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Practising Law Institute
New York City

#239430

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Legal Editor: Keith Voelker

LCCN: 2014934916
ISBN: 978-1-4024-3128-9

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About This Book

This book is designed to offer our readers easy access—through its question-and-answer format—to reliable guidance on an array of legal and practical issues arising in health care merger and acquisition (M&A) transactions. We wrote this book for those who find the health care sector or M&A generally mystifying or fascinating. We wrote it for those who regularly work at or for health care companies and are suddenly asked to advise on or manage an acquisition or sale. We wrote it for M&A practitioners who need to understand the intersection of their specialty with the pharmaceutical or biotech industries. We wrote it for the general counsels and other corporate lawyers who are expected to understand the health care M&A process and advise their directors and management on the legal issues arising at the various stages of a health care acquisition. And we wrote it for outside counsel, private equity deal professionals, industry executives and business development professionals, accountants, investment bankers, and anyone else interested in a detailed overview of the legal aspects of health care M&A transactions.

While the book touches on a number of general M&A topics and concepts, this is not a book about how to do M&A. Instead, we focused on the ways in which these general concepts apply to M&A transactions in the health care sector and sought to provide our readers with practical advice on how to address the various industry-specific issues arising in health care acquisitions, including structuring, regulatory, financing, and tax considerations, due diligence topics, and special issues arising in drafting and negotiating transaction documents. To this end, the book analyzes examples from recent health care transactions and provides practice tips on what to look out for and how to avoid the various pitfalls that our readers may encounter while working on health care transactions.

We endeavored in this book to cover a broad spectrum of health care M&A transactions, but we do not purport to have addressed every issue in every sub-sector of the health care industry: the book is long enough! The book does, however, cover deal-making involving pharmaceutical and biotech companies, hospitals, health insurers, private equity firms investing in health care, and other participants

of the health care sector. In addition to transactions involving outright acquisitions of health care companies, we also sought to review alternative structures used in health care M&A transactions, such as joint ventures, strategic alliances, product and portfolio acquisitions, option transactions, and licensing and collaboration agreements.

Part I: Structuring Health Care M&A Transactions focuses on the various considerations that can have an impact on the structure of a health care M&A transaction. These include provisions relating to purchase price (including earnouts and contingent value rights) and purchase price adjustments, as well as regulatory, antitrust, financing, tax, and accounting considerations. The covered topics also include special issues arising in transactions involving not-for-profit health care facilities and valuation techniques used in health care acquisitions.

Part II: Due Diligence explores the various industry-specific issues on which a buyer should focus in conducting its due diligence investigation of a health care target. It discusses, among others, such topics as the regulatory and compliance issues arising in health care transactions (including compliance with the federal and state health care fraud and abuse laws, Medicare and Medicaid rules, HIPAA, and other health care regulations), intellectual property rights, material contracts, and product liability and medical malpractice claims.

Part III: Transaction Documentation discusses the principal elements of a purchase agreement for a health care transaction. It covers, among others, industry specific representations and warranties, pre- and post-closing covenants, closing conditions, and indemnification provisions typically found in health care acquisition agreements.

Part IV: Special Topics covers several topics that we thought might be of interest to our readers. These include special issues arising in acquisitions of U.S. companies by non-U.S. buyers, as well as an overview of health care M&A transactions in France, Germany, Russia, England, Canada, and Japan.

A health care M&A transaction is a complex process fraught with pitfalls at every stage. The main purpose of this book is to share the authors' substantial practical experience with the various types of transactions discussed in the book. We hope you find these insights useful.

Acknowledgments

First and foremost, we want to thank all of our contributing authors, both our colleagues here at Debevoise and outside the firm, who have worked incredibly hard, often under intense time pressure, to make sure every chapter in this book is professional, accurate, accessible, and, we hope, terribly informative.

We could never have made this happen without the tireless efforts of the many folks at Debevoise—past and present—who contributed over the years to the effort and who have been so instrumental in making this project come together. On the top of the list are Michelle Maupin and former Debevoise counsel Dmitriy A. Tartakovskiy, former Debevoise associate Jonathan L. Lubin, and Debevoise associate Michael G. Stern. We are so appreciative of their incredible dedication to the project. And finally, we could never have gotten this done without our fabulous assistants, Darlene Ivan and Claudia Creason Moran.

On a more personal note, Andrew would like to dedicate this book to the memory of his father, Donald S. Bab, who passed away during its writing and who has been an inspiration to him.

Glossary and Abbreviations

340B Drug Pricing Program	A federal program established under section 340B of the Public Health Service Act (1992) that requires drug manufacturers to provide outpatient drugs to eligible nonprofit health care organizations at reduced prices
501(c)(3)	The provision of the Internal Revenue Code under which most not-for-profit health care providers are exempt from federal income tax
505(b)(2)	*See* **New Drug Application**
510(k)	*See* **Premarket Notification**
Abbreviated New Drug Application (ANDA)	The application submitted to the FDA for approval of a "generic drug product." A generic drug product is one that is comparable to an innovator drug product in dosage form, strength, route of administration, quality, performance characteristics, and intended use. The ANDA submissions are governed by 21 C.F.R. Part 314, Subpart C.
ACA	*See* **Patient Protection and Affordable Care Act**
Accountable care organization (ACO)	A group of doctors, hospitals, and other health care providers intended to give coordinated, high-quality care to patients
ACO	*See* **Accountable care organization**
Adverse event report	A report submitted by an NDA holder to the FDA containing information about an adverse event associated with its drug
Agence Nationale de Sécurité des Médicaments et des Produits de Santé (ANSM)	The French governmental agency responsible for the safety of health products

AIA	America Invents Act of 2011
ALJ	Administrative law judge
ANDA	*See* **Abbreviated New Drug Application**
ANSM	*See* ***Agence Nationale de Sécurité des Médicaments et des Produits de Santé***
Anti-Kickback Statute	A federal criminal statute, 42 U.S.C. 1320a-7b(b), that prohibits offering, giving, soliciting, or receiving anything of value in order to induce or reward the referral of business under a federal health care program
API	*See* **Bulk active pharmaceutical ingredients**
ASC	Ambulatory surgical center
AST	Aboveground storage tanks
ATM	*See* **At the market**
At the market (ATM)	A registered offering of listed securities sold directly into the public markets through a broker-dealer over a period of time. Usually involves a small number of shares being sold at the issuer's discretion on any given day at prevailing market prices.
Bayh-Dole Act	A federal statute that allows nonprofit organizations such as universities to elect to take title to federal agency funded inventions in return for the grant to the U.S. government of a royalty-free, nonexclusive license to the invention
Biologic (biological product)	Any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment, or cure of diseases or injuries of man, 21 C.F.R. § 600.3(h); typically created through a biological process rather than chemically synthesized
Biologics license application (BLA)	A request for authorization, or license, to introduce a biologic product into interstate commerce in the United States. 21 C.F.R. § 601.2. The content of a BLA and rules for biologics licensing are governed by 21 C.F.R. Part 601.

Biologics Price Competition and Innovation Act (BPCIA)	A federal statute that establishes an approval pathway for manufacturers of follow-on biologic products or "biosimilars" to obtain a biologic product license for a product that is biosimilar to a reference product without having to duplicate the innovator product manufacturer's safety and efficacy data. The BPCIA also provides a period of exclusivity to innovator biologic products.
Biosimilar	A biological product that is "highly similar" to an already-approved biological product, including in safety and efficacy, and thus receives approval for use based on these similarities
BLA	*See* **Biologics license application**
BPCIA	*See* **Biologics Price Competition and Innovation Act**
Bringdown condition	Condition to closing of an acquisition agreement that a party's representations and warranties be true and correct as of the closing date
Bulk active pharmaceutical ingredients (API)	Any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug. *See* 21 C.F.R. § 207.3. APIs are regulated as drugs pursuant to the FFDCA.
CAA	Clean Air Act
CAH	Critical access hospital
CAPA	*See* **Corrective and preventive action**
CBER	Center for Biologics Evaluation and Research, a unit of the FDA
CBP	Customs and Border Protection
CCN	*See* **CMS Certification Number**
CCSQ	Center of Clinical Standards and Quality, a unit of the Centers for Medicare and Medicaid Services (CMS)

CDC	Centers for Disease Control and Prevention
CDER	Center for Drug Evaluation and Research, a unit of the FDA
CDRH	Center for Devices and Radiological Health, a unit of the FDA
Center for Medicare and Medicaid Innovation	A unit of the Centers for Medicare and Medicaid Services charged with providing funding to support demonstration initiatives that test innovative ways to improve the delivery of health care and advance effective models for broader adoption, with a focus on high-cost populations, individuals dually eligible for Medicare and Medicaid, and individuals with chronic health conditions
CEPS	*See* ***Comité Economique pour les Produits de Santé***
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act, also known as "Superfund"
Certificate of need (CON)	Administrative approval of the construction, acquisition, or expansion of a hospital or other health care facility required in certain states
CfC	*See* **Conditions for coverage**
cGMP	*See* **Current good manufacturing practice**
CHAMPUS	*See* **TRICARE**
Children's Health Insurance Program (CHIP)	State-administered program intended to provide health coverage to children in families with incomes too high to qualify for Medicaid
CHIP	*See* **Children's Health Insurance Program**
CHOW	*See* **Medicare Change of Ownership**
CIA	*See* **Corporate integrity agreement**

Citizen petition	A formal submission to the FDA, in which a member of the public (including a company or industry group) may request FDA action. The specific format is dictated by regulation. *See* 21 C.F.R. § 10.30.
Civil Monetary Penalties (CMP) Law	A provision of the Social Security Act authorizing the government to assess money fines for a variety of conduct relating to health care fraud, including submitting false claims for payment to the government and violations of the Anti-Kickback Statute and the Stark law
Class I Medical Device	A medical device subject only to general controls because (1) such general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device or (2) there is insufficient information from which to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish "special controls" to provide such assurance, but the device is not life-supporting or life-sustaining or for a use which is of substantial importance in preventing impairment of human health, and does not present a potential unreasonable risk of illness of injury. *See* 21 C.F.R. § 860.3(c)(1); **General controls**.
Class II Medical Device	A medical device subject to "special controls" because general controls alone are insufficient to provide reasonable assurances of its safety and effectiveness and there is sufficient information to establish special controls to provide such assurance. For a device that is purported or represented to be for use in supporting or sustaining human life, the special controls must be determined to provide adequate assurance of safety and effectiveness. *See* 21 C.F.R. § 860.3(c)(2); **General controls**.

