SPECIAL REPORT

McDERMOTT'S 2021 ANNUAL HEALTH REPORT: 2020 YEAR IN REVIEW AND 2021 LOOK AHEAD

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McDermott Will & Emery

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INTRODUCTION

2020 was a tumultuous year for the healthcare and life sciences industries—marked by global disruption, it was also a testament to the power of innovation and collaboration. The year ended on a hopeful note with the approval and distribution of emergency-authorized vaccines, but the challenges facing healthcare are far from behind us.

In this report we've assembled a comprehensive overview of the healthcare industry in 2020, with particular emphasis on the legal implications of the unprecedented year. We also look ahead to the future of the industry, which is full of opportunities to break down long-standing barriers to innovation and move towards a more modern and patient-centric vision of care in many areas, including:

- Government response to COVID-19
- What to watch in FDA oversight
- Trajectory for digital health
- Changes in the hospital space
- Regulatory and compliance updates
- Reimbursement and managed care developments
- Collaborative transformations
- Healthcare investing and healthcare private equity
- Healthcare policy outlook
- Developments and future outlook for healthcare in Europe

REPORT SUMMARY

As we compiled highlights across sub-sectors of the healthcare industry, we observed several common themes:

BARRIERS BROKE DOWN across all sectors of healthcare to help providers respond rapidly to the COVID-19 pandemic. A flood of new rules and regulations were released to help save lives, protect doctors and patients, secure needed supplies, adapt healthcare delivery to a remote world, reduce financial burdens and open the door to produce innovative solutions quickly. While many of these rules and waivers were designed to be temporary and expire after the public health emergency, patients and providers alike have indicated that these changes are positive and should remain in place after the curve is flattened.

TECHNOLOGY TOOK CENTER STAGE for patients, providers and business leaders. When the world shut down in March 2020, some were better positioned than others to transition to virtual work. As the year progressed, virtual solutions—from telehealth visits to remote due diligence—became the new normal and even emerged as the preferred modality for many. This transition from in-person care to virtual care highlighted access issues and technology gaps for certain populations—a challenge to overcome and an opportunity to improve health equity in the year ahead.

COLLABORATIONS TRANSFORMED THE BUSINESS OF HEALTHCARE and initial slowdown in deal volume in the first half of 2020 due to cash flow, operational disruptions and overall uncertainty saw reversals—and in some sectors, spikes—in the tail end of 2020 as investors and dealmakers adapted to new ways of doing business and gained an understanding of how healthcare will look in the years to come. In some areas, such as digital health and life sciences, some remarkable and game-changing collaborations emerged between competitors and non-traditional health industry companies, continuing the trend of Collaborative Transformations the McDermott team has been watching—and often facilitating—in recent years.

REVIEWING 2020 AND LOOKING AHEAD IN 2021: TOP TRENDS IMPACTING HEALTHCARE PRIVATE EQUITY

The past year was unprecedented for the healthcare private equity industry. While investment activity largely came to a halt during the early stages of the pandemic, 2020 ended with record deal activity and valuations that continue to soar across diverse healthcare sectors. While 2021 will be a year of transition as the United States welcomes a new administration to the White House, continues to roll out vaccines and processes the pandemic's impact on the healthcare system, private equity investors should be proactive in pursuing innovative opportunities and investment strategies.

Here, the McDermott Health Private Equity team explores the trends that shaped the sector in 2020 and looks ahead to the issues that may shape markets and drive deals in 2021.

TOP TRENDS OF 2020

NEW MVP SECTORS

Despite the challenges brought on by the pandemic and, in fact, as a direct result of them, healthcare sectors saw record investments funnel in over the past year. The actions taken to help limit the spread of the virus highlighted inefficient practices within the healthcare system.

Technology became more important than ever, and is now a necessity for many patients to be able to access their providers. As a result, previous barriers were relaxed, driving new market opportunities and collaborations. There also was a surge in life sciences investment, including biopharmaceuticals and related services, as investors looked for innovations in healthcare technology and drug development. Telehealth, mental health technology and healthcare AI were also breakout subsectors, with startup funding reaching record highs.

DIGITAL INFRASTRUCTURE AND AGILITY CENTRAL TO SURVIVAL

The sudden shift to remote work forced major changes for companies and employees, and accelerated existing trends in telehealth and technological innovation. Companies that had strong digital infrastructures were poised for success in this new normal, while those that lagged behind had no option but to adapt.

A somewhat surprising consequence was that investment opportunities became easier to pursue in certain respects. With travel more limited, decision-makers were more readily available to meet remotely and consider opportunities that may have previously required a larger investment of time or opportunity cost to explore.

CREATIVE DEAL STRUCTURES THRIVE

The shift to a virtual work environment fundamentally altered the process for investment evaluations in 2020. Due diligence changed significantly, as investors were unable to meet face-to-face with a management team or see a company's offices in-person

While this presented obvious challenges, dealmakers adjusted and even discovered advantages around distance and speed. Further, in order to address the gaps and issues in the healthcare system exposed by COVID-19, stakeholders from across health, life sciences, technology and other sectors joined forces. In turn, more investors took part in new business

combinations, joint ventures and innovative transactions as they looked to address challenges and capitalize on new opportunities.

A DROP IN US HEALTHCARE SPENDING FOR THE FIRST TIME IN 60+ YEARS

In order to combat the spreading pandemic in early 2020, governments enacted shutdowns and social distancing guidelines, and healthcare organizations delayed or canceled many health services, including elective procedures. As a result, healthcare spending saw a historic decline.

The low point came in April before spending began to rebound in the summer and fall, primarily driven by resumed hospitalizations and increased COVID-19 testing. Still, spending on healthcare services declined year-over-year. Healthcare investments also saw an initial dip, but global healthcare funding roared back to hit a new record in 2020. As noted, the slowdown led to firms holding extra dry powder, fueling pent-up demand for new investment opportunities in the latter half of 2020 and continuing into 2021.

GROWING POTENTIAL FOR TRANSITION TO VALUE-BASED CARE

One of the vulnerabilities in the US healthcare system magnified by the pandemic was the fee-for-service payment system based on volume. Because of the system's previously acknowledged limitations, the desire to experiment with new models—such as pre-payment, shared savings and other value-based care approaches—was heightened.

The Trump administration introduced various models to test the effectiveness of these approaches, and we've already seen that the Biden administration will further those efforts, potentially helping to facilitate the transition to a value-based care system.

TRENDS SHAPING 2021

TAKING THE TEMPERATURE OF THE BIDEN ADMINISTRATION

A new administration always results in a wait-and-see approach, as the implications of policy changes, staffing and regulation will affect everyone in the healthcare and investment space, and beyond. Industry stakeholders will look for signs of how new agency leaders may shape the regulatory landscape and what potential changes they'll look to implement.

Of particular note will be the US Department of Health and Human Services, the US Food and Drug Administration, and the US Centers for Medicare and Medicaid Services. Each of these agencies will affect the health and life sciences sectors, including those areas that are likely to see significant investment as the battle against COVID-19 continues—notably, biopharma, drug development and telehealth.

