Health Industry Impacts of Changes in Regulatory/Payment Environment
Outlook for 2018 and Beyond

Sector	Opportunities	Threats/Headwinds
PROVIDERS		
Hospitals/Health Systems	• Opportunities remain in IT support—linking systems, physician integration, revenue cycle, among others • New organizational models for physician alignment to drive quality outcomes and cost management • Bundled payments gaining provider acceptance; but CMMI/CMS scaling back programs in joint replacement, cardiac disease and physician focused payment models • Alignment with insurers for operating joint ventures (e.g., Vivity in California) • Joint ventures around ASCs, imaging, laboratory, behavioral health, and post-acute care providers • Acquisition of physician specialties who infuse (e.g., PCP, oncology, rheumatology, etc.) to drive 340B revenue • Congress / White House want to open more pathways for the veteran population to seek care from private providers—reimbursed at Medicare rates and improved VA payment process	• Trump administration moves against ACA; new Medicaid waivers—more uninsured and uncompensated care • Medicare Part A payment reform (non-ACA) (e.g., further development of site-neutral payment policies) • Competitive challenges from physician-backed non-acute diagnostic and treatment facilities • Non-acute settings and telemedicine solutions eat into margins • Greater care coordination reduces hospitalizations • Can you make a profit at Medicare / Medicaid rates? • Challenges to 340B revenue • More aggressive management of infusion, advanced imaging and emergency room utilization moves these key revenue drivers from hospitals to offices and free standing centers • Greater anti-trust enforcement of hospital and health system consolidation
Physicians	• HHS leadership with focus on relieving regulatory and administrative burdens (e.g., fixing risk adjustment issues within CMMI demos) • Loosened Stark regulation: more co-investment, gainsharing options • MACRA drives consolidation—PPMC opportunities • Staffing companies step in where retirements and exits hit supply • Continued demand for solutions for large group management, IT, and otherwise • Opportunities for groups stepping up to risk assumption in Medicaid and Medicare markets • Alternate payment models that focus on physicians delivering care out of hospital • Growth of concierge or boutique medicine, particularly as insurance markets and CMS increase complexity of payment	• MACRA cuts to payment looming in 2019 • More downside risk for physicians in models qualifying as Advanced APMs under MACRA • Investments that rely on small group decision making • Vicissitudes of state budgets for downstream Medicaid risk assumption • Challenges to specialties with episode/bundling exposure (e.g., orthopedics); Is there a future for private practice for certain primary care specialties? • As hospitals are under financial pressure, will medical compensation decline for those physicians employed in hospital arrangements? • Are hospitals willing / prepared to spin out poorly performing providers? • Are hospitals prepared to replace PCPs with mid-level providers?

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	models and reporting • Specialists continue to embrace technologies that drive revenue while reducing hospital costs (e.g., CT angiography and approaches to identify high-risk individuals reducing need for many cardiac catheterizations and procedures) • Regulatory relief that allows balance billing of Medicare • Virtual medical groups that allow shared risk and reward • Define patient reported outcome measures ("PROM") that support the adoption of new drugs, diagnostics, and devices • More providers assessing local market share and electing to stay out of network • Upsurge of investment in specialty physician group roll-ups by private equity and venture funds • Models such as Comprehensive Primary Care Tracks I and II provide greater revenue for PCPs and strengthen care coordination	• Select networks; crackdown on out-of-network providers • Advent of Appropriate Use Criteria for imaging • MedPAC questions whether MACRA / MIPS is achieving its goals • Hospital acquired specialists looking for greener pastures • PROM embraced by FDA, but not influencing the adoption of new drugs / devices by plans and payors
Ambulatory Care	• Potential loosening of Stark regulation opens up investment for backing physician enterprises in non-acute treatment modalities • Opportunities to support growth of non-acute diagnostic and treatment facilities	• Hospital investments in ambulatory care create greater pricing pressure on free-standing ASCs, imaging centers, sleep centers, and other ambulatory ventures • More requirements for cost management lead to greater utilization management approaches for diagnostic and imaging procedures • MedPAC / Medicare reform / competition that drives HOPD pricing closer to ASC levels (site-neutral payment) • Implementation of appropriate use criteria ("AUC") for imaging
Behavioral	• Bi-partisan support for better substance abuse treatment and prevention • Opioid crisis now a declared national emergency • Payers may find DOL less adversarial;providing more flexibility in meeting parity requirements • CMMI has endorsed collaborative care models; paying more for integrated mental health and primary care • Growth of non-MD behavioral health models including telehealth	• Potential reduced enforcement of mental health parity • Shrinkage of Medicaid coverage could limit patient access to opioid treatment
Post-Acute Care ("PAC")	• Continued VBP momentum pushing patients out of PAC • Site-neutral payment good for home health	• Threats from episode payments and referral source behavior spillover from the episode payment programs