Class III Medical Device	A medical device (1) as to which insufficient information exists to determine that general controls and the additional "special controls" applicable to Class II Medical Devices are sufficient to provide reasonable assurance of its safety and effectiveness and (2) which is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury. *See* 21 C.F.R. § 860.3(c)(3); **Premarket Approval; General controls**.
Clinical Laboratory Improvement Amendments (CLIA)	Program for certification of laboratories (other than research laboratories), implemented by the Division of Laboratory Services, within the Survey and Certification Group, under the Center for Clinical Standards and Quality (CCSQ) of the Centers for Medicare and Medicaid Services (CMS)
Clinical research organization (CRO)	An entity created in the biopharmaceutical industry to further the development of and manage clinical trials
CMHC	Community mental health center
CMMI	*See* **Center for Medicare and Medicaid Innovation**
CMS	Centers for Medicare and Medicaid Services
CMS Certification Number (CCN)	A number unique to each Medicare service provider that identifies survey and certification reports performed by a state agency and is tied to that provider's Medicare participation agreement; also called a Provider Transaction Access Number (PTAN)
CNIL	*See* ***Commission Nationale de l'Informatique et des Libertés***
COBRA	Consolidated Omnibus Budget Reconciliation Act
Code de la Santé Publique (CSP)	The French Public Health Code

Comité Economique pour les Produits de Santé (CEPS)	A committee established by the French Ministry of Health, Ministry of Economy, and Ministry of Social Security that determines which products can be reimbursed by the French social security system, and to what extent
Commission Nationale de l'Informatique et des Libertés (CNIL)	The French data protection agency
Committed equity financial facility (CEFF)	Sale of a specific dollar amount of equity securities to an investor over a period of time. The issuer may determine in its discretion the timing, dollar amount, and floor price for any draw under the facility based upon a contractual formula tied to a volume-weighted average price of the common stock.
CON	*See* **Certificate of need**
Conditions for coverage (CfC)	Health and safety standards established by CMS that providers of health care services must meet in order to begin and continue participating in Medicare Part B (medically necessary services and preventive services) and Medicaid
Conditions of participation (CoP)	Health and safety standards established by CMS that providers of health care services must meet in order to begin and continue participating in Medicare Part A (hospital, nursing home, hospice) and Medicaid
Contingent value rights (CVRs)	Rights issued to stockholders of an acquired company that will pay out depending upon the acquiring company's achievement of specified financial milestones

Contract research organization (CRO)	A person that assumes, as an independent contractor with the sponsor of a clinical investigation, one or more of the obligations of a sponsor, for example, design of a protocol, selection or monitoring of investigations, evaluation of reports, and preparation of materials to be submitted to the FDA. 21 C.F.R. § 312.3.
Controlled premises	Registered establishments (including factories, warehouses, and other establishments) where regulated persons may lawfully hold, manufacture, and distribute controlled substances or where records relating to those activities are maintained
Controlled substance	A drug classified into one of five schedules based on its medical value, potential for abuse, and capacity for producing physical or psychological dependence
CoP	*See* **Conditions of participation**
Copyright	An exclusive right to reproduce, distribute copies, make derivative works, publicly perform, and publicly display an author's original expression that is fixed in a tangible media, such as printed or written on paper, audio or visually recorded, or saved on a computer media
CORF	Comprehensive outpatient rehabilitation facility
Corporate integrity agreement (CIA)	A contract between a company and the U.S. government in which the company agrees to undertake a set of defined obligations designed to promote compliance with federal law
Corporate practice of medicine (CPOM)	The practice of medicine by a business corporation or employment of a physician by a business corporation to provide professional medical services. Such practices are prohibited by law in certain states.

Corrective and preventive action (CAPA)	Systems adopted by medical device manufacturers (pursuant to QSRs) and drug and biologic manufacturers (under cGMPs) to monitor their processes, investigate complaints, identify and correct product nonconformities or quality problems, and prevent recurrence of such problems
CPG	Compliance policy guide
CPOM	*See* **Corporate practice of medicine**
CRO	*See* **Clinical research organization; Contract research organization**
CSA	Controlled Substances Act
CSP	*See* ***Code de la Santé Publique***
Current good manufacturing practices (cGMPs)	Manufacturing practices required by FDA regulations, 21 C.F.R. Parts 210 and 211, that contain the "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess," 21 C.F.R. § 210.1(a)
CVR	*See* **Contingent value rights**
DDC	Drug development company
DEA	Drug Enforcement Agency

Debarment	Statutory authority that permits the FDA to prohibit researchers from conducting clinical testing of new drugs and devices where a clinical investigator has repeatedly or deliberately submitted false information to the agency or the study sponsor in a required report; or it determines that the researcher has repeatedly or deliberately failed to follow the rules intended to protect study subjects and ensure data integrity. FDA also has authority to debar individuals and firms that have been convicted of certain felonies or misdemeanors related to generic drug products.
Derivation proceeding	A proceeding in which a patent may be awarded to an original inventor who shows that another inventor derived his, her, or its invention from the original inventor
DMF	*See* **Drug Master File**
DPA	Deferred prosecution agreement
DOJ	Department of Justice
Drug Master File (DMF)	Discretionary submission to the FDA that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more drugs
DTC	Direct-to-consumer
Earnout	A contractual provision by which the seller of a company or asset can receive additional compensation in the future if the acquired company or asset achieves financial goals or product milestones agreed upon in advance by the parties
EBITDA	Earnings before interest, income taxes, depreciation, and amortization

EBITDAR	Earnings before interest, income taxes, depreciation, amortization, and rent
EBITDARM	Earnings before interest, income taxes, depreciation, amortization, rent, and management fees
EEOC	Equal Employment Opportunity Commission
EIR	*See* **Establishment Inspection Report**
EPA	Environmental Protection Agency
ePHI	Electronic protected health information
ERISA	Employee Retirement Income Security Act of 1974
ESOP	Employee stock ownership plan
ESRD	End-stage renal disease
Establishment Inspection Report (EIR)	A final report on inspection of a manufacturing, processing, or storage facility by the FDA that contains the FDA's final judgment regarding regulatory violations and other observations
False Claims Act	A federal statute, 31 U.S.C. § 3729 *et seq.*, that imposes civil liability in the form of penalties and damages against those who knowingly present or cause to be presented a false or fraudulent claim to the federal government, as well as against those who knowingly make or use or cause to be made or used a false record or statement material to a false or fraudulent claim
FAS	Federal Antimonopoly Service of the Russian Federation
FASB	Financial Accounting Standards Board
FCPA	Foreign Corrupt Practices Act
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Amendments Act
FEHBP	Federal Employees Health Benefits Program
FFDCA	Federal Food, Drug, and Cosmetic Act

FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FOIA	Freedom of Information Act
Form 483	FDA form used to notify drug and device manufacturers of initial findings of violations of cGMP/QSR or other regulatory requirements identified in an FDA inspection
Form A	Statement Regarding the Acquisition of Control of or Merger with a Domestic Insurer, generally required to be filed with a state insurance regulatory authority to obtain approval of a change of control of an insurance company domiciled in the state
Form E	Statement filed with state insurance regulatory authorities in connection with a proposed business combination between insurers summarizing the competitive impact of the combination of the market share of the insurers
FQHC	Federally qualified health center
FTC	Federal Trade Commission
GCPs	*See* **Good clinical practices**
General controls	The controls applicable to the manufacture, sale, and marketing of medical devices in the United States under sections 501 (adulteration), 502 (misbranding), 510 (registration), 516 (banned devices), 518 (notification and other remedies), 519 (records and reports), and 520 (general provisions) of the FFDCA
GINA	Genetic Information Nondiscrimination Act of 2008
GLPs	See **Good laboratory practices**
GMPs	*See* **Current good manufacturing practices**
Good clinical practices (GCPs)	FDA guidances, regulations, and requirements that apply to clinical trials or studies of drugs, biologics, and medical devices

Good laboratory practices (GLPs)	Practices prescribed by FDA regulations that apply to preclinical testing and development of drugs, biologics, and medical devices. *See* 21 C.F.R. Part 58.
GRAS/E	Generally recognized as safe and effective
HAS	*See* ***Haute Autorité de Santé***
Hatch-Waxman Act	The Drug Price Competition and Patent Term Restoration Act of 1984, a federal statute that established the regulatory framework applicable to the approval of generic pharmaceuticals. The Hatch-Waxman Act framework includes various structures and incentives to protect the interests of both generic and innovator pharmaceutical manufacturers, such as the opportunity for streamlined approval of generic drugs, the possibility of obtaining certain periods of market exclusivity, a patent dispute resolution framework, and potential patent term extensions to account for the period of FDA regulatory review.
Haute Autorité de Santé (HAS)	The French National Authority for Health
HCERA	Health Care and Education Reconciliation Act
Health Care Fraud Prevention and Enforcement Action Team (HEAT)	A multiagency team of federal, state, and local investigators that investigates health care program fraud in various regions of the United States
Health Care Fraud Statute	A federal criminal statute, 18 U.S.C. § 1347, that prohibits fraud in connection with a submission to obtain health care benefits
Health Information Technology for Economic and Clinical Health Act (HITECH Act)	Act that provides incentives for the adoption of electronic health records, modifies HIPAA requirements, and imposes new obligations related to inappropriate disclosures of protected health information (PHI); passed as part of the American Recovery and Reinvestment Act of 2009

Health Insurance Portability and Accountability Act of 1996 (HIPAA)	Act that authorizes the Department of Health and Human Services (HHS) to promulgate regulations regarding standard electronic transactions and privacy and security for patient information. These rules establish the federal standards for protecting "protected health information" (PHI).
Health maintenance organization (HMO)	A type of health insurance plan that usually limits coverage to care from doctors who work for or contract with the HMO
Health Resources and Services Administration (HRSA)	A unit of the U.S. Department of Health and Human Services responsible for increasing access to health care services
HEAT	*See* **Health Care Fraud Prevention and Enforcement Action Team**
Herfindahl-Hirschman Index (HHI)	A measurement of market concentration commonly used in merger analysis
HHA	Home health agency
HHI	*See* **Herfindahl-Hirschman Index**
HHS	Department of Health and Human Services
HHS OIG	Office of Inspector General of the Department of Health and Human Services
HIPAA	*See* **Health Insurance Portability and Accountability Act of 1996**

HIPAA Privacy Rule	Regulations promulgated by the HHS Office for Civil Rights (OCR) under Title II of HIPAA, which establishes the federal requirements for the use and disclosure of individually identifiable health information by "covered entities," including health care clearinghouses, certain public and private health plans (that is, payors), and certain health care providers. The regulations also apply to certain contractors (called "business associates") that create, receive, transmit, or maintain protected health information on behalf of covered entities.
HITECH Act	*See* **Health Information Technology for Economic and Clinical Health Act**
HMO	*See* **Health maintenance organization**
Homeopathic drug	A category of drug products developed pursuant to the principles of homeopathy that generally do not require formal FDA approval, nor are they required to comply with an OTC monograph. Homeopathic medicines treat the symptoms and conditions of disease with drugs derived from substances that have produced similar symptoms in healthy subjects.
Homeopathic Drug CPG	Compliance policy guide published by the FDA that sets forth enforcement policies for manufacture and distribution of homeopathic drugs
Homeopathic Pharmacopeia of the United States (HPUS)	A compendium of homeopathic drugs, identified in the FFDCA as an "official" compendium
HPUS	*See* **Homeopathic Pharmacopeia of the United States**
HRSA	*See* **Health Resources and Services Administration**
HSR Act	Hart-Scott-Rodino Antitrust Improvements Act of 1976

IASB	International Accounting Standards Board
ICF/MR	Intermediate care facility for persons with mental retardation
IDE application	*See* **Investigational Device Exemption application**
Import alert	An FDA product-specific or categorical warning that generally prohibits the importation of specified articles
Import detention	An FDA administrative act requiring that imported articles that appear to violate FDA-administered laws be held intact
Import hold	An FDA administrative act requiring that an imported item be held pending further information from sampling or examination
IND	*See* **Investigational New Drug Application**
Independent Payment Advisory Board (IPAB)	An advisory body created by the PPACA that is charged with making recommendations for reducing Medicare costs
Institutional review board (IRB)	A board, committee, or other group formally designated by an institution to review biomedical research involving humans as subjects, to approve the initiation of and conduct periodic review of such research. 21 C.F.R. § 50.3(i).
Investigational Device Exemption (IDE) application	Application by the sponsor of an investigational medical device for exemption from the prohibition against transport, distribution, or marketing of medical devices across state lines without first obtaining FDA approval or clearance. The IDE application is governed by 21 C.F.R. Part 812, Subpart B.
Investigational New Drug (IND) application	Application by the sponsor of an investigational drug for exemption from the legal requirement that a drug be the subject of an approved marketing application before it is transported or distributed across state lines. The IND application is governed by 21 C.F.R. Part 312, Subpart B.