Investors also will keep an eye on proposed tax changes. During the run-up to the election, President Biden's campaign floated an increase on capital gains taxes in certain scenarios, which could affect private equity's use of carried interest.

ADAPTING TO THE NEW NORMAL > RETURNING TO NORMAL

With vaccine distribution underway, optimism around returning to normal continues to grow. However, healthcare companies can't afford to wait until normal life returns. Investors know that returning to "normal" doesn't mean reverting to pre-pandemic norms. A new normal will persist with technology and digitization playing a central role.

While virtual tools continue to improve, cybersecurity will grow in importance. Remote work can make companies more vulnerable to ransomware attacks

due to at-home set-ups, including distractions that wouldn't exist in the office. Intellectual property and personal data can be vulnerable if companies are not diligent.

PRICING CHALLENGES AHEAD

Debt/EBITDA multiples for buyouts have remained relatively steady over the last year, but certain factors could contribute to their rise in the year ahead. Low interest rates likely will continue to propel the use of leverage in 2021, and there is strong demand for high-yield debt. Further, funds are sitting on excess dry powder that they were unable to use during the slower months of 2020.

Firms will look to use those reserve funds, spurring more activity and increasing competition for the best deals. In order to compete aggressively and price deals most accurately, industry expertise will be crucial for PE firms.

INCREASING PARTICIPATION IN JOINT VENTURES

Joint ventures between health plans and providers grew in popularity over the past year. Expect that trend to continue in 2021 thanks to the mutual benefits they can bring.

These arrangements enable provider organizations to benefit from the support and resources offered by a health plan, while the plans are able to align themselves with provider networks to expand market share and reduce costs.

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SPECIAL REPORT

INVESTING IN HEALTHCARE

A GUIDE TO KEY LEGAL AND REGULATORY ISSUES IN HEALTH AND LIFE SCIENCES TRANSACTIONS

Today's global healthcare marketplace is marked by unprecedented transformation. This presents both challenges and opportunity to today's market participants. We know how important it is to structure cross-border investments and transactions to account for complex and ever-shifting regulations.

Within this dynamic environment, McDermott's health lawyers wield a deep knowledge of how healthcare services, medical technology and pharmaceuticals are delivered around the world, and how the laws that affect those entities and that help drive action are creating the market of tomorrow.

We're passionate about our role in shaping the alliances that will lead to next-generation digital health technologies, new pharmaceuticals and superior healthcare delivery.

If you're doing something that's never been done before, or looking to do something better than it's ever been done before, we're here to help. Together, we're pushing boundaries and knocking down barriers to usher in a new age of healthcare.

LEGAL AND REGULATORY

As a leading law firm for health and life sciences, we help clients find creative and unexpected solutions for cross-border transactions and investments. Our cross-practice team affords you the opportunity for unmatched legal experience while balancing local, regulatory, technological and structural needs.

We have developed this guide as a step in your journey to global healthcare collaborations and stand ready to help you implement a practical and operational approach. Together, we can transform healthcare.

WHAT YOU'LL DISCOVER FOR EACH JURISDICTION:

- The impact of COVID-19 on the provision of healthcare and life sciences
- Ownership or equivalent restrictions in relation to the provision of healthcare services
- Reimbursement of public or national healthcare services and award of contracts
- Drug approvals and reimbursement
- Devices certification and reimbursement
- Regulation of ai and software as a medical device
- Telemedicine and teleconsultation
- Anti-kickback rules and incentives to doctors
- Merger and foreign investment control
- Forthcoming and anticipated changes in healthcare and life sciences law

UNITED STATES

1. THE IMPACT OF COVID-19 ON THE PROVISION OF HEALTHCARE AND LIFE SCIENCES

The response to the COVID-19 pandemic has changed certain aspects of the delivery of healthcare services in the United States, although many of these changes are anticipated to be temporary. Key developments include the following:

- A significant growth in telehealth adoption rates, particularly among small providers that historically provided in-person encounters only, and in patient populations such as older patients that previously preferred in-person encounters.
- The Coronavirus Aid, Relief, and Economic Security (CARES) Act, subsequent legislation and regulatory changes supported the use of telehealth services during the pandemic by lowering long-standing barriers to Medicare reimbursement and the use of telehealth in additional care settings.
- State emergency declarations and orders expanded Medicaid coverage, eased licensure barriers, and generally expanded the ability of healthcare professionals to deliver services via telehealth.
- The increased availability of telehealth services during the pandemic has prompted further policy discussion around the appropriateness of lasting changes as well as addressing historical barriers to virtual care.
- Although buoyed by a large influx of cash through Provider Relief Funds (PRF) under the CARES Act, health systems have suffered significant financial losses due to the reductions in elective procedures as a result of state mandated shut-downs and lower consumer demand – and the PRF cash is a temporary fix, as funds provided need to be repaid.
- Health insurers have benefited financially from the reduction in demand, but the impact of significant unemployment and demand for COVID-related treatments are not yet fully understood.
- After a period of stagnation during the middle of 2020, investment in the healthcare services sector has picked up, and digital health and life science investing has remained strong.
- Technology sector interest in healthcare delivery and life sciences has increased.
- Election year politics diminished the prospect of another round of significant government support prior to the change in administration.

2. OWNERSHIP OR EQUIVALENT RESTRICTIONS IN RELATION TO THE PROVISION OF HEALTHCARE SERVICES

There are limited barriers to the ownership and operation of private healthcare services in the United States. Nonetheless, some restrictions do exist at both the federal and state levels. Individual state licensing regimes for health services and healthcare facilities make a national strategy challenging. Participation in government payment systems and private payment systems by healthcare service providers requires enrolling in those systems independent of any applicable state licensure requirements. Moreover, individual US states impose restrictions on the ability of unlicensed persons to practice medicine or employ medical professionals under a doctrine known as the "corporate practice of medicine" prohibition.

Investing in healthcare services must also conform to both federal and state fraud and abuse laws, designed to isolate clinical decision-making and patient choice from the financial incentives associated with care

delivery. Because these laws and regulations can exist at both a federal and state level, compliance efforts can be burdensome.

Strategies exist to address these hurdles, but the resulting structures can be complex and confusing to those unfamiliar with the US healthcare market. In addition, changes in ownership can trigger notice or consent requirements from the relevant government oversight agency, which present timing issues and additional administrative burden on completing these types of transactions.

3. REIMBURSEMENT OF PUBLIC OR NATIONAL HEALTHCARE SERVICES AND AWARD OF CONTRACTS

Unlike European jurisdictions, the United States has a significant market for the private reimbursement of healthcare services, which is generally offered by employers. Public reimbursement is largely limited to Medicare (federal health insurance for seniors and individuals with certain disabilities) and Medicaid (state-run insurance for individuals with low incomes).

