
Deloitte Risk & Financial Advisory
Deloitte & Touche LLP
jrecupero@deloitte.com

1. Organisation for Economic Co-operation and Development (OECD), "Pharmaceutical spending," https://data.oecd.org/healthres/pharmaceutical-spending.htm.
2. S.2543: Prescription Drug Pricing Reduction Act of 2019, https://www.congress.gov/bill/116th-congress/senate-bill/2543/; https://www.finance.senate.gov/imo/media/doc/FINAL%20Description%20of%20the%20Chairman's%20Mark%20for%20the%20Prescription%20Drug%20Pricing%20Reduction%20Act%20of%202019.pdf.
3. H.R.3: Lower Drug Costs Now Act of 2019, https://www.congress.gov/bill/116th-congress/house-bill/3/text.
4. OECD, "Pharmaceutical spending," https://data.oecd.org/healthres/pharmaceutical-spending.htm.
5. S.2543: Prescription Drug Pricing Reduction Act of 2019..
6. H.R.3: Lower Drug Costs Now Act of 2019.
7. LexisNexis State Net, CA S 17: Health Care: Prescription Drug Costs, http://custom.statenet.com/public/resources.cgi?id=ID:bill:CA2017000S17; CA A 315: Pharmacy Benefit Management, http://custom.statenet.com/public/resources.cgi?id=ID:bill:CA2017000A315; CA A 265: Prescription drugs: prohibition on price discount, https://custom.statenet.com/public/resources.cgi?id=ID:bill:CA2017000A265.
8. Centers for Medicare & Medicaid Services (CMS), "CMS provides new flexibility to increase prescription drug choices and strengthen negotiation for Medicare enrollees," August 29, 2018, https://www.cms.gov/newsroom/press-releases/cms-provides-new-flexibility-increase-prescription-drug-choices-and-strengthen-negotiation-medicare.
9. CMS, *Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses, Federal Register*, May 23, 2019, https://www.federalregister.gov/documents/2019/05/23/2019-10521/modernizing-part-d-and-medicare-advantage-to-lower-drug-prices-and-reduce-out-of-pocket-expenses.
10. US Department of Health and Human Services (HHS), *Withdrawal of Proposed Rule "Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbor Under the Anti-Kickback Statute for Waiver of Beneficiary Coinsurance and Deductible Amounts, Federal Register*, August 2, 2019, https://www.federalregister.gov/documents/2019/08/02/2019-16346/withdrawal-of-proposed-rule-medicare-and-state-health-care-programs-fraud-and-abuse-safe-harbor.
11. CMS, *ANPRM International Pricing Index Model for Medicare Part B Drugs, Federal Register*, October 30, 2018, https://www.federalregister.gov/documents/2018/10/30/2018-23688/medicare-program-international-pricing-index-model-for-medicare-part-b-drugs.
12. HHS, *Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP, Federal Register*, August 27, 2018, https://www.federalregister.gov/documents/2018/08/27/2018-18519/medicare-and-state-health-care-programs-fraud-and-abuse-request-for-information-regarding-the.
13. CMS, "CMS Approves State Proposal to Advance Specific Medicaid Value-Based Arrangements with Drug Makers," June 27, 2018, https://www.cms.gov/newsroom/press-releases/cms-approves-state-proposal-advance-specific-medicaid-value-based-arrangements-drug-makers; *Oklahoma State Plan Amendment*, https://www.medicaid.gov/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/OK/OK-18-08.pdf.
14. CMS, *Michigan State Plan Amendment*, https://www.medicaid.gov/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/MI/MI-18-0009.pdf.
15. CMS, *Colorado State Plan Amendment*, https://www.medicaid.gov/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/CO/CO-18-0044.pdf.

The individual insurance market

In 2019, the administration issued a final rule on health reimbursement arrangements,[1] the last in a series of regulatory actions taken in response to an executive order signed by President Trump on October 12, 2017.

The executive order directed federal agencies to revisit regulations on association health plans (AHPs), short-term limited duration insurance (STLDI), and health reimbursement arrangements (HRAs). These rules are part of a larger effort to increase competition and expand the availability of lower-premium coverage options.

The administration issued final rules on AHPs and STLDI in 2018, but some states have banned or otherwise limited access to them, resulting in greater variation in the types of insurance products available from state to state.