IPAB	*See* **Independent Payment Advisory Board**
IPR&D	In-process research and development
IRB	*See* **Institutional review board**
Joint Commission	A not-for-profit organization that accredits and certifies health care organizations and programs in the United States. A hospital accredited by the Joint Commission is deemed to have met applicable Conditions of Participation (CoPs) and other applicable regulatory requirements in some states. Formerly the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).
Joint venture	An arrangement between parties for a limited and specific purpose; especially an equity arrangement whereby two or more parties form a new entity or buy into an existing entity to carry out an enterprise together
JSC Law	The Russian federal law on joint stock companies
Lanham Act	A federal statute, 15 U.S.C. §§ 1051–1141n, that prohibits trademark infringement and dilution, false advertising, and cyberpiracy, among other things. It permits a private plaintiff to bring a claim based on false or misleading promotion, or based on a trademark or trade dress (product packaging or design) that is likely to cause consumer confusion as to the source or sponsorship of goods or services.
LTC	Long-term care
MAC	Medicare administrative contractor
MACPAC	*See* **Medicaid and CHIP Payment and Access Commission**
Managed care organization (MCO)	An organization, such as an HMO or PPO, that provides care using techniques intended to reduce costs

March-in right	Right of the federal agency that funds an invention to require the contractor or inventor electing to retain title to an invention under the Bayh-Dole Act to grant licenses to agency-elected applicants on reasonable terms or for the agency to grant sublicenses itself
Market withdrawal	Removal or correction of a distributed product that has a minor violation that would not be subject to FDA legal action or that involves no violation. 21 C.F.R. § 7.3(j).
Mass tort	A class of civil actions in which multiple plaintiffs are injured in a similar fashion, typically by the same defective or allegedly defective product. Mass tort litigation usually cannot be brought as a class action because of the different circumstances surrounding each individual plaintiff's use of the product and the unique factors relevant to each plaintiff's alleged damages.
Material transfer agreement (MTA)	A legal contract defining how materials may be transferred among parties as well as how they can be used
MCO	*See* **Managed care organization**
MD&A	Management discussion and analysis
MDR	*See* **Medical device reporting**
MDUFMA	*See* **Medical Device User Fee and Modernization Act**
Medicaid and CHIP Payment and Access Commission (MACPAC)	An advisory body directed to analyze Medicaid and CHIP services, payment policies, and costs and to make annual recommendations to Congress on ways to strengthen these programs

Medicaid rebate agreement	Agreement between a drug manufacturer and HHS under which the manufacturer is required to pay rebates directly to each state Medicaid agency using a statutorily defined formula that is based, in part, on the company's "best price," which is the lowest price at which the company sells its drug to certain categories of customers. 42 U.S.C. § 1396r–8.
Medical device	An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. 21 U.S.C. § 321(h).
Medical device reporting (MDR)	FDA requirements applicable to medical device user facilities, manufacturers, importers, and distributors that require reporting of an event in which a device has or may have caused or contributed to death or serious injury. 21 C.F.R. § 803.1(a).
Medical Device User Fee and Modernization Act (MDUFMA)	A federal statute enacted in 2002 and reauthorized in 2007 that permits the FDA to collect certain types of user fees in connection with the FDA's review of medical device applications and certain annual establishment registration fees

Medicare Advantage	A type of Medicare health plan offered by a private company that contracts with Medicare to provide Part A (hospital, nursing home, hospice) and Part B (medically necessary services and preventive services)
Medicare Change of Ownership (CHOW)	A change in the legal entity previously assigned a CCN and a UPIN, such that the CCN and UPIN are associated with a new federal taxpayer identification number, resulting in assignment of the seller's Medicare provider agreement
MPFS	Medicare Physician Fee Schedule
MTA	*See* **Material transfer agreement**
NAIC	National Association of Insurance Commissioners
National Provider Identifier (NPI)	A health care provider's Medicare billing number, used by CMS (and its fiscal intermediaries) for claims processing and frequently used by other payors, including commercial health insurers; formerly the Unique Provider Identification Number (UPIN)
NCE	*See* **New chemical entity**
NDA	*See* **New Drug Application**
Negative monograph	Publication by the FDA that lists therapeutic categories in which no OTC drugs can be marketed without approval
New chemical entity (NCE)	A drug in which no active ingredient has been previously approved in any other new drug application. Such a drug is eligible for five-year marketing exclusivity under the Hatch-Waxman Act.

New Drug Application (NDA)	The application submitted to the FDA for approval of the sale and marketing of a new drug in the United States. The standard form, based on a sponsor's own data, is referred to as a 505(b)(1) NDA (named for the relevant section of the FFDCA). An alternative form, used when a sponsor is submitting the application based on data it does not own or control, is referred to as a 505(b)(2) NDA. The NDA is governed by 21 C.F.R. Part 314, Subpart B.
NIH	National Institutes of Health
Notice of detention and hearing	A notice issued by the FDA following examination or sampling of an article offered for import indicating that the article appears to be in violation of the FFDCA or another act or regulation enforced by the FDA and may be detained
Notice of sampling	A notice issued by the FDA requesting an examination or sample of imported articles subject to FDA oversight and examination
NPA	Nonprosecution agreement
NPI	*See* **National Provider Identifier**
NPP	Nonphysician practitioner
OCR	Office for Civil Rights of the U.S. Department of Health and Human Services
OECD	Organization for Economic Cooperation and Development
Off-label	The use of a drug for indications for which the FDA has not reviewed safety or efficacy data as part of a new drug application or OTC drug review. Off-label drug promotion is the promotion of a drug product for uses that are outside the scope of the uses that are contained in an approved drug application or final OTC drug monograph.

Office of Prescription Drug Promotion (OPDP)	A unit of the FDA's Center for Drug Evaluation and Research (CDER) with responsibility for regulating drug advertising and promotion (formerly the Division of Drug Marketing, Advertising, and Communications (DDMAC))
ONC	Office of the National Coordinator for Health Information Technology
OPDP	*See* **Office of Prescription Drug Promotion**
OPO	Organ procurement organization
OPPS	Outpatient Prospective Payment System of Medicare
ORA	Office of Regulatory Affairs, a unit of the FDA
Orange Book	*Approved Drug Products with Therapeutic Equivalence Evaluations*, an FDA publication that identifies drug products approved on the basis of safety and effectiveness by the FDA, including the patents covered by such products
Orphan Drug Act	A federal statute that provides various incentives, including tax incentives and grant funding for clinical trials, and awards seven years of market exclusivity for a drug designated as an "orphan drug"—a drug for the treatment of a rare disease or condition
Order to show cause (OTSC)	May be issued by the DEA as a formal action to deny or revoke a DEA registration as a result of significant violations by a registrant involving failure to maintain effective controls against diversion of controlled substances or a pattern of violations occurring over a prolonged period of time
OTC	Over-the-counter
OTSC	*See* **Order to show cause**
PACE	Programs for All-Inclusive Care for the Elderly

PAPS	Promotion and Advertising Policy Staff of the FDA's Center for Devices and Radiological Health (CDRH)
Park doctrine	Doctrine established by the Supreme Court in *United States v. Park*, 421 U.S. 658 (1975), holding that executives and managers can be convicted of a criminal misdemeanor under the FFDCA based on the acts or omissions of their subordinates if, by virtue of the executive's or manager's position in the company, they had the responsibility and authority to prevent or correct a violation but failed to do so
Patent	A property right granted to the inventor of a novel, nonobvious, and useful invention, which gives the patent owner the exclusive right to make and sell the invention for a specified period of time
Patient Protection and Affordable Care Act (PPACA)	The U.S. health care reform statute enacted in 2010, P.L. 111-148, sometimes referred to as "Obamacare"
PBGC	Pension Benefit and Guaranty Corporation
PDMA	*See* **Prescription Drug Marketing Act**
PDUFA	*See* **Prescription Drug User Fee Act**
PECOS	*See* **Provider Enrollment, Chain, and Ownership System**
Phase 1	(1) Drugs: The initial introduction of an investigational new drug into humans. Phase 1 studies are typically closely monitored and may be conducted in patients or normal volunteer subjects. These studies are designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. 21 C.F.R. § 312.21(a). (2) Environment: An initial environmental site assessment.

Phase 2	(1) Drugs: The controlled clinical studies conducted to evaluate the effectiveness of an investigational new drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug. 21 C.F.R. § 312.21(b). (2) Environment: A more intrusive environmental site assessment, typically including soil or groundwater testing.
Phase 3	Expanded human trials of an investigational new drug performed after preliminary evidence suggesting effectiveness of the drug has been obtained. Intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. 21 C.F.R. § 312.21(c).
PHI	*See* **Protected health information**
PIM	Program Integrity Manual of the Centers for Medicare and Medicaid Services (CMS)
PIPEs	*See* **Private investments in public equity**
PMA	*See* **Premarket Approval**
PNO	Premerger Notification Office of the FTC
Potentially responsible person (PRP)	A person upon whom liability for cleanup costs is imposed under CERCLA, including the current owner or operator of a site at which there has been a release of a hazardous substance, and the former owner or operator of the site if such person owned or operated the site at the time the release of hazardous substances occurred
PPACA	*See* **Patient Protection and Affordable Care Act**
PPM	Physician practice management

PPO	Preferred provider organization
Premarket Approval (PMA)	FDA process of scientific and regulatory review to evaluate the safety and effectiveness of a Class III medical device, other than a Class III device that is "substantially equivalent" to a device legally marketed prior to May 28, 1976. An application for approval of such devices by the FDA is required under section 515 of the FFDCA. Such devices may not be marketed until approval is granted.
Premarket Notification	Notification provided by a medical device manufacturer to the FDA pursuant to section 510(k) of the FFDCA, informing FDA of the device manufacturer's intention to market a medical device for which there is a lawfully marketed, substantially equivalent, predicate device. When required, such notification must be submitted at least ninety days in advance of sale.
Prescription Drug Marketing Act (PDMA)	A federal statute that, among other things, prohibits the reimportation into the United States of a U.S.-made prescription drug by anyone other than the drug's original manufacturer
Prescription Drug User Fee Act (PDUFA)	A federal statute, reauthorized by Congress every five years since its original enactment in 1992, that authorizes FDA to collect fees from companies that produce certain human drug and biological products
Privacy Rule	*See* **HIPAA Privacy Rule**
Private investments in public equity (PIPEs)	An offering of equity securities to institutional investors. Can be implemented more quickly and less expensively than underwritten offerings.