Government Payors

Medicare is the largest government insurance program, providing insurance for over 59 million people. Medicare-eligible beneficiaries may choose either to receive insurance coverage directly from the federal government under so-called "Original Medicare," or to enroll in a Medicare Advantage plan, under which their Medicare benefits are administered by a private commercial insurance entity that shares in the risk of the cost of care. Medicare beneficiaries can also choose to purchase a prescription drug plan as part of a Medicare Advantage plan or as a standalone plan, as prescriptions are generally not covered under Original Medicare.

Original Medicare has typically been paid on a fee-for-service basis, under which providers submit claims for each reimbursable service. Increasingly, however, the federal government is exploring value-based purchasing programs and other innovative payment models that seek to link payment rates to quality of care, rather than simply volume of services. Shared risk models, such as Medicare Advantage and the Medicare Shared Savings Program, are increasingly popular and, in some instances, are proving to be cost effective.

Providers of healthcare services must enroll in order to participate in Medicare. Enrollment may also require accreditation by an approved non-government agency or government agency for facilities. Reimbursement from Medicare can be through fee-for-service, bundled services, and shared risk models. Appropriate coding of claims for care rendered and compliance with reimbursement requirements are also required.

Medicaid is administered by the individual states and shares many of the same characteristics as Medicare, although states have additional flexibility with how these programs are implemented and what is paid for.

Private Payors

Americans that do not qualify for Medicare or Medicaid largely receive health insurance from commercial health insurance coverage, either through their employer or the private marketplace created by the Affordable Care Act. Federal law sets standards for commercial health insurance coverage, which is often supplemented by state-specific requirements.

For example, commercial payors may be required to offer coverage and/or payment parity for telehealth services under applicable state law. Coverage parity refers to laws that require private payors to provide the same coverage for services provided via telehealth

as is offered when they are provided in person, while payment parity refers to laws that require private payors to offer the same reimbursement rates, regardless if the service is provided in-person or via telehealth. Currently, 43 states and the District of Columbia have private payor laws governing telehealth.

As with government payment regimes, healthcare service providers that participate in private health payment systems must enroll and comply with the private reimbursement regimes, which are mandated through participation agreements entered by the providers with the payors. While government reimbursement rates are non-negotiable, the reimbursement rates under private payor contracts can be subject to significant negotiation.

Most healthcare providers participate in Medicare, Medicaid and private payment regimes that are relevant in their markets. Accordingly, they must comply with multiple enrollment and reimbursement regimes, which can place a significant administrative burden on providers.

4. DRUG APPROVALS AND REIMBURSEMENT

The US Food and Drug Administration (FDA) evaluates new drugs and biological products before they can be sold in the United States. For novel therapeutic products, the FDA generally requires substantial clinical and non-clinical data before it will approve or license a product for distribution.

Medicare is the largest third-party payer in the United States. Medicare pays for most outpatient drugs and biological products under Part D, which involves Medicare paying competing private plans to deliver benefits to enrollees, and those plans establishing coverage criteria, formularies, and payment rates for therapeutic products. However, a limited number of drugs are reimbursed under Part B (e.g., certain physician-administered drugs), which allows Medicare to pay providers directly at rates established by statute or regulation.

Commercial payers may cover drugs or biologics under their pharmacy or medical benefit, depending on the drug and the payer's preference. Subject to certain federal and state laws, commercial payers generally have substantial flexibility when deciding whether to cover and how much to pay for a drug.

5. DEVICES CERTIFICATION AND REIMBURSEMENT

The FDA also regulates the development, manufacturing, and distribution of medical devices in the United States. Depending on the device, a manufacturer may need to obtain premarket approval (PMA), clearance (510(k)), or a de novo classification before offering the product for sale in the United States.

Medicare is a defined benefit program, which means the program can only pay for items and services if there is a statutorily defined "benefit category" for such items and services. While there are Medicare benefit categories for certain types of medical devices (e.g., durable medical equipment), there is no general "device" benefit category. As a result, payment for devices is often bundled into the payment for other covered services (e.g., physician office visits, outpatient hospital admissions).

Commercial payers typically take a similar approach to Medicare, and with certain limited exceptions, consider medical devices an expense incurred by providers when furnished as part of a covered service, as opposed to making separate payment for the device itself.

6. REGULATION OF AI AND SOFTWARE AS A MEDICAL DEVICE

Depending on its technological characteristics and the indications for which its developer intends to market the product, an AI-based or software product may be subject to regulation by the FDA as a medical device.

The FDA's existing regulatory structure for medical devices was not designed with rapidly-evolving products in mind. However, in 2019 the FDA issued a white paper, announcing plans to consider adapting its existing regulatory framework to promote the development of safe and effective medical devices that use advanced AI algorithms. The FDA's proposed approach would allow developers to make certain modifications to previously-cleared or previously-approved algorithms based on real-world learning and adaptation without requiring a new clearance or approval for the modified product in many cases. If finalised as outlined in the white paper, the FDA's plans would attempt to better accommodate the iterative nature of AI products while ensuring that the FDA's standards for safety and effectiveness are maintained.

7. TELEMEDICINE AND TELECONSULTATION

In the United States, telemedicine is regulated at the state and federal level, and by multiple regulatory bodies. At the federal level the Centers for Medicare and Medicaid Services (CMS), the federal agency overseeing federal health reimbursement programs, establishes Medicare reimbursement policies (subject to applicable legislation), and has a certain level of oversight over state Medicaid programs. Many of the reimbursement requirements imposed by these programs have been relaxed during the COVID-19 pandemic. In addition, the federal Drug Enforcement Administration (DEA) plays a role in determining, subject to federal law, whether and how controlled substances may be prescribed via telemedicine. Historically, federal law requires an in-person examination prior to any such prescribing, but the DEA has temporarily waived this requirement during the COVID-19 pandemic.

At the state level, state legislatures and professional licensing boards may create telehealth standards of care that govern telehealth practice. Such standards may relate to licensure requirements, the types of modalities are permitted, remote prescribing of controlled and non-controlled substances, informed consent, medical recordkeeping, technology, confidentiality / privacy requirements, and more. In addition, it is essential to understand that telemedicine practitioners are regulated by both the state where the patient is located and the state where the practitioner is located. This typically requires the provider to be licensed within the state where the patient is located, regardless of where the provider is physically located at the time of the encounter.

Every telemedicine regulatory regime has its own definitions regarding telemedicine. That said, it is typically categorised into three modalities: (1) live, synchronous, audio-visual interactions (e.g., a patient directly speaking to a provider), (2) store-and-forward technology (e.g., a patient sends an image of a clinical concern to a healthcare professional for review), and (3) remote patient monitoring (e.g., mobile applications that track an individual's blood pressure and send readings to a healthcare professional).

There is significant variation in state and federal regimes relative to these modalities. For example, most, if not all, states permit physicians to prescribe non-controlled substances on the basis of a synchronous, audio-visual encounter. Beyond that, there is a significant amount of variation in terms of the types of (a) healthcare professionals that are

permitted to provide services via telehealth, (b) modalities deemed sufficient to prescribe, and (c) healthcare professionals permitted to use telehealth to prescribe when prescribing is otherwise within the professionals' scope of practice.