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	• Recognition that variation in post-acute care is the major cost driver for Medicare, and that networks with high performing PAC providers will evolve	• Site-neutral payment bad for PAC facilities • Congress Medicare Part A reform debate focused on PAC; while high performers could gain, PAC VBP proposal withholding a percentage of reimbursement to fund incentive pool may lead to aggregate cut
Long-Term Care ("LTC")	• Home- and community-based alternatives to nursing facilities grow as cost-savings alternative	• Growth of managed LTC—especially more states get waivers • Reduced Medicaid funding could undo a significant amount of the public financing of LTC; private coverage unlikely to grow
Hospice	• Commercial insurance interest in palliative care beyond a life expectancy of 6 months	• Despite the difficulty for the prognosis of life expectancy, US prosecutors focus on false claims
INSURER/MANAGED CARE & INFO TECH		
Commercial	• Potential passage of bipartisan ACA stabilization measure could restore individual / small group coverage opportunities	• Trump decision to halt cost-sharing subsidies and promote less regulated options (e.g., association health plans, short-term plans) upends exchange mediated individual / small-group market • Provider and venture based entities may be too small to successfully manage risk and out-of-network leakage
Medicare Advantage ("MA")	• Bipartisan support remains short term; long range upside if premium support gains traction • MA remains best opportunity to demonstrate effectiveness of integrated delivery and financing organizations • Enrollment growth provides some political protection for future cuts • Acquisition of MA plans by national insurers outside of their traditional states / geography	• Hospital price increases post-consolidation • Increased CMS RADV audit activity in 2018 and beyond
Medicaid Managed Care	• Continued state reliance on managed care / privatization • LTC next growth push for shift to managed care	• GOP budget proposal contemplates massive spending cuts to Medicaid—similar to vision in failed ACA repea l / replace bills • CMS encouraging state waivers that could limit eligibility and benefits