Protected health information (PHI)	Information that is subject to privacy and security regulation under HIPAA. It includes "individually identifiable health information" held or transmitted by a "covered entity" or its "business associate," in any form. For this purpose, "individually identifiable health information" is information that relates to an individual's past, present, or future physical or mental health or condition, the provision of health care to the individual, or the past, present, or future payment for the provision of health care to the individual, and that identifies the individual.
Provider Enrollment, Chain, and Ownership System (PECOS)	Internet-based system by which a licensed health care facility may enroll in the Medicare program in order to be eligible to receive Medicare payment for covered services provided to Medicare beneficiaries
Provider Transaction Access Number (PTAN)	*See* **CMS Certification Number**
PRP	*See* **Potentially responsible person**
PTAN	*See* **CMS Certification Number**
PTO	Patent and Trademark Office
Quality System Regulations (QSR)	FDA regulations (21 C.F.R. § 820 *et seq*.) that require medical device manufacturers to establish and maintain quality systems to help ensure that their products consistently meet applicable requirements and specifications
Qui tam	A lawsuit brought by a private plaintiff on behalf of a government. The plaintiff may be entitled to a portion of the government's recovery in the suit. Qui tam suits are authorized under the False Claims Act.
QSR	*See* **Quality System Regulations**
R&D	Research and development
RBC	Risk-based capital

RCO	Responsible corporate officer
RCRA	Resource Conservation and Recovery Act
RDO	*See* **Registered direct offering**
REC	*See* **Recognized environmental condition**
Recognized environmental condition (REC)	Condition defined under applicable engineering rules as "the presence or likely presence of any hazardous substances or petroleum products on a property under conditions that indicate an existing release, a past release, or a material threat of a release of any hazardous substances or petroleum products into structures on the property or into the ground, ground water, or surface water of the property"
Registered direct offering (RDO)	A public offering of equity securities marketed by a placement agent on an agency basis to a limited number of institutional investors
Right of first offer	Obligation of a party to a joint venture or other multilateral arrangement to offer to sell the interests to the other joint venture participants and keep such offer open for a specified period of time
Rospatent	The Russian Federal Service on Intellectual Property
RPM	Regulatory project manager
SA	*See* **Survey agency**
Schedule I	Controlled substance classification applicable to drugs with a high potential for abuse and no currently accepted medical use; Schedule I controlled substances are not legally available to the public
Schedule II	Controlled substance classification applicable to drugs with a high potential for abuse and dependence but also a currently accepted medical use (for example, opioids such as morphine and oxycodone)

Schedule III	Controlled substance classification applicable to drugs with a moderate potential for abuse and an accepted medical use
Schedules IV and V	Controlled substance classification applicable to drugs with medical uses and successively lower potentials for abuse and dependence
Schéma Régional d'Organisation des Soins (SROS)	A regional plan for the provision of health care services developed by a French regional health agency
SCHIP	State Children's Health Insurance Program
SEC	Securities and Exchange Commission
Second request	A formal request by the DOJ or FTC for additional information concerning a proposed business combination
SOP	*See* **Standard operating procedure**
SPARC	Special purpose accelerated research company
SPCC	*See* **Spill Prevention, Control, and Countermeasure**
Spill Prevention, Control, and Countermeasure (SPCC)	EPA requirements applicable to both aboveground and underground storage of petroleum and other oils. 49 U.S.C. § 5103(a).
SROS	*See* ***Schéma Régional d'Organisation des Soins***
Standard operating procedure (SOP)	A written document that formalizes specific operational processes
Stark law	A federal law that prohibits a physician from making a referral to an entity with which the physician, or an immediate family member of the physician, has a financial relationship, for the furnishing of designated health services for which payment is made by the federal government under the Medicare or Medicaid programs, and prohibits the entity from presenting or causing to be presented a claim to the federal government for such services. 42 U.S.C. § 1395nn.

Stock recovery	Removal or correction by a company of a product that has not been marketed or distributed, or has not left the direct control of the company
Strategic Investments Law	The Russian federal Law on Foreign Investments in Entities of Strategic Importance for National Defense and National Security
Survey agency (SA)	An office or division of a state's department of health tasked with determining whether an institutional health care provider meets the requirements for participation in the Medicare program
SWORD	Stock and warrant off-balance sheet research and development
Tentative Final Monograph (TFM)	A publication by the FDA in connection with the second phase of OTC drug review process that sets forth the findings of the relevant advisory review panel with respect to safety and effectiveness, labeling, strength, dosage form, and route of administration of the proposed drug. Following a comment period, the FDA publishes final regulations in the form of a final monograph.
TFM	*See* **Tentative Final Monograph**
TPA	Third-party administrator
Trade secret	Valuable information that is not generally known, not readily ascertainable by others, and subject to secrecy
Trademark	Any word, name, symbol, or device, or any combination thereof, that identifies or distinguishes one's goods from those manufactured or sold by others and indicates the source of the goods

TRICARE	U.S. Department of Defense health care program that provides civilian health benefits for military personnel, military retirees, and their dependents; formerly known as Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)
TSCA	Toxic Substances Control Act
UBTI	*See* **Unrelated business taxable income**
UCC	Uniform Commercial Code
UKBA	United Kingdom Bribery Act 2010
Uniform Standards of Professional Appraisal Practice (USPAP)	A code of ethics and standards developed by the Appraisal Foundation; adopted by most major appraisal organizations in North America and recognized as the generally accepted standards of appraisal practice
Unrelated business taxable income (UBTI)	Income to a tax-exempt organization that is taxable because it is deemed not to be substantially related to the fulfillment of the organization's exempt purposes
Untitled letter	A letter issued by the FDA indicating that it has identified an alleged violations of a statutory or regulatory requirement that does not reach a level of regulatory significance sufficient to result in a warning letter
UPIN	*See* **National Provider Identifier**
URA	*See* **Utilization Review Agency**
U.S. Preventive Services Task Force (USPSTF)	A government-appointed expert panel in primary care and prevention that systematically reviews the evidence of effectiveness and develops recommendations for clinical preventive services
USPAP	*See* **Uniform Standards of Professional Appraisal Practice**
USPSTF	*See* **U.S. Preventive Services Task Force**

UST	Underground storage tank
Utilization Review Agency (URA)	An entity that conducts prospective, concurrent, or retrospective review of the medical necessity and appropriateness of health care services provided or proposed to be provided to a covered individual
VA	Department of Veterans Affairs
Valid Marketing Authorization	An affirmative decision by the appropriate public health authority in a foreign country to permit a drug, biological product, or device to be sold in that country, even where the item is unapproved by the FDA
VIE	Variable interest entity
WARN	Worker Adjustment and Retraining Notification Act of 1988
Warning letter	A formal advisory letter issued by the FDA indicating its belief that an individual or a company has committed a significant violation of a statutory or regulatory requirement

Current Trends in Health Care M&A

Andrew L. Bab, Jennifer L. Chu & Samantha L. Berkovits

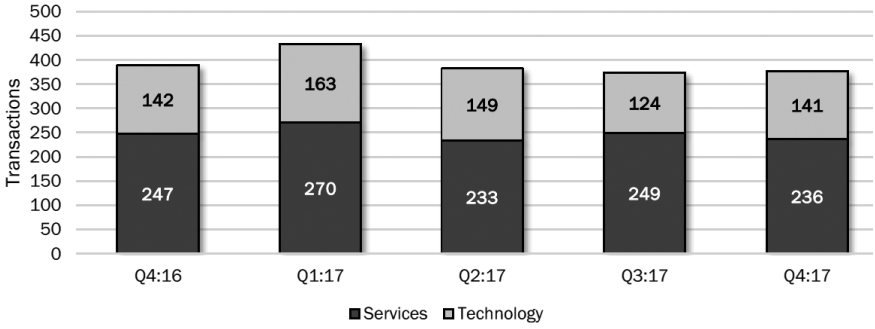
By one key metric, global M&A activity in 2017 remained relatively consistent with 2016. Total deal value in 2017 was $3.6 trillion, on par with total deal value of $3.7 trillion in 2016. However, total deal volume increased by 3%; 49,448 deals were announced in 2017, an increase from the 46,055 deals announced in 2016 and the most deals ever recorded in a single year. This increase can be in part explained by a 7% increase in the number of deals valued at less than $1 billion.[1]

Health care was the third most active sector, measured by deal volume, in global M&A in 2017.[2] 1,566 health care sector deals were announced in 2017, a slight decrease from the 1,593 health care sector deals reported for 2016.[3] Deal value in the health care sector in 2017 increased to $315.3 billion from $256.7 billion in 2016,[4] although this number still did not approach 2015 levels, when health care sector deal value was $563 billion.[5] Health care deal activity was most pronounced during the first quarter of 2017, when it spiked from the fourth quarter of 2016, but thereafter activity levels fell and remained relatively constant for the remainder of the year.[6]

Quarterly health care transaction volumes for 2017, broken down by deals involving health care "services" (including behavioral health, home health, hospitals, long-term care, managed care, physician medical groups, and rehabilitation services) and those involving health care "technology" (including biotech, medical devices, and pharmaceuticals) are shown in Table 1.

Table 1

Health Care Mergers & Acquisitions
Total Transactions in 2017
by Quarter



Source: Irving Levin Associates, Inc., Health Care M&A Report (Fourth Quarter 2017)

Within the health care sector, the long-term care subsector was the most active based on deal volume, with 300 deals in 2017. The biotechnology subsector was also active, accounting for 208 deals.[7] Deal volume by subsector for each quarter of 2017 is shown in Table 2 and Table 3.

Table 2

Health Care Mergers & Acquisitions Deal Volume by Subsector in Q1 and Q2 2017

	Q2:17 Deals	Q1:17 Deals	Change	Q2:16 Deals	Change
Services					
Behavioral Health Care	8	16	-50%	17	-53%
Home Health & Hospice	9	15	-40%	13	-31%
Hospitals	23	20	15%	20	15%
Labs, MRI and Dialysis	13	12	8%	13	0%
Long-Term Care	75	76	-1%	90	-17%
Managed Care	5	4	25%	5	0%
Physician Medical Groups	30	59	-49%	42	-29%
Rehabilitation	6	12	-50%	10	-40%
Other	51	53	-4%	49	4%
Services subtotal	220	267	-18%	259	-15%
Technology					
Biotechnology	54	63	-14%	34	59%
eHealth	43	48	-10%	60	-28%
Medical Devices	33	23	43%	27	22%
Pharmaceuticals	16	29	-45%	44	-64%
Technology subtotal	146	163	-10%	165	-12%
Grand Total	366	430	-15%	424	-14%

Source: Irving Levin Associates, Inc., Health Care M&A Report (Second Quarter 2017)

Table 3

Health Care Mergers & Acquisitions
Deal Volume by Subsector in Q3 and Q4 2017

	Q4:17 Deals	Q3:17 Deals	Change	Q4:16 Deals	Change
Services					
Behavioral Health Care	12	14	-14%	10	20%
Home Health & Hospice	13	12	8%	24	-46%
Hospitals	21	15	40%	23	-9%
Labs, MRI and Dialysis	16	15	7%	9	78%
Long-Term Care	70	74	-5%	93	-25%
Managed Care	10	8	25%	4	150%
Physician Medical Groups	32	43	-26%	28	14%
Rehabilitation	11	17	-35%	11	0%
Other	51	51	0%	45	13%
Services subtotal	**236**	**249**	**-5%**	**247**	**-4%**
Technology					
Biotechnology	49	42	17%	56	-13%
eHealth	30	42	-29%	30	0%
Medical Devices	28	23	22%	23	22%
Pharmaceuticals	34	17	100%	33	3%
Technology subtotal	**141**	**124**	**14%**	**142**	**-1%**
Grand Total	**377**	**373**	**1%**	**389**	**-3%**

Source: Irving Levin Associates, Inc., Health Care M&A Report (Fourth Quarter 2017)

In the first and third quarters, biotechnology constituted 55% ($32.5 billion) and 33% ($14.1 billion) of total deal value. Johnson & Johnson's first quarter $30.2 billion acquisition of Actelion Ltd. and Gilead Science's third quarter acquisition of Kite Pharma for $11.9 billion accounted for the majority of those quarterly totals. Likewise, in the fourth quarter, a mega-deal in the managed care subsector, CVS Health's acquisition of Aetna for $77.0 billion, alone accounted for 67% of the quarter's total deal value.