HRAs

On June 13, 2019, the Departments of Health and Human Services, Treasury, and Labor (collectively, the agencies) issued a final rule that expands the availability of 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 reimburses an employee for medical care expenses incurred by the employee, their spouse, or dependents, up to a maximum dollar amount for a coverage period.

In the October 2018 proposed rule on HRAs, the agencies explained that the regulatory changes aim to promote "individually-selected and portable health insurance coverage" while effectively extending the "tax advantage for traditional employer group insurance (exclusion of premiums and benefits received from federal income and payroll taxes) to HRA reimbursements of individual market insurance market premiums."

To achieve this goal, the agencies modified regulations and other guidance related to the Affordable Care Act (ACA) and amendments to the Employee Retirement and Income Security Act (ERISA), Public Health Services Act (PHSA), and Internal Revenue Code (IRC) made by the ACA. The agencies, respectively, have jurisdiction over each of these laws, hence the tri-agency rule.

The rule also outlines conditions for employers to offer limited HRAs as excepted benefits alongside traditional employer-sponsored group coverage.

The new rule took effect for plan years beginning after January 1, 2020. The agencies estimate that about 1 million individuals would receive an HRA integrated with individual coverage in 2020 and that roughly 800,000 employers would provide HRAs covering more than 11 million individuals by 2029, including about 800,000 individuals who would otherwise be uninsured.

Where the individual market is headed

As access to HRAs integrated with individual coverage expands, it will be important for health plans to evaluate their product offerings, especially if employers make HRAs a larger focus of their employee benefits strategies.

Similarly, providers will want to evaluate how growth in HRA enrollment might affect individuals' out-of-pocket health care spending (that is, whether individuals shopping for themselves in the individual market are more likely to choose lower premium coverage with higher deductibles or less generous benefits.)

Let's talk

Anne Phelps
Center for Regulatory Strategy,
Health Care Leader
Principal
Deloitte Risk & Financial Advisory
Deloitte & Touche LLP
annephelps@deloitte.com

Daniel Esquibel
Senior Manager
Deloitte Risk & Financial Advisory
Deloitte & Touche LLP
desquibel@deloitte.com

Ryan DeMerlis
Senior Manager
Deloitte Risk & Financial Advisory
Deloitte & Touche LLP
rdemerlis@deloitte.com

Lindsay Wisdom
Manager
Deloitte Risk & Financial Advisory
Deloitte & Touche LLP
lwisdom@deloitte.com

1. Internal Revenue Service, Employee Benefits Security Administration, and HHS, *Health Reimbursement Arrangements and Other Account-Based Group Health Plans, Federal Register,* June 20, 2019, https://www.federalregister.gov/documents/2019/06/20/2019-12571/health-reimbursement-arrangements-and-other-account-based-group-health-plans.

Advanced payment models

The 2015 Medicare Access and CHIP Reauthorization Act (MACRA)[1] repealed the sustainable growth rate (SGR) formula for updates to the Medicare Physician Fee Schedule (PFS) and replaced it with a system that provides higher payment updates and bonus payments for clinicians who participate in advanced alternative payment models (AAPMs). AAPMs feature more than nominal downside financial risk, payment linked to quality, and required use of certified electronic health record technology (CEHRT).

Clinicians who do not have sufficient participation in AAPMs will have their Medicare Part B payments adjusted based on their performance in the Merit-based Incentive Payment System (MIPS). Clinicians' MIPS composite scores are based on their performance in four categories: quality, cost, promoting interoperability, and improvement activities.

In response to feedback from stakeholders and other public comments, CMS is moving forward with the MIPS Value Pathways (MVP) transition. Over the next five years, MIPS reporting will shift from a number of unaligned measures to a more cohesive set of measures that are closer to clinician practice realities and public health priorities. The transition is intended to reduce reporting burdens for clinicians and prepare providers to join AAPMs by creating a common language of quality across the growing set of payment arrangements.

New payment models

Partly in an effort to continue to expand participation in AAPMs, CMS and CMMI put forward a number of new payment models in 2019, with a particular focus on conditions or areas of the health care system where costs are high or increasing faster than other parts of the health care system.

Highlights of select new payment models are provided below.