These variations make national telemedicine programs challenging to implement. Further, as we see telemedicine evolve with the utilisation of more technology, including artificial intelligence, these variations can multiply along with the many use cases being developed.

8. ANTI-KICKBACK RULES AND INCENTIVES TO DOCTORS

The healthcare industry is subject to a number of fraud and abuse laws. Most notably, this includes federal statutes known commonly as the Anti-Kickback Statute and the Stark Law, which regulate financial relationships within and among healthcare stakeholders, and the False Claims Act, which prohibits providers from submitting false or fraudulent claims to government payment programs. The Anti-Kickback Statute is a criminal law that prohibits the knowing and willful payment of remuneration to induce or reward patient referrals, while the Stark Law prevents healthcare providers from referring patients for certain services to entities in which they have a financial interest. In addition, states have their own fraud and abuse laws, which often mirror – and sometimes extend beyond – federal law.

The Department of Justice (DOJ) has long played a significant role in bringing enforcement actions against healthcare providers for fraud and abuse violations. As we have highlighted in prior editions of the Healthcare Enforcement Quarterly Roundup (see here and here), the DOJ is increasingly bringing enforcement actions against telemedicine providers. Recently, in October 2020, it brought charges against 345 defendants for, among other things, paying healthcare providers to order over $4.5 billion dollars' worth of unnecessary durable medical equipment, genetic testing, and pain medications either without a patient interaction or based upon a brief telephone encounter. The DOJ said that this is its largest healthcare fraud enforcement action taken to date.

9. MERGER AND FOREIGN INVESTMENT CONTROL

Investment in the healthcare and life sciences industries in the United States is not subject to specific foreign investment protocols or specific merger or acquisition controls outside of those related to licensure requirements for healthcare facilities and professionals and regulated insurers. Some of these regimes can be burdensome, and are generally state-based. Participation in public and private reimbursement regimes also includes following specific protocols related to change in control transactions.

Some states are more active in overseeing the availability of healthcare resources and require approval of expansions or changes in the control of healthcare services through "certificate of need" laws, which in addition to other regulatory approvals require independent government agency approval over a transaction. Like every industry in the United States, healthcare and life sciences transactions are subject to antitrust laws, the enforcement of which has increased in recent years with respect to hospital and physician markets. While state antitrust regimes can also play a role, federal antitrust enforcement generally takes precedent.

In recent years, the role of the Committee on Foreign Investment in the United States (CFIUS) has expanded through legislation, regulation and high-profile action. The focus of CFIUS is on transactions

that could impact the national security of the United States, but the broad scope of concern – ranging from critical technologies to critical information – and the increased utilisation of technology in the healthcare and life sciences sectors has made CFIUS much more relevant now than it has been in past years. Compliance with CFIUS requires a careful review of transaction structure and assets and a determination whether a pre-closing filing may be required.

10. FORTHCOMING AND ANTICIPATED CHANGES IN HEALTHCARE AND LIFE SCIENCES LAW

The results of the 2020 presidential and congressional elections are now finally known, and the Democrats control both the legislative and executive branches of government. The Democratic majorities in the House and Senate, however, are slim and include moderates, who are not likely to go along with the more extreme proposals that may emanate from the progressive wing of the party. In addition, a Senate rule provides Republicans with the power to prevent the body from voting on legislation unless 60 of the 100 Senators vote in favour of moving forward. While this tool cannot stop all legislation, it can limit what Democrats are able to pass. Traditionally, the party in control of the Presidency loses seats in the legislative branch in mid-term elections, and while the dynamics may be unusual, there will be pressure for the Biden administration to move quickly.

While pandemic response will be the most public area of focus for the Biden administration in healthcare, there are other areas where the administration is already acting or signalling its attention to act. The Biden administration is likely to reverse a series of Trump administration executive actions to limit or roll-back aspects of insurance coverage under the Affordable Care Act. In other areas, the Biden administration is likely to review or reduce enforcement prioritization of Trump administration rules for which there is general support.

The failure of the Republicans to repeal the Affordable Care Act means that it is unlikely the Biden administration will propose broad-based legislative change. Instead, we should expect to see efforts to modify aspects of the existing legal and regulatory infrastructure. Enforcement priorities may change as well, although it is still too early to predict with certainty in what ways.

UNITED KINGDOM

1. THE IMPACT OF COVID-19 ON THE PROVISION OF HEALTHCARE AND LIFE SCIENCES

The pandemic has affected all aspects of the UK healthcare system including:

- Adoption of technology at an accelerated rate, including greater use of telemedicine, precipitating a fall in the number of face-to-face appointments and a rise in appointments conducted remotely by telephone, email and video.
- The introduction of a fast-track certification and authorisation process for medical devices and medicines accelerating the route to market for manufacturers and distributors. A new regulatory framework came into force on 1 January 2021 following the conclusion of the EU-UK Trade and Cooperation Agreement with respect to the UK's withdrawal from the EU (Brexit).
- A reduction in levels of elective care, cancer care and levels of non-COVID-related diagnosis and care throughout the pandemic.

- During the initial pandemic phase, the public sector purchasing capacity from across private sector hospitals.
- Rapid re-purposing of large non-healthcare venues to provide additional capacity, although new venues have, so far, seen limited use.
- An impact on clinical trials and possible delay to development of other medicines.
- Urgent authorisation of vaccines and the implementation of a mass vaccine roll-out programme.
- The adoption of urgent/emergency procurement procedures to ensure rapid letting of contracts to source essential supplies and equipment (for example, to source PPE for the medical workforce).

2. OWNERSHIP OR EQUIVALENT RESTRICTIONS IN RELATION TO THE PROVISION OF HEALTHCARE SERVICES

There are limited barriers to the ownership and/or operation of private healthcare facilities in England. Any provider is able to operate healthcare facilities if the provider is registered with the Care Quality Commission (CQC) and holds relevant registrations.

Most NHS contracts may be awarded to and/or held by any provider, and current rules prevent discrimination on the basis of ownership.

There are, however, some restrictions on the entities and persons that may hold NHS primary care contracts. Under legislation, certain of these contracts may only be held by general practitioners or other healthcare professionals (or by companies wholly owned by these individuals). In addition, for certain elective and other services, patients are entitled to choose providers that are authorised to provide these services by commissioners ("patient choice").

3. REIMBURSEMENT OF PUBLIC OR NATIONAL HEALTHCARE SERVICES AND AWARD OF CONTRACTS

The United Kingdom's national healthcare system is the NHS. The NHS is funded through general taxation, and healthcare is provided free at the point of use and without co-payment. Privately purchased healthcare (through insurance or self-paying patients) accounts for about 11 per cent of the market.

The NHS marketplace is underpinned by legislation, with national and local payor bodies (NHS England and clinical commissioning groups) which commission and contract for healthcare services.

All NHS contracts are currently subject to EU, UK and NHS procurement rules, which require that contracts are subject to a tendering regime. Changes are proposed to procurement rules following Brexit and the UK government is currently consulting on changes to the procurement regime.