In the second quarter, "Other Services," a subsector which includes contract research organizations, dental practices, and institutional and specialty pharmacy companies, was the largest subsector measured

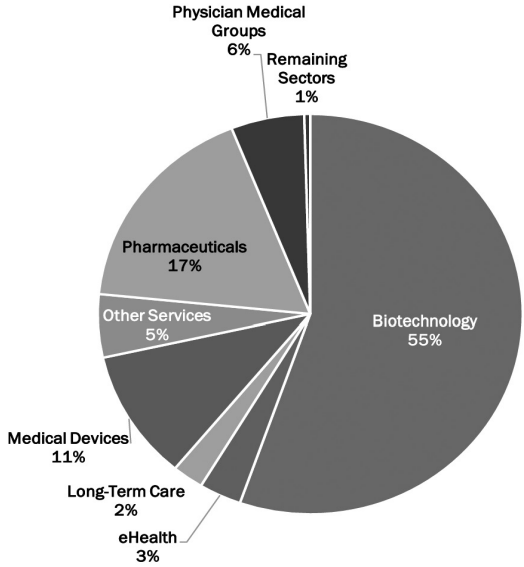
by deal value, representing 37% ($34.0 billion) of deal value that quarter with three large transactions announced (for companies involved in pharmaceutical research and laboratory support products and services), each with a value exceeding $5 billion. The medical devices subsector was nearly tied for total value at 35% ($33.8 billion) and was bolstered by Becton, Dickinson & Co.'s $24.0 billion acquisition of C.R. Bard, Inc.[8]

The percentage breakdown of total deal value by subsector in each quarter of 2017 is shown in Table 4.

Table 4

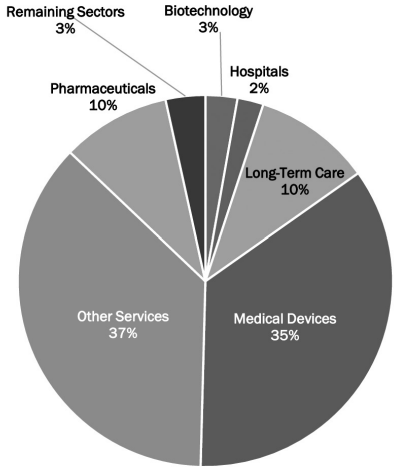
Health Care Mergers & Acquisitions
Dollar Volume and Share by Subsector

Q1 2017



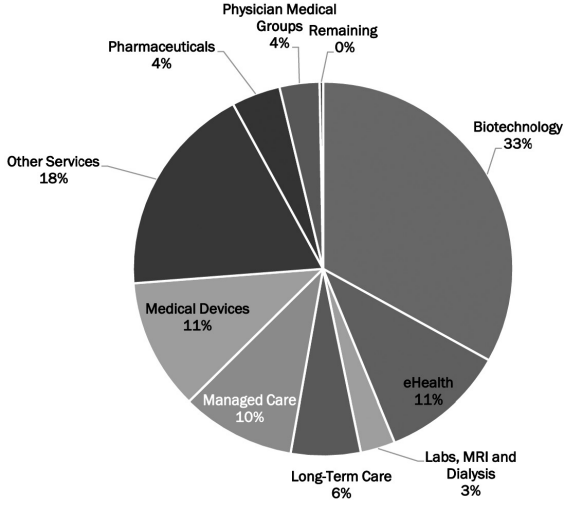
Source: Irving Levin Associates, Inc., Health Care M&A Report (First Quarter 2017)

Q2 2017



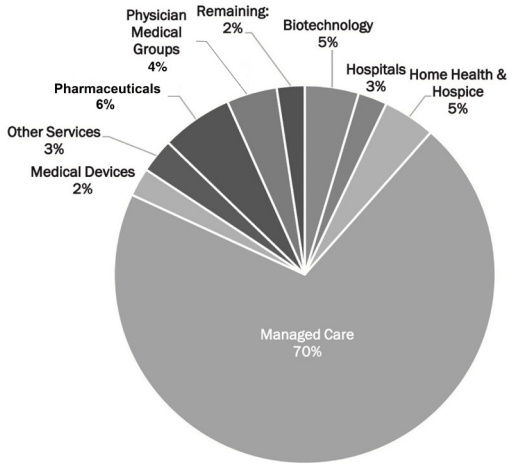
Source: Irving Levin Associates, Inc., Health Care M&A Report (Second Quarter 2017)

Q3 2017



Source: Irving Levin Associates, Inc., Health Care M&A Report (Third Quarter 2017)

Q4 2017



Source: Irving Levin Associates, Inc., Health Care M&A Report (Fourth Quarter 2017)

In the remainder of this report, we outline a couple of the trends and developments driving health care M&A activity today. A proactive focus on utilizing highly strategic business structures and deal structures has driven recent health care M&A activity, and we believe will continue to do so.

Vertical Integration

Vertical integration, the practice of merging businesses which operate at different levels of the same industry, is not a new concept for the health care industry. However, in recent years, as industry participants have become increasingly focused on providing cost-effective health care, these deals have become front-page news.[9]

These transactions generally involve three traditionally distinct kinds of health care industry players: insurers, health care providers, and participants in the prescription drug space, whether pharmacies or pharmacy benefit managers. By aligning the interests of parties

with historically divergent goals, buyers aim to create opportunities to develop new ways to control health care costs and models for value-based care,[10] for example, by facilitating access to cost-effective primary/preventive care and decreasing the amount of unnecessary and costly hospitalizations.

In recent years, major health insurers have continued on acquisition sprees for vertical integration opportunities, even while horizontal mergers among the same insurers have been blocked by antitrust regulators. In 2016, Aetna and Texas Health Resources, a twenty-seven-hospital not-for-profit health system based in Arlington, Texas, established a joint venture to own and operate a new health plan.[11] During the same year, Anthem joined forces with Aurora Health Care, a fifteen-hospital system based in Milwaukee, Wisconsin, to form a new health insurance company.[12]

UnitedHealthcare Group, through its Optum health services unit, has been at the forefront of health insurers seeking to transform health care delivery. Optum has its own pharmacy benefits manager (PBM) business, as well as a data and analytics arm, and in recent years has been aggressively expanding its health care delivery offerings. In 2017, Optum announced several acquisitions of physician groups, including the acquisition of the DaVita Medical Group for $4.9 billion.[13] If the DaVita acquisition closes (which it has not as of the time of writing), it would provide Optum access to 280 clinics offering primary/specialist care, thirty-five urgent care centers, and six outpatient surgery centers. Earlier in the year, Optum also announced the acquisition of ambulatory surgery center and surgical hospital provider Surgical Care Affiliates for $2.3 billion.[14] The pace of growth for companies like Optum does not appear to be slowing down. During the first quarter of 2018, UnitedHealthcare Group's CEO signaled that the company would continue to be "very strong deployers of capital."[15]

Other competitors are following suit. In 2017, Humana, in the wake of its failed merger with Aetna, pivoted to a vertical integration opportunity in the home health sector. Humana teamed up with private equity firms TPG Capital and Welsh, Carson, Anderson & Stowe to acquire Kindred Healthcare, a publicly traded post-acute health care

provider. The transaction, which closed on July 2, 2018, separated Kindred into two businesses: a hospital business owned by the private equity consortium, and a home health, hospice and community care business, owned 40% by Humana and 60% by the private equity consortium.[16] In 2018, Humana and the TPG-Welsh Carson consortium also teamed up to acquire Curo Health, a leading hospice operator, which they intend to combine with the hospice business of Kindred.[17]

In late 2017, CVS announced its acquisition of Aetna, a mega-merger valued at approximately $69 billion. If completed, this deal would integrate an insurer (Aetna), a pharmacy benefits manager (CVS's Caremark unit), CVS's almost 10,000 pharmacies, and CVS's 1,000 Minute Clinics, which offer primary care.[18] The aim is to continue the transformation of CVS's drugstores to one-stop shops for health care.

In the first quarter of 2018, Cigna followed suit and announced it had entered into an approximately $52 billion agreement to purchase Express Scripts, the country's largest pharmacy benefits manager.[19] The announcement of this deal was less than a year after Cigna's proposed merger with competitor Anthem was terminated. Filings made in connection with the Cigna-Express Scripts merger indicate that Cigna had considered other horizontal merger opportunities before ultimately pursuing the Express Scripts transaction and that Cigna's board discussed changes in the health care environment, including the recently announced CVS-Aetna merger.

By blurring the lines between traditionally separate spheres, the move towards vertical integration has the potential to transform the health care industry. While antitrust regulators have historically reserved their scrutiny for horizontal mergers, this recent wave of vertical integration mega-deals has also drawn their attention. Both the CVS-Aetna and the Cigna-Express Scripts mergers have been subject to DOJ review (although it was reported in July 2018 that the DOJ will not challenge the CVS-Aetna merger), and both deals have attracted congressional scrutiny as well with requests for hearings on the deals.[20] At the time of writing, the Optum-DaVita transaction has been similarly held up by requests from the FTC for additional information.[21] Whether antitrust scrutiny of these deals will impact vertical M&A activity remains to be seen, but the trend towards transformative vertical activity seems likely to continue.

Alternatives to Traditional M&A

There continues to be growing interest in the health care industry in licensing, joint ventures, options, collaborations, and other alternatives to the traditional M&A deal structure. Alternative transactions allow buyers to acquire new capabilities with less up-front financial investment and potentially fewer regulatory approvals.[22] Licensing and partnerships can provide smaller companies with the scale and sophistication of a larger organization while allowing the companies to maintain local control. Options allow large buyers to temper their risk while infusing necessary early capital in research and development processes. The downside is that the success of these transactions often depends on the parties being able to effectively collaborate and align their goals.[23]

Option transactions—in which a buyer purchases an option to acquire another company or its product or to license another company's product at some future date—have become increasingly popular ways for big pharmaceutical and biotech companies to partner in early-stage products and technology, as well as an important source of potential financing for those early-stage companies. This strategy allows the potential buyer to wait and see how the technology progresses; for instance, the buyer can see whether the research is successful or the FDA approves the drug or device.