Primary care transformation

Since the beginning of its payment innovation initiatives, CMS has tested various ways that primary care can be used to better manage complex care needs, conduct patient outreach, and coordinate among specialists.

On April 22, 2019, CMMI released a series of payment models that will enhance the role of primary care in managing Medicare FFS, Medicare Advantage (MA), and Medicaid beneficiaries through several distinct approaches known collectively as the Primary Cares Program. The Primary Cares Initiative comprises Primary Care First (PCF) (two models) and Direct Contracting (DC) (three models).

The PCF model builds on the experiences CMS, other payers, and providers have had with the Comprehensive Primary Care Plus (CPC+) models, offering both a flat, population-based payment and a flat primary care visit fee. Quarterly performance adjustments range from an upside adjustment of up to 50 percent, to a downside of 10 percent.

Under the DC models, CMS intends to build on the experience of the Medicare ACOs, such as the Medicare Shared Savings Program (MSSP) and the Next Generation ACO Model, while also incorporating approaches from MA and other private-sector risk-sharing arrangements. Thus, CMS intends to offer three DC options:

1. Professional population-based payment (PBP)
2. Global PBP
3. Geographic PBP

Organizations participating in DC arrangements (referred to as Direct Contracting Entities, or DCEs) will receive a flat monthly payment with adjustments for outcomes.

Three distinct DC models allow participants to range in scope from the assessment of primary care costs and outcomes to payments based on the total cost of care. The DC payment models will use January 2020 as the beginning of an initial alignment year for organizations that want to align beneficiaries to meet program requirements. Performance periods will begin January 2021 and will be five years.

In addition, the 2020 Physician Fee Schedule Final Rule[2] creates a new opportunity for other payers to coordinate with CMS on enhanced primary care. The Aligned Other Payer Medical Home Model is designed to encourage the adoption of alternative payments for primary care by other payers. Eligible models include primary care practices or multispecialty practices that include primary care physicians and practitioners and offer primary care services. To qualify, a practice must empanel patients to a particular clinician and the care must consist of at least four of:

- Planned coordination of chronic and preventive care
- Patient access and continuity of care
- Risk-stratified care management
- Coordination of care across the medical neighborhood
- Patient and caregiver engagement
- Shared decision-making and/or payment arrangements in addition to, or substituting for, FFS payments (for example, shared savings or population-based payments)

Bundled payments in radiation oncology

Notably, in 2019, CMS proposed the Radiation Oncology (RO) Model,[3] which follows a similar protocol to the Oncology Care Model (OCM), currently featuring participation by 175 practices and 10 payers. Under the RO Model, prospective episode-based payments would be adjusted for achieving preset benchmarks. In particular, the RO Model would feature mandatory participation from radiation therapy providers and suppliers that furnish radiation therapy services within a subset of randomly selected geographies.

Kidney care

CMS also has sought to drive payment reform in kidney care with the End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model, designed to encourage the greater use of home dialysis and kidney transplants for Medicare beneficiaries with ESRD. The ETC Model also has an element of mandatory participation, with randomly selected ESRD facilities and managing clinicians accounting for around 50 percent of these groups nationally.[4]

Alternative payments for drugs

Value-based and other payment alternatives for prescription drugs have become central themes of the administration's health care agenda. For example, in 2020, CMMI will begin a new Part D payment modernization model that draws from the lessons of medication therapy management (MTM) and other models. The Part D payment modernization model introduces two-sided risk to Part D plans while also giving model participants tools and incentives to increase beneficiary engagement and to select lower-cost alternative drugs.

A look at the future of payment

As regulators continue to drive health care reimbursement away from the FFS system, private payers are making similar moves and—in some cases—are actively working to align their own payment and delivery innovations with models that CMS and CMMI are piloting. The move away from FFS will push providers, payers, and other health care stakeholders to invest in new capabilities and explore new business relationships and other ways of working together.