In practice, many contracts held by NHS hospitals are not tendered. Private providers commonly provide non-urgent and non-emergency care including elective, mental health, dental, primary care, diagnostics, pharmacy and community services contracts.

In general, NHS services are reimbursed at rates set out in a statutory mechanism known as the NHS tariff, although the NHS tariff allows for local modifications and variations, which have been used more frequently in recent years including in relation to NHS system-wide payments. Under the NHS constitution, patients may exercise "patient choice" when choosing a provider for elective services provided that the "choice" provider meets commissioner standards for those services.

The NHS Long Term Plan proposes changes in NHS law. It is anticipated that in 2021 the government will

introduce legislation that may affect the structure of NHS bodies and the future NHS market place.

4. DRUG APPROVALS AND REIMBURSEMENT

Marketing authorisation for drugs is substantially regulated by UK law. Prior to Brexit, the procedure for marketing authorisations was regulated by both EU and UK law. As a consequence of Brexit, a separate marketing authorisation is required in the UK. As part of the UK's post Brexit regulatory system, community marketing authorisations will be converted to UK marketing authorisations and there are transitional provisions allowing (inter alia) the UK to authorise medicines on a fast track process in reliance upon decisions of the European Medicines Agency (EMA). The EU-UK Trade and Co-operation Agreement includes certain co-operation and facilitation arrangements with respect to medicinal products.

The NHS is the largest purchaser of drugs in the United Kingdom. A range of policies and statutory mechanisms regulate the prices payable by the NHS for drugs. There is no statutory regime for the drug prices payable by private providers.

For branded medicines, the main mechanism for pricing drugs and controlling medicines spend is a voluntary scheme known as the Pharmaceutical Price Regulation Scheme (PPRS). The PPRS sets out permitted growth of the NHS branded medicines spend (set at two percent per year for the period 2019 to 2023). The scheme requires the industry to make rebate payments if NHS expenditure exceeds the permitted growth. Any company that is not a member of the PPRS is automatically subject to statutory regulations (the Statutory Scheme) under which the Department of Health and Social Care (DHSC) may limit prices and profits of NHS medicines. In practice, most large companies participate in the PPRS. Generic (unbranded, out-of-patent medicines) are covered by the Drug Tariff (produced by an executive arm of the DHSC).

New medicines and technologies are assessed by the National Institute for Health and Care Excellence (NICE) on the basis of clinical and economic evidence. While NICE's role is to make availability decisions, in practice it also influences product prices through cost effectiveness thresholds. The NHS is legally obliged to fund and resource medicines and treatments recommended by NICE. If NICE is unlikely to recommend a drug for use, then drug prices and access to the market may be agreed with NHS England (as part of a patient access scheme or commercial agreement).

5. DEVICES CERTIFICATION AND REIMBURSEMENT

From 1 January 2021 and following Brexit, the Medicines and Healthcare Products Regulatory Agency (MHRA) will be the regulator of medical devices in the United Kingdom and will undertake responsibilities currently managed through the EU system, including vigilance reporting. For a transitional period (up until 30 June 2023), CE marking will continue to be recognised in the United Kingdom and certificates issued by EU notified bodies will continue to be valid. In addition, there will be a new certification route from 1 January 2021 (known as UK Conformity Assessed marking). In the United Kingdom, there are proposed legislative changes to the medicines and medical devices regulatory framework through the Medicines and Medical Devices Bill.

There is no statutory reimbursement scheme for medical devices in the United Kingdom. Medical devices purchased by NHS providers are subject to

procurement law. The NHS operates a centralised procurement and purchasing system for medical devices and other supplies to NHS providers. NHS providers are reimbursed for health services they provide through the NHS tariff. The NHS tariff includes the cost of most medical devices although in certain cases, high cost devices are excluded from the NHS tariff and reimbursed separately. As with medicines (see section 4 above), NICE appraises certain devices which meet its criteria and evaluates clinical effectiveness and budget impact. NHS commissioners are legally obliged to fund treatments which are recommended by NICE.

Separately, the CQC regulates all healthcare, including online healthcare and telemedicine (to the extent this is not software as a medical device).

6. REGULATION OF AI AND SOFTWARE AS A MEDICAL DEVICE

The MHRA regulates medical technology software and artificial intelligence (AI) tools as medical devices under medical device legislation. Online software tools, such as symptom checkers, are typically regulated as Class I medical devices. However, if the device allows for diagnosis, it may be a Class II medical device or higher. If the software is only a reference or decision support tool, and the healthcare professional is required to use his or her own knowledge for the care, the tool may not be a device.

In the European Union, the Medical Device Regulation 2017 (which comes into force on 26 May 2021) will change certain classifications for medical devices. In the United Kingdom, there are proposed legislative changes to the medicines and medical devices regulatory framework through the Medicines and Medical Devices Bill. In addition, software provided to NHS organisations must also meet certain mandatory standards published by NHS Digital.

In 2019 and 2020, the DHSC published various guidance and codes of practice in relation to AI and digital health services which set out principles and expectations for the use and purchase of AI in healthcare in the United Kingdom. It also sets out principles in relation to the use of and access to data.

7. TELEMEDICINE AND TELECONSULTATION

Telemedicine and teleconsultation, including remote, online and digital health services (which are not medical devices) located in England, are regulated by the CQC and providers of these services must register with the CQC. Services are assessed through investigations and other regulatory interventions to check that they are safe, effective, caring, responsive and well-led.

8. ANTI-KICKBACK RULES AND INCENTIVES TO DOCTORS

In the United Kingdom, financial relationships between pharmaceutical companies and healthcare professionals are governed by the Human Medicines Regulations and related guidance, which prohibit the use of inducements in connection with the promotion of medicinal products to healthcare professionals. The legislation is supplemented by the UK regulatory guidance published by the MHRA and industry codes which set out detailed guidance about payments to healthcare professionals.

Professional rules (for example, issued by the General Medical Council) also prohibit doctors from accepting any inducement or gift that may affect or be seen to affect the way the doctor treats patients.

Bribery legislation also applies to payments to doctors and other healthcare professionals.

There are currently no legislative requirements to disclose financial relationships with healthcare professionals, although there are disclosure obligations in medicine and medical device codes of practice. NHS contracts and guidance include an obligation to disclose and publish all financial interests, including gifts and hospitality received by staff.

A Competition and Markets Authority Order also sets out rules about certain payments and share-ownership by doctors in relation to private patient services where such payments and interests may operate as incentive arrangements to influence referrals and care.

9. MERGER AND FOREIGN INVESTMENT CONTROL

The Competition and Markets Authority oversees merger control in the United Kingdom. From 1 January 2021, the CMA has jurisdiction to review the effects of certain mergers previously reviewed by the European Commission, although certain transitional provisions will apply.

The United Kingdom presently operates a generally liberal approach to foreign investment. The UK government has some powers to intervene under merger controls in relation to mergers that are against the public interest for national security reasons. This power has been exercised on rare occasions and never in relation to healthcare.