2017 saw a number of deals involving the exercise of existing options as well as entry into new option arrangements. For example, Astellas exercised its option to acquire 100% of the equity of Mitobridge, Inc. for total consideration of up to $450 million—an option which it held under the parties' 2013 partnership agreements, which were focused on developing novel drugs that target mitochondrial function.[24] Other notable recent deals include Novartis AG's $665 million exercising of its exclusive option to buy Selexys Pharmaceuticals Corporation and its developing sickle cell anemia drug following successful completion of its Phase 2 study (the fourth-largest biotechnology deal in 2016); Pfizer Inc.'s $250 million option to exclusively license OncoImmune Inc.'s ONC-392 drug; Amgen's $35 million option to license Arrowhead's technology to reduce elevated lipoproteins; and Johnson & Johnson's option to acquire Bird Rock Bio, Inc., a biopharmaceutical company developing an antibody to treat nonalcoholic steatohepatitis.[25]

Licensing has always been a critical tool in the health care toolkit and historically has been useful in circumstances where the asset owner is not a suitable M&A target (such as a university). However, in recent years, it is increasingly being used in much larger deals as an alternative to traditional M&A. Licensing arrangements allow for risk sharing and retention of talent at the original developer, while avoiding taking on unwanted products and liabilities. Fees and royalties in such deals can include up-front payments, an opt-in payment payable on exercise of the option, development and commercialization milestone payments, standard royalties, or combinations thereof. Depending on how developed the product is and its prospects for success, there is significant freedom for parties to negotiate how profits will be distributed. These deals tend to be extremely complex and involve all aspects of a product, portfolio of products, or business.

By utilizing licensing agreements, large pharmaceutical companies with struggling research and development pipelines are able to tap into innovative biotech while providing the biotech firm additional resources and marketing. A biotech firm may be working on innovative new formulas and solutions, but will not have the capacity to market and distribute a drug globally, while a large, established pharmaceutical company has that capacity, but may be striking out when it comes to developing a drug that addresses a specific market need.

During the fourth quarter of 2017, of the over 1,100 licensing deals reported, forty-nine were valued in excess of $100 million, including several worth potentially over $1 billion. For example, in late 2017, Eli Lilly announced a $1.8 billion licensing and collaboration deal to work with CureVac on five mRNA cancer vaccines, a therapeutic area where pharmaceutical companies have had a disappointing development track record. Under the terms of the arrangement, Eli Lilly agreed to pay CureVac an up-front payment of $50 million and to take an equity stake in CureVac valued at $53 million. In addition, CureVac is eligible to receive up to $1.7 billion in milestone payments plus royalties on sales if the vaccines are approved.

Also in late 2017, Bayer and Loxo Oncology announced a $1.55 billion development and collaboration partnership to develop medicines for patients with genetically defined cancers. Under the terms of the arrangement, Bayer agreed to pay Loxo an up-front payment of $400 million,

and Loxo is eligible to receive up to $650 million in milestone payments upon regulatory approvals and first commercial sales in certain major markets. In addition, Bayer will pay up to $475 million in royalties on net sales.

In February 2018, the Janssen Pharmaceutical Companies of Johnson & Johnson entered into a global collaboration and licensing agreement with Theravance Biopharma, Inc. to jointly develop TD-1473, the total consideration for which may reach approximately $1 billion.[26] Johnson & Johnson agreed to pay $100 million up front with an option to enter into an exclusive license agreement with Theravance Biopharma for an additional $200 million following the completion of certain Phase 2 activities. Theravance Biopharma is further entitled to receive up to an additional $700 million based on development and commercialization milestones. In this example, the licensor was granted an option to acquire an exclusive license of important intellectual property related to the compound in exchange for funding research and development activities and taking certain (joint) responsibility for development activities.

For 2018, signs seem to indicate that industry players will continue to pursue M&A to grow and to respond to what appear to be inevitable shifts in the industry driven by reimbursement models, developing technology, and increasing patient-centrism in the consumption of health care.

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Today's Health Care Legal and Regulatory Environment and Its Impact on the Health Care Marketplace

Jacob W. Stahl

In 2016, President Trump and Congressional Republicans campaigned—and won—on pledges to "repeal and replace" the ACA. Although the Republicans' transformative health care reform plans in Congress have collapsed, the Trump Administration, Congress, and state governments have implemented a variety of initiatives that are likely to have a significant impact on the health care industry for years to come.[1] These changes have created opportunities and risks for strategic companies and investors in the health care industry.

The ACA: What Has and Has Not Changed

The Original ACA Framework

Prior to the enactment of the ACA, people who did not receive health insurance from large employers or government programs often had difficulty obtaining private health insurance. Insurers offering plans for individuals or small groups often refused to cover preexisting conditions or would charge high premiums. The ACA drafters attempted to address these issues through provisions that were designed to ensure that insurance met three objectives, namely that it was (1) affordable, (2) accessible to those who needed it, and (3) provided adequate coverage.

With a few notable exceptions, most of these provisions remain in effect:

- *ACA exchanges*: The ACA provides that each state must have an exchange on which individuals and small groups can purchase health insurance. Insurers must treat everyone who

purchases insurance on the applicable state's exchange as being part of the same risk pool. Insurance plans are categorized into four principal tiers based on the percentage of health care costs the plans are supposed to cover (on an actuarial basis): platinum (90%), gold (80%), silver (70%), and bronze (60%). People under age 30 are also eligible to purchase catastrophic plans, which have lower premiums than bronze plans but have very high deductibles.

- *Insurance regulations to promote accessibility*: The ACA requires insurers to offer insurance to any qualified individuals who want to purchase it and precludes insurers from excluding preexisting conditions from coverage. It also precludes insurers from charging people different rates depending on their health status, although insurers are allowed to charge more (within limits) based on tobacco use and age. The ACA also provides that children can stay on their parents' insurance plan until age 26.
- *Minimum essential benefits*: Plans sold on ACA exchanges must cover ten categories of minimum essential benefits, including emergency services, hospitalization, ambulatory care, maternity care, and prescription drugs.
- *Payout caps*: The ACA prohibits insurers from capping the amount of money an insurer would pay out on an annual or lifetime basis for essential health benefits.
- *Subsidies*: The ACA provides for two forms of subsidies to facilitate the ability of lower income individuals to purchase insurance on exchange plans. The Advance Premium Tax Credit (APTC) provides subsidies on a sliding scale for people making between 100% and 400% of the federal poverty level. Additionally, the ACA originally included Cost Sharing Reductions (CSRs) for anyone making between 100 to 250% of the federal poverty level who purchased a "silver" plan on the exchanges. CSRs were meant to subsidize out-of-pocket expenditures for people with very low incomes. President Trump abolished CSRs in 2017.

- *Individual mandate*: The ACA includes an "individual mandate," which is a tax on people who do not purchase qualifying health insurance. The tax is $695 per adult, or 2.5% of taxable income, whichever is larger. The mandate is intended to discourage people from delaying the purchase of health insurance until they become sick. The ACA would otherwise have incentivized such behavior, because the ACA does not allow insurers to charge more or exclude people with preexisting medical conditions. When healthy people decline to purchase health insurance, health insurance premiums typically rise because the risk pool becomes relatively sicker. The mandate is abolished starting in 2019.
- *Medical loss ratios* (MLRs): The ACA requires insurers who offer plans that cover individual and small group plans to have an MLR of at least 80%, meaning that they must spend at least 80% of their premiums on health care claims and quality improvement. The remainder is for administration, marketing, and profits. For insurers that offer insurance to large groups, the MLR must be at least 85%.
- *Medicaid expansion*: Before the ACA, Medicaid covered children and their parents and the low-income elderly; Medicaid did not cover "childless adults." The ACA allows state Medicaid programs to cover childless adults who earn up to 138% of the federal poverty level. Although the Medicaid expansion was supposed to be mandatory, the Supreme Court held that each state could decide for itself whether to accept the expansion. To date, thirty-three states and Washington, D.C. have expanded Medicaid. The other states have declined to expand Medicaid, typically because of opposition from conservative governors or legislatures to expanding social welfare programs.

What Has Changed During the Trump Administration?

1. Abolition of the Individual Mandate

In December 2017, the Tax Cuts and Jobs Act abolished the individual mandate starting in 2019. The abolition of the mandate may lead some people to stop purchasing health insurance, because they no

longer will be penalized for declining to do so. There is a debate over how many people are likely to stop purchasing insurance after the mandate is abolished. While the Congressional Budget Office estimates that the abolition of the mandate will result in 13 million additional people being uninsured by 2027, others argue that this estimate is too high for several reasons: (1) the mandate has many exceptions and in any event has not actually been enforced; (2) people with lower incomes receive heavily subsidized insurance, so they have a strong incentive to purchase insurance even without the mandate; (3) premiums for many ACA-compliant health insurance plans are so high that some people have decided that it is more economical to pay the mandate tax than health insurance premiums; and (4) some healthy people purchase health insurance without regard to the individual mandate because they are risk-averse.

2. Proposed Expansion of the Availability of Association Health Plans (AHPs)

In January 2018, the Department of Labor issued a Proposed Rule to expand the availability of AHPs. AHPs are business and employer trade associations that offer health insurance to their members. Previously, AHPs were limited to organizations that had a bona fide purpose other than offering health insurance, and AHP plans were subject to the ACA's consumer protection provisions. If the Proposed Rule is finalized and survives potential legal challenges, AHPs could be established for the sole purpose of providing health insurance, provided that the members are either (1) in the same trade, industry, line of business, or profession, or (2) have a principal place of business within the same region—defined as either a state or a metropolitan area, even if it crosses state lines. The Proposed Rule would also allow AHPs to be classified as large group health insurance plans. This categorization is significant because large group plans are exempt from some of the ACA's consumer protection provisions, including the minimum essential benefits requirement. The Proposed Rule would also loosen restrictions on the rates that AHPs could charge members. While AHPs would still be subject to the ACA's prohibitions against charging insured with preexisting conditions higher rates or refusing to cover them altogether, AHPs could still alter premium levels based on age, gender, and location.

3. Proposed Expansion of Short-Term, Limited Duration Insurance (SDLI) Plans

In February 2018, the Departments of Health and Human Services, Labor, and the Treasury issued a Proposed Rule that would expand the availability of SDLI plans. This type of insurance was originally intended for people between jobs. SDLI plans typically provide only limited coverage. For example, such plans may not cover all of the ACA's minimum essential benefits; may charge more for people with preexisting conditions; and may impose caps on the amount that can be paid out over the life of the policy. SDLI plans are often profitable for insurers, because they are not subject to the ACA's MLR requirements. In 2016, the Obama Administration issued a rule which provided that a SDLI plan could have only a three-month term. The Proposed Rule would expand the maximum duration of such policies to 364 days.

Even if the Departments issue a final rule expanding access to SDLI plans, the availability of such policies will vary by state because such plans are subject to state regulation. Some states prohibit SDLI plans from being sold altogether, some states have durations on such policies that are less than a year, and others require SDLI plans to cover certain minimum benefits.

The Departments predict that between 100,000 and 200,000 people will shift from ACA-compliant plans to SDLI plans. Most of these people would not have been eligible to purchase subsidized plans on the ACA exchanges.

4. Abolition of CSRs

In August 2017, the Trump Administration ended CSRs. The Administration justified this decision on the basis of a court ruling that CSRs were unconstitutional because Congress had never appropriated funds for this program. When the Administration made this decision, some warned that it would lead to a spike in prices for "silver" plans because insurers are generally required to fund the CSRs regardless of whether they receive reimbursement from the federal government. In retrospect, the impact appears to be relatively small because the size of the APTC is directly correlated to silver plan premiums. Thus, for low-income individuals, the increase in APTC offset the premium resulting from the termination of CSRs.