Let's talk

Anne Phelps
Center for Regulatory Strategy,
Health Care Leader
Principal
Deloitte Risk & Financial Advisory
Deloitte & Touche LLP
annephelps@deloitte.com

Daniel Esquibel
Senior Manager
Deloitte Risk & Financial Advisory
Deloitte & Touche LLP
desquibel@deloitte.com

Ryan DeMerlis
Senior Manager
Deloitte Risk & Financial Advisory
Deloitte & Touche LLP
rdemerlis@deloitte.com

Lindsay Wisdom
Manager
Deloitte Risk & Financial Advisory
Deloitte & Touche LLP
lwisdom@deloitte.com

1. Public Law 114–10, April 16, 2015, https://www.congress.gov/114/plaws/publ10/PLAW-114publ10.pdf.
2. CMS, *2020 Physician Fee Schedule Final Rule, Federal Register*, November 15, 2019, https://www.federalregister.gov/documents/2019/11/15/2019-24086/medicare-program-cy-2020-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other.
3. CMS Innovation Center, "Radiation Oncology Care Model," https://innovation.cms.gov/initiatives/radiation-oncology-model.
4. CMS Innovation Center, "ESRD Treatment Choices (ETC) Model," https://innovation.cms.gov/initiatives/esrd-treatment-choices-model.

The opioid crisis

The United States is in the grip of an opioid epidemic. In 2017 alone, opioid overdoses cost more than 47,000 lives.[1] According to the US Centers for Disease Control and Prevention (CDC), 36 percent of those deaths involved prescribed opioid painkillers, despite the fact that opioid prescriptions have declined recently.[2] In total, the opioid epidemic is responsible for about 400,000 deaths over the past 20 years.

The national opioid crisis is not isolated by geography; however, its impacts have been greater in some regions. Faced with soaring social and economic costs from opioid abuse, overwhelmed communities are pressing for solutions. CDC researchers say the crisis cost the country $78.5 billion in 2013,[3] including the cost of health care, lost productivity, addiction treatment, and criminal justice involvement. One-fourth of these costs are falling on the public sector.[4] As a result, companies involved in the manufacturing, distribution, and dispensing of opioids—a $13 billion industry[5]—are under increasing pressure to address this public health crisis, which shows no sign of letting up.

Litigation and enforcement

Litigation brought forward by states, local governments, tribal governments, private litigants, and other parties has not yet been fully successful in reaching settlements with various drug manufacturers and distributors—and the pursuit of this litigation has been costly for state and local governments, with the taxpayers ultimately footing the bill.

In 2019, major court cases moved forward against some drug manufacturers and distributors. Also, lawsuits from state attorneys general against those types of companies have been increasing over the past few years. These cases, which are largely still pending, are being tried under a variety of legal theories, including negligence, nuisance, fraud, and claims under state consumer protection laws; however, many cases center around lack of compliance with the Controlled Substances Act.

In late October 2019, a proposed global settlement of $48 billion by state attorneys general was rejected by local governments. It would have allowed defendant companies to exit any remaining litigation and avoid further liability for the crisis. Some states and counties, including two counties in Ohio, reached separate settlements with some of the defendants. However, there is no telling if or when the consolidated cases will be settled.

Regarding enforcement, criminal prosecutions and enforcement by federal, state, and local agencies pose real risks to health care organizations that are not implementing data-driven and proactive compliance strategies to address the opioid epidemic. Enforcement is increasing, and monitoring efforts are becoming more sophisticated. Federal agencies are increasingly using data-mining techniques to identify noncompliance and are pursuing legal action and other remedies, including financial penalties, to hold individuals and organizations accountable.

In 2018, the Department of Health and Human Services' (HHS) Office of the Inspector General (OIG) stated that its top priority was to minimize risks to beneficiaries, including protecting beneficiaries from prescription drug abuse.[6] Recent OIG reports on opioids describe concerns about extreme use and questionable prescribing practices. As a follow-up to its reports, the OIG released a toolkit (OEI-02-17-00560) to help public and private stakeholders address the opioid crisis. The toolkit outlines steps that health care organizations can follow to analyze data for prescription drugs and identify patients who may be misusing or abusing prescription opioids and thus may require additional case management or other type of follow-up. Health care organizations can play an important role in identifying questionable prescribing trends by providers, and some are using this new toolkit and other novel data-driven techniques to do so.

The Justice Department's Inspector General recently concluded that the Drug Enforcement Administration (DEA) had not only allowed large increases in opioid manufacturing, but was also slow to react to the opioid crisis. The Inspector General's report stated that "the rate of opioid overdose deaths in the United States grew, on average, by 8 percent per year from 1999 through 2013 and by 71 percent per year from 2013 through 2017. Yet, from 2003 through 2013, DEA was authorizing manufacturers to produce substantially larger amounts of opioids."[7]

Legislation and regulation

In the face of the nationwide epidemic, federal and state legislators are establishing new requirements around opioid pain medications.