Recent developments, however, suggest that there will be increasing intervention from government. On 23 June 2020, in response to COVID-19, the government introduced a new public interest ground on which it can intervene in mergers in order to maintain the United Kingdom's capability to combat and mitigate public health emergencies. Furthermore, a draft National Security and Investment bill was recently put before parliament and is expected to establish a new mandatory foreign direct investment regime for the United Kingdom. The bill has a focus on particular industry sectors, including: advanced robotics, AI, critical suppliers to government, critical suppliers to emergency services and engineering biology. Should it become law, this is likely to have an impact on certain healthcare and life sciences investments in the United Kingdom.

10. FORTHCOMING AND ANTICIPATED CHANGES IN HEALTHCARE AND LIFE SCIENCES LAW

The NHS Long Term Plan and consultation documents published in 2019 set out certain proposals for legislative change to the NHS. The proposals included changes to procurement and competition rules and provided for certain structural changes to the NHS. The adoption of the proposals is subject to the full legislative process and parliamentary approval, and it is not clear if or when the proposals will be implemented.

Changes in law, including some mentioned above, will arise as a consequence of the United Kingdom formally leaving the European Union following the end of the Brexit transition period.

FRANCE

1. THE IMPACT OF COVID-19 ON THE PROVISION OF HEALTHCARE AND LIFE SCIENCES

The pandemic has affected all aspects of the French healthcare system, including:

- Telemedicine has grown exponentially during the COVID-19 crisis. Teleconsultations will be fully reimbursed by the French statutory health insurance scheme (SHI) until the end of 2020, a measure

which will likely be extended to the end of 2021 at least (see section 6 below).

- The e-health sector, including digital health, medtech, and biotechnology start-ups have emerged and investment in the field is expected to increase significantly. France has amended its foreign investment control framework accordingly by extending the scope of its screening to the biotechnology industry (see section 8 below).
- The pandemic emphasised the need for simplified administrative approval for health products. As a result, a bill for SHI financing for 2021 (projet de loi de financement de la sécurité sociale pour 2021), has been adopted by the National Assembly but is still under review by the Senate. The bill aims to simplify the fast-track procedure for medicinal products and will replace the procedure for exceptional use of unauthorised medicine (authorisations temporaire d'utilisation) and off-label use of medicine (recommendations temporaire d'utilisation) with two regimes: early access authorisation (for innovative products) and compassionate access authorisation (for therapeutic needs not yet covered).
- The levels of care for non-communicable diseases and non-COVID-19-related diagnoses have plummeted and Healthcare Professionals (HCPs) have expressed their concerns regarding the lack of early screening and missed opportunities to treat potentially deadly diseases.
- Transitional measures that have been implemented for ongoing and COVID-19 related clinical trials during the first wave of the pandemic to enable the conduct of such trials (e.g., delivery of experimental drugs at home, collection of data via teleconsultations) could be reactivated following the announcement of the second lockdown.

2. OWNERSHIP OR EQUIVALENT RESTRICTIONS REGARDING THE PROVISION OF HEALTHCARE SERVICES

Healthcare services in France can be provided either by independent physicians through their private practices (outpatients) or during a hospitalisation in public or private healthcare facilities (inpatients).

There is no restriction applicable to the operation of private healthcare facilities. Such facilities are often constituted in legal form as limited liability companies and can be operated by physicians or non-physicians. Subject to the grant of administrative permits, these facilities do not differ from commercial companies.

3. AWARD OF PUBLIC CONTRACTS AND REIMBURSEMENT

Every person born in France, working in France or regularly living in France can benefit from SHI. SHI provides reimbursement of outpatient and inpatient treatments.

Physicians: Prices are fixed by the national physician agreement (between SHI and physicians' associations). Physicians can apply higher prices under specific conditions. If a physician is not part of the national physician agreement, he or she can set prices freely. National reimbursement rates apply to services provided by physicians except when the physician is not part of the national physician agreement, in which case lower rates apply. Healthcare services are reimbursed at more favourable rates if provided within the mandatory care pathway (parcours de soin).

Public healthcare facilities: Applicable prices are fixed annually by the Ministry of Health. SHI reimburses 80 percent of the applicable fees. The remaining 20 percent can be covered by private insurance.

Private healthcare facilities: There are two types of private facilities:

- Private facilities under contracts: most private healthcare facilities enter into contracts with the Local Health Agency (Agence Régionale de Santé or ARS), and health services are reimbursed as if they were performed in a public facility.
- Other private facilities: for the few facilities that do not enter into contracts with ARS, prices are not fixed. For these facilities, the applicable 80 percent reimbursement rate will be based on the prices fixed by the Ministry of Health rather than the price allocated by the private facility.

4. DRUG APPROVALS AND REIMBURSEMENT

Medicinal products cannot be placed on the market if they have not received a prior French or centralised marketing authorisation (MA). French MAs are granted by the French Medicine Agency (Agence Nationale de Securité du Médicament, or ANSM). MAs are granted upon demonstration of quality, safety and efficacy. Any variation to the terms of the MA must be notified to or approved by the ANSM, depending on the nature and importance of the variation.

Whether the SHI reimburses a medicinal product depends on its degree of efficacy (Service Médical Rendu), which is evaluated by the High Health Authority (Haute Autorité de Santé or HAS).

The General Director of the French National Union of Health Insurance (Union Nationale des Caisses d'Assurance Maladie) decides the reimbursement rate (from 15 percent to 65 percent, or in certain circumstances, 100 percent), depending on the drug's efficacy compared with other therapies that are already on the market.

5. PAYMENTS TO HEALTHCARE PROFESSIONALS AND INCENTIVES

Anti-kickback rules currently prohibit companies that manufacture or market health products reimbursed by SHI from directly or indirectly offering any benefits in cash or in kind to healthcare practitioners. Healthcare practitioners are also prohibited from receiving such benefits.

The law of 24 July 2019 expanded the scope of this prohibition to any companies manufacturing or marketing health products (regardless of their reimbursement status) or providing health services. Exceptions to this prohibition include: remuneration for research activities, grants in cash or in kind that are allocated to research activities, and hospitality offered at promotional, professional and scientific events to HCPs by companies operating in the health sector. Such companies will ask the relevant professional association for authorisation to offer any benefit (other than for negligible value) to a HCP for implementing any contract exceeding a specific threshold with a HCP. Below this threshold, a declaration will be sufficient. In August 2020, two ministerial orders set the thresholds, which vary depending on the categories of activities concerned (e.g., research grants above 5 000 EUR or hospitality above 2 000 EUR must be authorised). These amounts were eagerly awaited and they facilitated the full application of the updated version of the anti-kickback regulation, which came into force on 1 October, 2020. A failure to comply with such regulation can lead to criminal sanctions.