What Do the Changes Over the Past Year Mean for the Health Care Industry?

Implementation of the ACA led to a significant increase in the number of people with insurance. That benefitted many health care industry subsectors. Hospitals often treat patients without regard to their ability to pay. When hospitals treat low-income, uninsured patients, the hospital often has to write off the cost of care as charity care or bad debt. Therefore, when there are fewer people who are uninsured, hospitals have lower charity care/bad debt writeoffs. Further, more people with insurance means additional purchasers of services offered by health care providers and products sold by drug and device manufacturers.

These benefits may be partially undone by the changes made over the course of the past year. During the Obama Administration, many people who did not receive health insurance from their employer or the government had essentially two options: (1) purchase ACA-compliant health insurance, or (2) pay the "individual mandate" penalty. This structure was intended to incentivize healthy people to join the exchange risk pool, which would result in healthy people subsidizing the cost of medical care for the sick. As a result of the recent changes, there will be no mandate starting in 2019 and there may be new non-ACA qualified options on the market (either through AHPs or SDLI plans) that are attractive to healthy people who want lower premiums (even at the tradeoff of limited coverage). To the extent that healthy people stop purchasing plans on the ACA exchanges, the risk pool on the ACA exchanges will become sicker. Premiums on ACA-compliant plans may increase as a result. In states which allow non-ACA plans to proliferate, the ultimate result may be that purchasers of plans sold on the ACA exchanges are largely limited to people who receive large subsidies and those that have expensive health conditions.

The cumulative impact of these changes is likely to be more people who have no health insurance at all or elect to purchase plans that offer limited coverage. These trends are likely to intersect with another development that predates the Trump Administration: To limit the rate in increase of premium growth, many health insurers

are increasing the annual deductible (that is, the amount of money consumers must spend out of pocket before insurance coverage kicks in). Thus, either because of high deductibles or "thin" insurance coverage, consumers are likely to be paying for more health care out of pocket.

The increase in the number of people with no health insurance or health insurance with limited coverage is generally bad news for the health care industry, because people paying out of pocket in many cases are unwilling or unable to pay for health care goods and services. Nonetheless, this trend may create opportunities for one subsector: retail providers of health care, including urgent care clinics and providers of primary care in facilities such as pharmacies. To the extent such providers can offer cost-effective care and transparent pricing, they may be uniquely suited to providing care to people who pay for it out of pocket.

What Does Tax Reform Mean for Health Care Companies?

The Tax Cuts and Jobs Act dramatically altered the existing corporate tax framework. The bill reduced the corporate tax rate from 35% to 21% while limiting interest deductibility. For health care companies that derive substantially all of their revenues from the United States—including hospitals, managed care organizations, and physician practices—this reduction in corporate taxes offers a significant benefit.

For multinational health care companies, including pharmaceutical and medtech companies, the impact of the statute is more complex because of the changes in taxation of overseas earnings. The bill imposed a one-time repatriation tax on deferred overseas earnings at a rate of 15.5% for earnings held in cash and 8% for earnings held in noncash assets. The repatriation tax is payable over eight years. Going forward, the United States will have a "territorial" tax system in which dividends received by U.S. companies from their foreign subsidiaries will generally be tax-free. However, there will be a minimum tax imposed on the "excess profits" (defined as the overall income in excess of a stated return on tangible depreciable property) of foreign subsidiaries of U.S. companies, whether or not repatriated. The bill

also contained anti-base erosion provisions that limit the deductibility of payments from U.S. companies to foreign related parties.

These tax reforms are likely to be beneficial to U.S. companies that desire to bring foreign cash back to the United States. These repatriated funds may result in additional research and development and mergers and acquisition activity. For U.S. companies that plan to expand overseas, the repatriation tax is likely to be viewed as a negative, because U.S. tax law previously permitted deferral of offshore earnings.

The other international changes are likely to be of particular interest to multinational health care companies. Although the territorial tax is generally positive, the current tax on excess foreign profits is likely to affect existing structures (including intellectual property holding structures) of U.S. parented groups. The broad anti-base erosion rules will significantly affect the tax planning of foreign parented groups with U.S. affiliates. Companies with significant internal cross-border transactions will be the most heavily affected.

The Tax Cuts and Jobs Act also included a provision that affects only the pharmaceutical industry: a reduction in the orphan drug tax credit. Orphan drugs are drugs that are designed to treat rare diseases that either impact (1) fewer than 200,000 people in the United States or (2) more than 200,000 people in the United States if the cost of developing the drug exceeds anticipated revenue from the drug. The Orphan Drug Act of 1983 provided a variety of incentives to develop orphan drugs. One of those incentives was a tax credit in the amount of 50% of the cost of human clinical testing. That credit has now been reduced to 25%.

While the reduction of this tax credit will hurt the bottom line of pharmaceutical companies that are developing drugs, there are still other provisions of the Orphan Drug Act that make orphan drug development lucrative. Most importantly, approved drugs have seven years of marketing exclusivity—during which time there can be no competitors in the market. Orphan drugs are also exempt from a program which requires certain drugs to be sold to government-supported hospitals and clinics at a discount.

What Changes May Be in Store for the Medicaid Program?

The Medicaid program plays a significant role in U.S. health care. In 2016, Medicaid spending was $565 billion, which is 17% of total national health expenditures. Approximately two-thirds of Medicaid expenditures nationwide are borne by the federal government. State governments are responsible for the remainder. Medicaid expenditures constitute one of the largest budget items in most states, and the amount states are spending on Medicaid has been growing rapidly.

As part of the health care reform debates of 2017, Congressional Republicans proposed taking steps that would have limited the growth of Medicaid spending. Those efforts failed. Efforts to limit Medicaid expenditures have now shifted to the state level. The Medicaid statute allows states to file section 1115 waiver applications with the Centers for Medicare and Medicaid Services (CMS). If approved, section 1115 waivers allow states to deviate from certain Medicaid requirements. States have been exploring different ways that section 1115 could be used to limit Medicaid eligibility or otherwise restrain Medicaid spending.

Currently, ten states have submitted waiver applications to CMS seeking to impose work requirements on certain categories of adults. In January 2018, CMS approved Kentucky's waiver application. Under the application, applicable adult Medicaid beneficiaries (basically healthy nonpregnant adults ages 19 to 64) must complete eighty hours per month of "community engagement activities," which could include working, education, job skills training, or community service. Applicable beneficiaries who fail to satisfy this requirement would have their Medicaid coverage suspended. Kentucky anticipates that this program would result in 95,000 fewer Medicaid beneficiaries and save the state $2 billion over five years. This waiver has been challenged in court by Kentucky Medicaid enrollees who have argued that the Medicaid statute does not authorize the imposition of work requirements. CMS has also approved Medicaid work requirements submitted by Indiana and Arkansas.

Arizona, Kansas and Utah have proposed lifetime limits on Medicaid coverage for healthy adults. These lifetime limits range from three to five years. CMS has never approved lifetime limits on Medicaid eligibility and has not acted on these waiver requests. It is unknown if CMS will impose these lifetime limits. If they are approved, they will almost certainly be challenged in court by Medicaid recipients arguing that the Medicaid statute does not allow for lifetime caps.

Massachusetts submitted a section 1115 waiver under which it proposes to control Medicaid spending by establishing "closed formularies" that would exclude certain prescription drugs from coverage. Under the Massachusetts plan, the Medicaid formulary would include at least one prescription drug in each therapeutic class, but not necessarily more than that. Massachusetts believes that if were allowed to adopt a closed formulary, it could negotiate volume discounts for the drugs that are included in the formulary. Massachusetts also wants permission to review, and possibly exclude, drugs that have been approved by the FDA under the accelerated approval program. This program applies to drugs that are intended to treat serious conditions for which there is no approved treatment. The FDA can approve qualified drugs on the basis of surrogate endpoints, which are clinical markers that predict clinical benefit (for example, tumor shrinkage) rather than the ultimate clinical benefit itself (prolonged life expectancy). Notwithstanding that the FDA thoroughly reviews drugs that are approved under the accelerated approval program, Massachusetts wants to be able to exclude these drugs if it believes they do not provide sufficient benefit.

CMS has not yet taken action on Massachusetts's waiver request. If CMS approves it, the waiver would almost certainly be challenged by the pharmaceutical industry. The Pharmaceutical Research and Manufacturer of America (PhRMA) has publicly stated that it believes Massachusetts' proposal is unlawful because the Medicaid Drug Rebate Program is not subject to section 1115 waivers and, with limited exceptions, requires coverage for all qualifying drugs.

It is too early to assess the cumulative impact of the types of waiver requests described above, because CMS has not acted on many of them. Moreover, because all of these waiver requests are controversial, they are likely to be subject to challenges in court if approved. At

the very least, these waiver applications show that states are thinking about restraining Medicaid spending either by taking steps that may reduce the number of eligible beneficiaries or by reducing the amount states spend on those beneficiaries. Since Medicaid purchases health care goods and services from the private sector, a reduction in the number of individuals covered by the Medicaid program or limitations in what Medicaid will cover is likely to directly impact the bottom line of health care companies.

What Steps Is the Government Taking to Address Drug Pricing?

In recent years, the issue of prescription drug pricing has been politically charged. During the 2016 presidential campaign, Democrats proposed implementing controls on prescription drug costs while candidate Trump proposed other measures that were intended to reduce drug prices. With the election of President Trump, the issue of price controls was taken off the table, but that has not reduced the focus on drug pricing.

In 2017, the FDA undertook initiatives that may indirectly reduce drug prices, and California enacted two high-profile drug pricing measures. During his 2018 State of the Union Speech, President Trump stated that he "directed [his] administration to make fixing the injustice of high drug prices one of our top priorities. Prices will come down. Watch." Since that time, the President signed one bill that addresses drug pricing and his Administration has made a variety of other drug pricing proposals as well. These developments are discussed below.

FDA Initiatives to Promote Generic Drug Competition

Although drug pricing is technically outside of the FDA's statutory mandate, the agency has implemented a number of initiatives that may encourage competition and indirectly reduce drug prices. In 2017, the FDA announced the highest annual total of generic approvals (1,027) in the agency's history.

First, the FDA is expediting the review of ANDAs for generic drugs when there are fewer than three drugs in the marketplace. Research has confirmed that when there are three or more versions of the same

drug in the marketplace, prices drop substantially as compared with no generic or even a single generic option. Relatedly, in 2017, the FDA published a list of off-patent and off-exclusivity drugs for which there is not an approved generic and now includes patent submission dates in Orange Book listings. This enables generic companies to determine the earliest date on which they may be able to market new generics. Even though this information has always been available to interested stakeholders, the FDA is streamlining the presentation of the data in an effort to make it easier for generic companies to determine which drugs should be prioritized.

Second, the FDA is facilitating approval of generic versions of "complex drugs." Complex drugs include drugs that act locally (for example, an eye drop that acts on the eye's surface) or drugs that require administration through a device such as metered dose inhaler or autoinjector. These drugs possess features that may make it difficult for an ANDA sponsor to satisfy the requirement of establishing therapeutic equivalence to the branded drug. The FDA has developed guidance documents to facilitate development of such complex generic drugs. The FDA has also developed channels for enhanced communication between the FDA and the sponsors of complex generics to allow for more efficient development and regulatory review of such drugs.