State and federal controlled substance acts are designed primarily to govern the possession, use, sale, distribution, and manufacture of medications that have a potential for abuse. Medication-assisted treatment (MAT), including opioid treatment programs (OTPs), take a different angle, treating substance use disorders with a combination of behavioral therapy and medications.

Congress is working to impose stricter requirements on controlled substances and is introducing legislation that emphasizes increased access to nonopioid pain management alternatives and opioid use disorder (OUD) treatment (such as MAT) and encourages improved insurance coverage of such services.

Examples of enacted legislation aimed at addressing the opioid crisis include:

- **The SUPPORT for Patients and Communities Act.** The SUPPORT act addresses widespread overprescribing and abuse, treatment, and prevention by bolstering law enforcement, public health, and health care financing and coverage. Its provisions include expanding the definition of "covered recipient" and imposing stricter standards for reporting payments and other items of value to providers, particularly in light of the growing number of clinical professionals who are able to legally prescribe medication; requiring the government to develop and disseminate materials for pharmacists around the declining of suspect prescriptions; and authorizing programs to expand consumer education on opioid use and train providers to treat individuals with OUDs.

  The Act moves forward efforts to identify, report, and stop suspicious orders of opioids; increases the penalties for nonreporting to combat diversion; and provides for additional access to government-collected drug supply chain movement information. Also, it strengthens current monitoring programs, which already exist in 49 of 50 states, by supporting data-sharing across state lines and providing enhanced federal matching funds for implementing sharing among states.

- **DEA Order Clearinghouse Act.** Companion Senate and House bills have been introduced that would require the DEA to establish a national drug order clearinghouse, where orders would undergo enhanced analysis to look for anomalous or suspicious characteristics.

In addition to this new enacted legislation, the Department of Justice, as part of its regulatory agenda for 2018, proposed to revise its regulations relating to suspicious orders of controlled substances. The proposed rule could further define the term "suspicious order" and specify the procedures a registrant must follow upon receiving such orders.

Industry actions and public opinion

Large industry players are making significant investments to combat the opioid epidemic. Companies are searching for ways to improve access to care for the general population and for employees and people at risk and/or struggling with opioid problems. Also, many of the investments aim to improve companies' brand reputations within the communities they serve. Focus areas for investment include:

- **Safe disposal:** Safe medication disposal programs that protect individuals against the misuse of medications expired and unused by safely disposing of prescription and over-the-counter medications
- **Prescriber analytics:** Utilization management that promotes patient safety through prescription utilization management tools and systems
- **Access to medications that counter the effects of opioids:** Providing improved access to opioid-antagonists
- **Community support:** Initiatives dedicated to supporting communities in the face of the opioid epidemic
- **Clinical programs:** Programs that address the opioid epidemic from the provider and clinical perspective
- **Education and awareness:** Education and awareness efforts—often targeted at vulnerable populations—that address themes such as prevention, abuse, and misuse of prescription opioids
- **Opioid crisis management:** Broad enterprise strategies aimed at tackling the opioid epidemic
- **Research:** Company investments to initiate, drive, and/or support research efforts to find better treatments

What to expect in the future

Expanded use of data and analytics. Enforcement and litigation tactics are becoming more sophisticated, with state and federal governments increasingly looking to more efficiently and effectively collect and analyze data from stakeholders involved in the controlled-substance supply chain. Also, government agencies will increasingly be looking for supply chain members, including prescribers and pharmacists, to leverage new and existing data sets to combat diversion.

Government funding for new treatment models. CMS recently announced the Maternal Opioid Misuse (MOM) Model, which is an important step in advancing the agency's multipronged strategy to combat the opioid crisis. The model addresses the need to better align and coordinate care of pregnant and postpartum Medicaid beneficiaries with OUD through state-driven transformation of the delivery system surrounding this vulnerable population. By supporting the coordination of clinical care and integration of other services critical to health, well-being, and recovery, the MOM model has the potential to improve quality of care and reduce expenditures for mothers and infants.