6. REGULATION OF AI AND SOFTWARE AS A MEDICAL DEVICE

The use of medical devices, regardless of whether they involve artificial intelligence (AI), is substantially regulated by EU law. Medical devices

must be CE marked prior to placement on the market. As AI-powered medical devices are built on the basis of experiences and accumulation of observations, the quality and quantity of the incoming data and the learning ability of the AI software are crucial elements for the device's operation. Therefore, the actual CE marking process of certifying the conformity of a medical device prior to its placement on the market seems incompatible with the reality of AI-powered devices. The permanent evolution of said devices due to their ability to learn would in theory require a continuous evaluation in order to assess the service provided. The HAS published a press release in October 2020 disclosing a new assessment scheme for AI-powered medical devices, which sets out a roadmap to adapt to these specificities. Companies operating medical devices are required, amongst others, to provide detailed information on the incoming data used to develop the learning ability of the software. The next step for the HAS is publication of a functional classification chart for software according to its use (screening function, diagnosis, prevention, aid in understanding hygieno-dietary measures, etc.). This classification chart should be finalised by the end of 2020.

7. TELEMEDICINE AND TELECONSULTATION

Compared to other European states, the French legal framework for telemedicine is relatively advanced. After a period of experimentation, telemedicine is now fully integrated in the practice of medicine. Telemedicine includes six type of activities, ranging from teleconsultation (i.e., remote consultation between patient and physician) to tele-expertise (i.e., remote solicitation by a medical professional of the opinion of colleagues with particular skills), and preliminary medical reviews conducted by emergency services. Tele-care was added in July 2019, to connect pharmacists or paramedics with patients (e.g., to enable remote nurse care). Teleconsultation must be carried out by video transmission (as opposed to a telephone call). However, during the pandemic, teleconsultations by phone have been permitted in specific cases (e.g., no access to internet). Since September 2019, teleconsultation can also be performed in pharmacies at booths that may be connected to medical devices.

Teleconsultation became eligible for SHI reimbursement on September 2018. To be reimbursable, the teleconsultation must be performed under specific conditions: it must be conducted within the mandatory care pathway and the physician must be an independent doctor adhering to the national physician agreement who already knows the patient (i.e., a physical consultation must have been performed in the 12 months preceding the teleconsultation). Teleconsultations may, in certain cases be reimbursed when conducted outside the mandatory care pathway, provided that they are performed in a local organisation such as a care home (centre de santé). Due to COVID-19, all teleconsultations are now fully reimbursed by SHI following an ordinance dated 18 June 2020 and such reimbursement scheme will apply until 31 December, 2020. The bill for SHI financing (see section 1 above) plans to extend this to the end of 2021.

8. FOREIGN INVESTMENT CONTROL

Under current law, foreign investments in relation to activities "in the protection of public health" and AI are considered strategic or sensitive and may require prior governmental authorisation. Recent changes to the law entered into force in April and July 2020 and extended the activities that are considered strategic or sensitive to activities relating, inter alia, to biotechnologies, food safety and additive manufacturing. In addition, such changes resulted in

increased sanctions for non-compliance with foreign investment regulations. In July 2020, a decree also lowered the threshold of control applying to non-EEA entities' investment in public corporations transacting in those sensitive sectors, from 25 percent to 10 percent.

9. FORTHCOMING CHANGES IN HEALTHCARE AND LIFE SCIENCES LAW

Advertising by healthcare practitioners: Advertising by physicians is prohibited in France. Recent rulings from the European Court of Justice (Luc Vanderborght, C-339/15 dated 4 May 2017 and Cabinet dentaire du docteur RG, C-296/18 dated 23 October 2018) found that such prohibition conflicts with EU law. Thus, in two rulings dated 6 November 2019, the Conseil d'Etat invalidated the decision of the Government to refuse to repeal the prohibition of advertising. However, the prohibition on advertising is still currently applicable as the rulings have only invalidated a governmental decision refusing to repeal such prohibition. Therefore, physicians advertising their activities could in theory be sanctioned by the National Board of Physicians or in the course of judicial proceedings. Nevertheless, any such sanction could be challenged, as it would be based on a statutory provision ruled illegal as contrary to EU law.

Compared to other European states, the French legal framework for telemedicine is relatively advanced.

GERMANY

1. THE IMPACT OF COVID-19 ON THE PROVISION OF HEALTHCARE AND LIFE SCIENCES

COVID-19 has had a significant impact on the healthcare sector worldwide.

In Germany, the implementation of telemedicine and other digital health services or applications by the general healthcare system has increased. German legislators both on federal and on state level, as well as medical professional associations have acted promptly and implemented measures to facilitate the use of telemedicine services within a very short timeframe. In particular, the legal options for remote medical treatment and consultation have been extended, including the option to prescribe drugs and provide certificates for sick leave in online consultations. Pilot projects for digital healthcare services have been transferred into the general statutory healthcare insurance (SHI) payment system and thus, digital healthcare services are now fully reimbursed.

Other measures to alleviate the impact of the pandemic in Germany have included the granting of emergency powers to governmental authorities to enable them to act more quickly and to set up an emergency plan for face-masks, sanitisers and other required medical equipment. Furthermore, healthcare providers, in particular care home facilities and hospitals, have been provided with additional funds.

2. OWNERSHIP OR EQUIVALENT RESTRICTIONS IN RELATION TO THE PROVISION OF HEALTHCARE SERVICES

There are no ownership restrictions for hospitals as the German hospital market consists of public community or state hospitals, private not-for-profit hospitals and private for private hospitals alike. But there are some ownership restrictions in the outpatient health services sector. Prior to 2004, physicians were only allowed to render outpatient services when working in their own practice or clinic or in partnership with other physicians. No investor was entitled to directly or indirectly own shares in those

clinics or partnerships. Now, outpatient physician services can also be rendered in so –called Medizinische Versorgungszentren (MVZ), i.e., Medical Care Centers. MVZ are often established in the legal form of limited liability companies and operating with employed physicians. MVZ needn't necessarily be owned by physicians. Rather, they can also be owned by hospitals, local communities, not-for-profit organisations and – under certain conditions - so-called non-physician dialysis services providers. Investors who want to own MVZs usually choose hospitals as their preferred vehicle. Since 2019, particular local market share restrictions (far below any antitrust threshold) have applied to hospital-owned MVZs rendering dental care services. No other ownership restrictions apply in the German health and care market.

3. REIMBURSEMENT OF PUBLIC OR NATIONAL HEALTHCARE SERVICES AND AWARD OF CONTRACTS

Around 90 percent of the German population are covered by public health insurance (Gesetzliche Krankenversicherung, i.e., the so- called Statutory Health Insurance (SHI system)). To provide medical or other healthcare services to SHI patients, the following requirements must be met:

- Physicians (or MVZ, see section 2 above) providing outpatient services must be admitted to practice under a certain regulatory regime which only applies to the outpatient sector, i.e., the Zulassungsausschüsse of the Kassenärztliche Vereinigungen ("Admission Boards" of Panel Doctors Associations). In addition to medical qualification a strict needs assessment applies. As most German regions are considered to have an oversupply of physician services, a physician or MVZ aiming at rendering services to SHI patients, usually needs to buy a retiring physician's practice in order to be eligible to treat SHI patients.
- Hospitals must be included in the so-called hospital plan of the relevant German federal state in order to be entitled to accept and treat SHI patients.
- All other care service providers (e.g., nursing care facilities) must enter into care agreements with the SHI funds.