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Pharmacy Benefit Manager ("PBM")	• The solution to Pharma pricing? • PBMs create greater value through specialty pharmacy management and new pricing for value models such as indication-based pricing • Management of compounded products • Non-interference of negotiating in drug pricing altered to allow CMS / Trump to reduce prices for some patent protected drugs • PBM diversification (e.g., ExpressScripts acquisition of eviCore) • Anthem commits to building a PBM after 10 year relationship with ExpressScripts signals coming attractions for national health plans (e.g., Aetna, Cigna)	• PBMs are under microscope for pricing transparency with PhRMA and BIO trade groups leading the chorus • Provider dispensing of pharmaceuticals / specialty meds • Specialty benefit management (e.g., oncology) erodes PBM power
Information Technology	• Opportunities in telemedicine and clinical decision support • FDA regulation less of a threat • Delay of Meaningful Use stage III • Technologies supporting patient engagement and bundled payment (e.g., HealthLoop) to coordinate care and reduce overall costs • More payer and regulator acceptance of telehealth and mobile apps • Significant number of new entrants in health care informatics and advanced data analytics; growth of incumbents such as OptumInsight and IBM Watson Health • Big data goes molecular: analytics in cancer; GRAIL	• Meaningful use less of a market maker—MACRA MIPS IT impact to be evaluated
LIFE SCIENCES		
Pharmaceuticals	• FDA supports discussions between pharma and payers prior to NDA approvals • Regulatory changes could allow industry to share risk and reward directly with physician providers • New health technology assessment and value models including ICER; those from professional organizations (ASCO), patient centered organizations (Faster Cures), and Innovation and Value Initiative to look at value beyond QALYS • Define PROM to support adoption of new drugs	• FDA as forum for industry-private payer evidence discussions could exert longer-term tilt to more aggressive FDA requirements • Trump / Congress calling out perceived price gouging • State legislatures pushing measures that limit price increases; expanding transparency • Lawmakers face challenge balancing public pressure to address pharma with a smooth FDA user fee reauthorization • Physician aggregation promotes group formularies • Health plans and PBMs continue to limit formulary options increasing price competition amongst drug classes (e.g., insulins

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		and TNF inhibitors) • Restricting coverage of 'sacred cows' (e.g., oncology, hemophilia, orphan drugs) • Attack on authorized generics • FDA likely to move to address egregious generic drug price hikes • Crackdown on captive pharmacies • Unclear how payers will pay for costly CAR-T and gene therapies • Unclear whether PROMs and RWE will drive payer coverage
Medical Device	• Easier regulatory pathway to market entry • Regulatory changes could allow industry to share risk and reward directly with physician providers • Alignment with physician-hospital risk-bearing entities could sidestep need for multi-year clinical outcome trials • Seek coverage directly with self-funded employers / unions • Device manufacturers taking over management of hospital service lines (e.g., Medtronic and University Hospitals Cleveland) • Define PROM to support the adoption of new devices • Congress's and the Trump administration's attention to providing more support for bringing new technology to the market did not end with 21st Century Cures • ACA repeal and tax reform agendas are two opportunities for repeal of ACA medical device excise tax	• FDA as a forum for industry-private payer evidence discussions could exert longer-term tilt toward more aggressive FDA requirements • Continued assault on sales strategies that are based on creating physician preference • Value-based purchasing and aggregated groups hit margins • Greater scrutiny by commercial payers and Medicare regarding clinical outcomes with more restrictive coverage decisions unless better clinical trials are conducted • Growth of SharedClarity business model limits access for novel technologies • CPT Editorial Panel remains hostile towards the development of new category I CPT codes for new device-driven procedures
Diagnostics	• Favorable regulatory pathway for lab-developed tests • Greater development of companion and complementary diagnostics • Reducing the cost for whole genome sequencing facilitates the expansion of personalized medicine and molecular diagnostics but uncertainty for best clinical use of this knowledge • Hospital pricing excluded from PAMA calculation • Provider risk-bearing entities transforming into esoteric diagnostic labs • Greater incorporation of laboratory driven risk-assessment tests into episode / bundled payments	• Greater review by health plans and Medicare of diagnostic testing (e.g., requiring AUC) • Competition dramatically lowers the costs for certain molecular diagnostic tests • Greater scrutiny directed towards specific performance of diagnostic tests (the "Theranos effect") • Restricted coverage of tests and panels unless outcomes are defined and better clinical trials are conducted • These potential changes are set against a challenging evidentiary backdrop–one in which it is often difficult to show a causal connection between a test result and a treatment outcome

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	• Define PROM to support adoption of patient-focused diagnostics	
Biosimilars	• New FDA guidance to promote biosimilars in the marketplace	• Current CMS reimbursement model blunts impact of biosimilars • Originator manufacturers striking deals to limit biosimilar market share • Little interest by PBMs/payers to prefer biosimilars unless discounts are greater than thirty-five percent

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