Also, new care models are emerging that feature financial incentives designed to drive care transformation and improve care delivery for vulnerable Medicaid and Children's Health Insurance Program (CHIP) beneficiaries—particularly those affected by the opioid crisis.

Actions for industry participants to consider

- Take a proactive approach to preventing, detecting, and responding to overutilization, patient doctor shopping, overprescribing, and drug diversion so that health care organizations are not at risk for enforcement action from local, state, and federal agencies which could result in severe reputational damage and potentially costly criminal and civil penalties.
- Use the *Prevent, Detect, Respond* method:
  - **Prevent.** Support research aimed at developing clinically effective pain management protocols and physician education to limit opioid use and dependence and alter opioid prescribing practices. Refine drug diversion policies, procedures, staff education and training content, and protocols for diversion monitoring and management of diversion events. Expand prevention and educational efforts for patients and community members.
  - **Detect.** Leverage analytics to identify opioid hotspots and high-risk individuals in order to formulate appropriate treatment methods and allocate appropriate resources for treatment. Review physician prescribing data to help reduce inappropriate prescribing and modify lax prescribing habits. Utilize statewide prescription monitoring databases to identify patients exhibiting pill-seeking behaviors in order to prevent opioid addiction and dependency before habits form and to reduce success rates of "doctor shoppers." Review system activity logs, inventory logs, and dispensing data to identify anomalies and pinpoint responsible employees in order to reduce employee drug diversion within hospital facilities. Conduct ongoing compliance assessments, controls testing, and medical record reviews to identify diversion risks.

  - **Respond.** Support or partner with government agencies to develop strategies to improve access to effective pain management and addiction treatment. Develop a crisis management plan to respond quickly and effectively to regulatory and reputational incidents. Develop and implement remediation plans and take corrective action (such as new controls or business process redesign) to respond to risk events and mitigate risks in a timely manner.

- Use analytic tools to identify and address problems, including:
  - Dashboards to identify demographic and geographic patterns of opioid-related hospital encounters, as well as potential predictors of opioid abuse
  - Diagnostic analytics of prescription drug monitoring program (PDMP) data to help identify individuals with high risk of addiction and/or overdose
  - Diagnostic analytics of prescription data to identify inappropriate prescribing habits and high-volume opioid prescribers
  - Diagnostic analytics of inventory data and system audit logs to help detect and prevent drug diversion
  - Prescriptive analytics to deemphasize opioid medication use for at-risk individuals and formulate personalized nonopioid alternatives for treatment

Let's talk

Lou Pichini
Managing Director
Deloitte Risk & Financial Advisory
Deloitte Financial Advisory Services LLP
lpichini@deloitte.com

Peter A. Khoury
Manager
Deloitte Risk & Financial Advisory
Deloitte & Touche LLP
pkhoury@deloitte.com

Chelsea Mullin
Manager
Deloitte Risk & Financial Advisory
Deloitte & Touche LLP
cmullin@deloitte.com

1. CDC, NCHS data brief, November 2018, https://www.cdc.gov/nchs/data/databriefs/db329_tables-508.pdf.
2. CDC, "CDC Foundation's New Business Pulse Focuses on Opioid Overdose Epidemic," March 15, 2017, https://www.cdc.gov/media/releases/2017/a0315-Business-Pulse-opioids.html.
3. CDC, "Overview of the Drug Overdose Epidemic: Behind the Numbers," December 19, 2018, https://www.cdc.gov/drugoverdose/data/index.html.
4. Florence CS et al., "The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013," *Medical Care* 54, no. 10 (2016): pp. 901–6, https://www.ncbi.nlm.nih.gov/pubmed/27623005.
5. Scott Higham and Lenny Bernstein, "Drug makers and distributors face barrage of lawsuits over opioid epidemic," *Washington Post*, July 4, 2017, https://www.washingtonpost.com/investigations/drugmakers-and-distributors-face-barrage-of-lawsuits-over-opioid-epidemic/2017/07/04/3fc33c64-5794-11e7-b38e-35fd8e0c288f_story.html.
6. HHS and US Department of Justice (DOJ), *Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2018*, May 2019.
7. DOJ Office of the Inspector General, "Review of the Drug Enforcement Administration's Regulatory and Enforcement Efforts to Control the Diversion of Opioids," September 2019.