Third, the FDA is continuing to target practices of innovator drug manufacturers who attempt to prolong marketing exclusivity beyond the period allowed by law. For example, the FDA is concerned about innovator drug manufacturers who, for a variety of legal reasons, are reluctant to provide a branded drug product to generic companies for bioequivalence and bioavailability studies.

California's Drug Pricing Measures

In October 2017, California enacted two statutes designed to address drug pricing.

The first statute requires a prescription drug manufacturer to notify the California government and private payors in the state sixty days before it issues a price increase that would raise the drug's wholesale acquisition cost by more than 16% over two years. The notification must include (among other things) an explanation as to what factors

drove an increase of a drug's price and a description of any changes or improvements in the drug.

While this statute does not formally restrict drug price increases, it will make it more challenging for drug manufacturers to increase prices by an amount that triggers the disclosure threshold. Once a disclosure is required, payors would have two months to push back against any price increases before they went into effect. PhRMA filed a lawsuit (currently ongoing) arguing that the statute is unconstitutional because it impermissibly seeks to regulate pharmaceutical manufacturers nationwide (something only Congress is entitled to do) and interferes with their First Amendment right to free speech.

The other statute prohibits innovator drug companies from offering any type of rebate that reduces out-of-pocket costs for drugs for which there is a cheaper generic available that is therapeutically equivalent to the branded drug. Proponents argue that this statute will help reduce drug costs by making it more difficult for innovator companies to maintain market share for their higher-priced products when lower-cost generic versions of therapeutically equivalent drugs are available.

Bipartisan Budget Act of 2018

The Bipartisan Budget Act, which was signed by President Trump on February 9, 2018, contains a provision that should reduce prescription drug prices for some seniors who are beneficiaries of the Medicare Part D program.

As background, Part D assists seniors in purchasing prescription drugs. It includes four phases, depending on how much money the beneficiary spends on prescription drugs:

- The deductible phase, where the beneficiary pays for all costs;
- The initial coverage phase, where the beneficiary pays 25% coinsurance up to the initial coverage limit;
- The "coverage gap" (also known as the "doughnut hole"), where the beneficiary is responsible for a significant portion of the drug costs; and

- The "catastrophic" phase, where the beneficiary is responsible for 5% coinsurance.

The ACA included a provision that gradually closed the coverage gap between 2013 and 2020 such that by 2020, the beneficiary's cost-sharing requirement would be 25% (the same as the initial coverage limit). The Bipartisan Budget Act accelerated the closure of the coverage gap from 2020 to 2019. It also reallocates responsibility for payment of drug costs for patients in the coverage gap. Going forward, pharmaceutical manufacturers will be required to discount the cost of prescription drugs by 70% (instead of the current 50%), and the Part D insurer will be responsible for paying 5% of the drug cost (instead of the current 25%). This means that the beneficiary's coinsurance obligation would become 25% (the same percentages as in the initial coverage phase). This provision is likely to cost the pharmaceutical industry billions of dollars and may offer a significant benefit to insurance companies that sponsor Part D plans. The pharmaceutical industry was caught off guard by the insertion of this provision into the budget bill and is seeking to repeal it.

The White House Blueprint

On May 11, 2018, the White House released the President's "Blueprint to Lower Drug Prices." The Blueprint focuses in large part on promoting competition and altering misaligned incentives. In the aftermath of the announcement, the stock price of many drug companies and other health care companies such as pharmacy benefit managers (PBMs) rose. Key elements of the Blueprint are discussed below.

1. FDA-Related Proposals

The Federal Food, Drug, and Cosmetic Act (FFDCA) does not grant the FDA direct regulatory authority over drug pricing. The Blueprint, however, includes several initiatives that the FDA is already implementing with the aim of promoting competition and thereby indirectly reducing drug prices. These measures include:

- *Facilitating development of biosimilars*: Scientific advances have resulted in the increased development and marketing prominence of biologics. Biologics are chemically complex, long-chain molecules, and are therefore more challenging to

produce than most small-chain synthetic drugs. After the applicable patent and exclusivity periods expire, pursuant to the Biologics Price Competition and Innovation Act of 2009, biologics may be subject to competition from lower-cost "generic" versions (known as "biosimilars"). The FDA is working on facilitating the development of biosimilars and educating providers, consumers, and payors regarding applicable regulatory pathways and their overall availability.

- *Facilitating approval of Abbreviated New Drug Applications (ANDAs)*: The FDA has expressed concern about innovators allegedly misusing the Risk Evaluation and Management Strategies (REMS) process to prevent generic drug companies from obtaining necessary drug samples for testing purposes. Pursuant to the REMS process, safety and mitigation strategies are implemented for drugs that potentially present serious risks. The REMS process sometimes will involve limitations on how a drug can be prescribed or distributed. As a result of such restrictions, generic manufacturers may be unable to obtain drug samples in certain situations. Without such samples, generic manufacturers cannot conduct the bioequivalence testing that is required to file ANDAs. The Blueprint does not specify how the FDA plans to address this issue. On May 17, 2018, the FDA publicly released a list of approximately fifty innovator drugs for which the agency received complaints that the manufacturer was allegedly prohibiting access to drug samples (thereby purportedly impeding competition from generic drug companies). The FDA stated that this unprecedented step was taken "because we believe greater transparency will help reduce unnecessary hurdles to generic drug development and approval." Critics contend that public shaming in the guise of "transparency" may not have the effect the FDA is intending.
- *Accelerating development of over-the-counter (OTC) drugs*: Many drugs that do not require a prescription are sold pursuant to OTC drug monographs developed as part of the OTC Drug Review. OTC drug monographs specify the ingredients, claims, warnings, and other aspects of an OTC drug that, if implemented,

authorize the drug for marketing in the absence of a new drug application. In other words, an OTC drug monograph is the equivalent of a "recipe book" for specific OTC drugs.

The OTC monograph process, however, has not been appreciably updated since the 1970s, and the FDA believes many aspects of the process are antiquated. The FDA and industry players are working with Congress on new monograph legislation. In one of its most recent iterations, this proposed legislation would, among other things, (1) impose user fees on manufacturers of OTC drugs (these fees would fund the FDA's review of applications to approve new monographs or change existing ones); (2) accelerate the process for changing OTC drug labeling; and (3) provide a period of exclusivity to companies that, among other things, receive FDA approval to add a new active ingredient to an OTC monograph.

- *Communications between drug companies and payors*: As a general rule, federal law prohibits drug manufacturers from promoting drugs for uses other than those on FDA-approved labeling. The Blueprint alludes to a proposal by Commissioner Gottlieb indicating that it may be appropriate for pharmaceutical manufacturers to provide information to payors about potential off-label uses for their drugs if those off-label uses can result in cost savings. The FDA has not yet issued a guidance document addressing this subject.
- *Direct-to-consumer (DTC) drug advertising*: The Blueprint also includes a new proposal: an FDA review of the potential mandatory inclusion of drug prices in direct-to-consumer (DTC) drug advertising. Alex Azar, Secretary of the Department of Health and Human Services, recently argued that, from a perspective of "fair balance" in DTC advertising, consumers should be told how much drugs will cost them. The Blueprint, however, does not provide any further details regarding this proposal. In particular, it does not address the challenging question of determining what is meant by a drug's price. Consumers typically do not pay the drug's list price. Unlike OTC drugs, the price paid by consumers for prescription drugs is dependent on a variety of factors, including (1) whether the consumer

has a high-deductible insurance policy and/or a prescription drug deductible; (2) which tier of the formulary the drug is placed on; and (3) the size of the co-pay for the applicable drug. Price may also vary because of other factors including geographic region and pharmacy. Thus, there is no standard price that is paid by consumers.

The Blueprint's proposal to include prescription drug prices in DTC advertising also fails to address the impact of such a policy on price flexibility and the potential unintended consequences that may result if drug companies were precluded from lowering prices during the course of an advertising campaign. In addition, the Blueprint does not address contentious legal issues that may emerge, including issues implicating the First Amendment and the FDA's authority to require price disclosures under the FFDCA. Finally, this proposal would have no relevance to many of the highest-priced orphan drugs, which are aimed at a very small population and therefore are often not widely advertised.

2. CMS-Related proposals

- *Medicare Part D*: The Blueprint includes several proposals that would facilitate the ability of Part D plans to manage prescription drug costs. For example, the Blueprint raises the concern that Part D plans are not currently able to negotiate prices for drugs in the six "protected classes." Part D formularies must cover all drugs in these classes because they are vital to treating certain conditions. The Blueprint proposes giving Part D plans "full flexibility" to manage the cost for such drugs, but it does not state how the administration plans to accomplish that objective.
- *Medicare Part B*: Part B covers drugs that are administered in outpatient clinical settings. Part B covers many high-cost specialty drugs that treat conditions such as cancer, blood disease, and eye disorders. Part B drugs are reimbursed based on a formula dictated by law. That is different than Part D, where PBMs generally can decide which drugs are included

on formularies (outside of the protected classes) and drug manufacturers may have to offer rebates to be included on the formularies. The Blueprint suggests that some unspecified prescription drugs might be shifted from the Part B to the Part D program.

- *Value-based pricing*: The last decade has seen increased interest in tying the level of health care reimbursement to the value of the health care services or drugs provided. The Blueprint proposes that CMS develop value-based pricing models for prescription drugs—but it does not identify the types of criteria that could be used as the basis for value-based pricing. There are multiple value-based pricing models that could be implemented, and it remains to be seen whether it becomes commonplace, for example, for drug and health care companies to make reimbursement contingent on satisfying a performance metric in individual patients (or cohorts of patients).

3. PBMs

The Blueprint reflects the view that PBMs have contributed to rising drug prices. PBMs often condition the placement of a drug on their formularies on the manufacturer's willingness to offer a sizeable rebate off the drug's list price. PBMs often keep a portion of the rebate as compensation. This practice could be seen as encouraging high list prices and large rebates, although PBMs cite procompetitive benefits associated with their services.

The Blueprint raises the prospect of imposing a fiduciary obligation on PBMs to act in the interest of patients. Separately, Commissioner Gottlieb raised the possibility that the government could consider eliminating the "safe harbor" under the Anti-Kickback Statute for drug rebates. Were that to happen, it might become impossible for drug companies to continue offering rebates for drugs whose purchase was subsidized by the federal government.

The health care marketplace, however, is in flux and may already be in the process of addressing the market impact of PBMs. In recent years, private insurers have been merging with PBMs, including (1) UnitedHealth's purchase of Catamaran in 2015; (2) the 2017 agreement by CVS (which owns Caremark PBM) to purchase Aetna; and

(3) the 2018 agreement by Cigna to purchase Express Scripts. Moreover, UnitedHealth recently announced that, starting in 2019, it would have rebates passed on to consumers enrolled in fully insured commercial group plans. To the extent there is increased integration between PBMs and health insurance companies, the combined entities may have a greater interest in controlling drug prices.

What Do These Drug Pricing Developments Mean for the Pharmaceutical Industry?

In this challenging political environment, the pharmaceutical industry to date has emerged relatively unscathed. The initiatives described above may diminish the profitability of some drugs, but none of them are likely to significantly change how drug prices are set. That said, there are likely to be more initiatives at all levels of government aimed at reducing or controlling drug prices. The pharmaceutical industry will therefore have to remain vigilant against the possibility of future harmful measures.

Note

1. This section addresses the legal and regulatory environment as of March 2018.