Hospital price transparency: 2020 Outpatient Prospective Payment System (OPPS) update

In recent years, hospital charges have been published on various social media platforms. This has heightened awareness and sensitivity about hospital price transparency. Patient misunderstandings about the true cost of care are fueled by the rising cost of hospital care, as well as rising health insurance premiums, deductibles, and coinsurance amounts.

President Trump and Seema Verma, administrator for CMS, have both been outspoken about controlling pricing and driving consumerism in the health care market, and they are currently leading the charge to promote "competitive pricing" and urge "patient choice."[1]

The following recent federal guidelines and CMS guidance are moving hospital pricing to the top of the agenda for today's health care organizations:

- The 2019 Inpatient Prospective Payment System (IPPS) Final Rule provided guidance on making hospital charge description master files available online—in an appropriate electronic format—including the specific content to be published (for example, chargemaster charges or standard charge amount).
- On June 24, 2019, the president signed an executive order focused on health care price transparency and providing access to multiple areas of patient-required information (including further details on hospital listed prices, physician performance details, and other areas important to patients when choosing a physician or provider for a given service).
- On July 29, 2019, CMS proposed a number of updates to the existing Hospital Price Transparency rules that provide further guidance on making standard charges more informative and meaningful in order to aid public understanding.

The 2020 OPPS update to price transparency

On November 11, 2019, CMS released the final OPPS rule with a comment period and an effective date of January 1, 2021.[2] Key provisions of the final rule are highlighted below.

Calculating the negotiated rate

Although the calculation of the negotiated rate is currently under CMS review, it may be defined as one of three proposed calculations:

1. *Volume-driven negotiated charge*—Defining the negotiated amount based on a mode of distribution or as the "modal negotiated charge" (the frequently charged rate across the hospital for that service across hospital managed care payers)
2. *Minimum, median, maximum negotiated charge*—Creating multiple charge points across each third-party payer to help the patient visualize the high, low, and average charge for a given service
3. *Average percentage discount* with third-party payers

The negotiated charge is not easy to calculate, and several factors need to be considered when performing the calculation. One method is to review existing charges with managed care payers and calculate the average managed care rate (weighted, based on historic utilization). Another method is to use a simple average across managed care payers (average of managed care contracts, not just top contracts); this does not provide consideration to payers who predominantly pay on many services. A third method will be to review the medium charge across each managed care payer; this requires reviewing charges individually. Each of these methods should be evaluated to assess which one makes the most sense to use going forward.

Publishing shoppable services

CMS has proposed a list of 300 shoppable services[3] to be published annually by hospitals. Seventy of the shoppable services are to be selected by CMS. The remaining 230 are to be selected by each individual hospital. The listing for each service should reflect both the standard charge amount and the negotiated charge amount. According to CMS, this will provide useful insight to patients shopping for services across local hospitals—offering greater transparency to help them find the lowest price for the same service.

Tool development and education

Hospitals and health systems are developing new tools to help customers get a better handle on pricing. They are creating dedicated websites to address price transparency, helping patients understand not only their medical bills, but also the total charges submitted to payers—and the relationship between charges and

costs. Also, they are developing tools to estimate out-of-pocket costs for common services (based on individual insurance carriers). In addition, some hospitals are incorporating pricing tools into their health system mobile applications as a way to provide patients with relative cost information more quickly and directly. These examples illustrate how hospitals are approaching pricing transparency with technology and helping patients better understand costs and charges.

Other efforts include educational video tutorials and/or reader guides that help customers understand future negotiated and standard charge amounts. Also, some hospitals are providing actual examples to help patients visualize the relationship between charges, medical claim submissions, and reimbursement. These education programs help patients understand the complexities of medical billing and reimbursement.

Payer impact

On September 27, 2019, Matt Eyles, president and CEO of America's Health Insurance Plans (AHIP), issued a statement about the impact of these updated price transparency rules. Eyles argued that the updated rules do not align with CMS' intent to drive lower hospital pricing; in particular, "privately and competitively-negotiated rates, as proposed in this rule, will not provide information that is actionable by, or helpful to, consumers."[4] AHIP is pushing to remove the language specifically about "payer-specific negotiated rates," as this is proprietary to hospitals and payers nationally (and separate from understanding individual patient costs and charges).

Instead, AHIP is offering to engage with CMS to develop an alternative solution that provides information at the individual patient and consumer level. The emphasis on personalized information continues throughout the comment, as does the need for mandatory qualitative information on patient services.

In the statement, Eyles also expressed concern about compiling this information at the hospital level and then releasing the data to third-party vendors (as suggested by CMS in the 2020 OPPS update), stating that the data is "inaccurate" and "will not consider patient-specific coverage, where patient's current deductible is, and other considerable information to determine out-of-pocket costs."

Monetary penalties

For the first time since the 2009 Affordable Care Act (ACA) provided guidance on hospital price transparency measures, the 2020 OPPS update confirms the enforcement of monetary penalties for noncompliance. Noncompliance will be primarily enforced through patient or consumer referral complaints; however, CMS may reach out to hospitals directly as well. Hospitals deemed noncompliant will receive a notice from CMS documenting the specific observation and establishing the suggested timeline for remediation with a corrective action plan (CAP). The hospital will then work with CMS to develop the CAP and obtain approval prior to acknowledging the corrective action(s). If noncompliance continues or hospitals do not comply within the suggested timeframe, penalties of $300 per day may be enforced for each hospital.

Moving forward

As patients begin making sense of the pricing information being posted nationally and regionally, hospitals should make it clear how their pricing information is understood. Also, as CMS continues to monitor and adjust price transparency rules, health care organizations should be having team discussions around price transparency efforts and addressing pricing challenges quarterly or monthly.

The high cost of health care continues to prevent many patients from seeking the medical attention they need. Developing tools, technologies, and appropriate guidance to enhance price transparency can help patients make difficult, but informed discussions about the cost and quality of care.

Let's talk

John Valenta
Managing Director
Deloitte Risk & Financial Advisory
Deloitte & Touche LLP
jvalenta@deloitte.com

Andy Hollinden
Manager
Deloitte Risk & Financial Advisory
Deloitte & Touche LLP
ahollinden@deloitte.com

1. CMS, "Remarks by Administrator Seema Verma at the American Hospital Association Regional Policy Board Meeting," September 10, 2019, https://www.cms.gov/newsroom/press-releases/remarks-administrator-seema-verma-american-hospital-association-regional-policy-board-meeting.
2. CMS, *Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Revisions of Organ Procurement Organizations Conditions of Coverage; Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Changes to Grandfathered Children's Hospitals-Within-Hospitals; Notice of Closure of Two Teaching Hospitals and Opportunity To Apply for Available Slots, Federal Register*, November 12, 2019, https://www.federalregister.gov/documents/2019/11/12/2019-24138/medicare-program-changes-to-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center.
3. HHS, *Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children's Hospitals-Within-Hospitals, Federal Register*, August 9, 2019, p. 579, https://s3.amazonaws.com/public-inspection.federalregister.gov/2019-16107.pdf.
4. Matt Eyles, letter to Seema Verna, "RE: [CMS-1717-P]: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children's Hospitals-Within-Hospitals," September 27, 2019, https://www.ahip.org/wp-content/uploads/AHIP-OPPS-Plan-Comment-Letter-9-27-2019-1.pdf.

Staying ahead

The regulatory landscape is constantly shifting. Some changes are big enough to grab headlines. Others are nearly invisible but can have a big impact. For the latest regulatory updates and insights, please visit www.deloitte.com/us/HealthcareRegulatoryOutlook.

Leadership

Alok Sinha
Regulatory & Operations Risk Leader
Principal | Deloitte Risk & Financial Advisory
Deloitte & Touche LLP
asinha@deloitte.com

Anne Phelps
Center for Regulatory Strategy, Health Care Leader
Principal | Deloitte Risk & Financial Advisory
Deloitte & Touche LLP
annephelps@deloitte.com

CENTER *for*
REGULATORY STRATEGY
AMERICAS

About the Center
The Deloitte Center for Regulatory Strategy provides valuable insight to help organizations in the financial services, health care, life sciences, and energy industries keep abreast of emerging regulatory and compliance requirements, regulatory implementation leading practices, and other regulatory trends.

Home to a team of experienced executives, former regulators, and Deloitte professionals with extensive experience helping clients solve their complex regulatory issues, the Center exists to bring relevant information and specialized perspectives to our clients through a range of media, including thought leadership, research, forums, webcasts, and events.

Deloitte.