In most healthcare sectors there are no public procurement proceedings for awarding permissions or entering into agreements with SHI funds. Generally any provider who meets the legal requirements is admitted, yet subject to the same conditions as any other comparable provider in the relevant region. Formal public procurement tenders usually only take place where there is no free choice of providers, e.g., for certain drugs, such as drugs intended for use in surgeries.

4. DRUG APPROVALS AND REIMBURSEMENT

Marketing authorisation for drugs is substantially regulated by EU law. Under certain conditions, drugs may be authorised in a centralised EU procedure handled by the European Medicines Agency (EMA), e.g., orphan drugs and most biologics. The EU marketing authorisation is valid throughout the EU. Drugs can also be authorised by the competent national authority if the drug is only to be authorised in one member state, or if several EU member states work together to grant authorisations.

Most marketing authorisations for drugs require preclinical and clinical testing, but there are exemptions to this rule (e.g., bibliographic authorisation). Expedited approval procedures are also available, such as Conditional Approval or the PRIME procedure.

Like most EU member states, Germany regulates drug distribution and pricing to a certain extent. Pharmacy-only drugs are not allowed to be dispensed outside a licensed pharmacy, prescription-only drugs are subject to a statutory pricing scheme.

The reimbursement of drugs within SHI and the private insurance system differs to some extent. SHI funds generally only reimburse prescription-only drugs, but there are exceptions to this rule.

5. DEVICES CERTIFICATION AND REIMBURSEMENT

Medical devices law in the EU is currently governed by three directives (Medical Devices Directive (MDD), In Vitro Diagnostic Medical Devices Directive (IVDD) and Active Implant Medical Devices Directive (AIMDD)) that are not directly applicable in the Member States and that have been transposed into Member States national law. Medical devices do not require a genuine marketing authorisation comparable to drugs in the EU but are subject to a certification procedure. Before being placed on the market, a medical device has to undergo a conformity assessment procedure in order to confirm that it complies with the essential requirements under the MDD. The type of conformity assessment procedure to be used depends on the medical device's risk class. Medical devices of risk Class I are subject to a basic conformity assessment procedure that does not require the involvement of a notified body. Medical Devices of higher risk classes are required to have aspects certified by a notified body, which is a private entity vested with certain regulatory competencies. After successful completion of the conformity assessment, the manufacturer affixes the CE mark to the product. The CE mark entitles the manufacturer to place the product on the market in the CE zone, which currently covers the EEA (the EU plus EFTA-countries Norway, Liechtenstein and Iceland), as well as Turkey and Switzerland.

In 2017, new EU regulations on medical devices were adopted. The new regime will become applicable on 26 May 2021 (for medical devices – after a postponement of one year due to the COVID-19 pandemic) and on 26 May 2022 (for in vitro diagnostic medical devices), respectively. The new legal framework modifies the risk classification system, resulting in many devices being classified in higher risk classes. Due to this up-classification, but also as a result of increased requirements in the conformity assessment procedure, placing medical devices on the market in the EU will become more difficult. However, as the certification system is maintained and no genuine authorisation procedure is introduced, market clearance of medical devices will continue to be significantly less challenging than placing a drug on the market.

6. REGULATION OF AI AND SOFTWARE AS A MEDICAL DEVICE

Medical software is in certain conditions considered a medical device and therefore subject to the requirements of EU medical devices directives and the related Member State laws implementing it.

Currently, medical software is often classified as medical device of risk Class I and therefore can be certified under the most basic conformity assessment procedure without involvement of a notified body.

When the MDR becomes applicable on 26 May 2021, many medical software products will be classified in higher risk classes, and therefore, manufacturers of medical software will often need CE certificates issued by notified bodies. The transition provision under the MDR allows for manufacturers of Class I medical devices to benefit from a grace period that

enables them to continue to market their products under the conditions of the MDD until 2024.

7. TELEMEDICINE AND TELECONSULTATION

For a long time, the German market lagged behind in the teleconsultation sector because of restrictive and/or inconsistent regulations. Physicians and their professional associations were still very reluctant to accept legalisation of telehealth services and/or the use of digital devices.

Since 2019, this has dramatically changed. Pre-COVID-19, various laws and other regulatory acts were adopted to allow telemedicine services, including physician videoconsultation, and their coverage by private and public payers. Likewise, public licensing of medical apps was anticipated to allow SHI to cover licensed medical apps prescribed by a doctor. Even though the laws were already been adopted in 2019, their implementation sharply accelerated under COVID-19.

As a consequence of this regulatory change, the number of video-consultations, online prescriptions and other kinds of remote treatment and consultation are rapidly increasing. Correspondingly, restrictions once in place on the advertisement of remote consultation and treatment have to some extent been lifted.

8. ANTI-KICKBACK RULES AND INCENTIVES TO DOCTORS

Professional and social security law rules ban kickbacks and incentives to physicians and other healthcare professionals for referrals or prescriptions. Any such incentives are unlawful and from 2016 may be subject to criminal sanctions.

Cooperation among players in the healthcare sector is not generally prohibited, but has to comply with the requirements of various provisions under public health insurance law, advertising law, professional codes and criminal law. Cooperation agreements between different health providers and public payors are exempt from those rules to encourage cooperation.

9. MERGER AND FOREIGN INVESTMENT CONTROL

If a non-EU acquirer obtains at least 25 percent of the voting rights in a German healthcare company, such acquisition is subject to German foreign investment control (FIC). The parties may on a voluntary basis pass through the applicable FIC proceedings in order to obtain deal certainty. In specific cases, where domestic target companies qualify as operators of critical infrastructure, the relevant threshold is 10 percent only and clearance by the Federal Ministry of Economic Affairs and Energy (BMWi) is mandatory, i.e., the acquisition only becomes effective if and when BMWi has cleared the acquisition without conditions.

In FIC proceedings, BMWi investigates whether and to what extent foreign investments might pose a threat to Germany's public order or security. If BMWi has concerns in this regard, it may restrict or, in particularly critical cases prohibit foreign investments. Currently, in light of the COVID-19 pandemic, foreign investments in the German healthcare sector are subject to particular scrutiny by the German government.

10. FORTHCOMING AND ANTICIPATED CHANGES IN HEALTHCARE AND LIFE SCIENCES LAW

Recently, a law was adopted that restricts the scope of activities of pharmacies that are located outside of

Germany and are therefore not bound by the German statutory pricing scheme for drugs. The law is ambiguous in several aspects which will likely trigger related litigation in the near future.

Further amendments are also expected regarding the German telematics infrastructure, nursing care homes and digital apps for home care services, as well as for use of personal health data for scientific health research purposes.

Numerous laws have been adopted in the course of the COVID-19 pandemic and will likely be subject to further discussion and amendment. On an EU level, plans are in place to establish a new Health Emergency Response Agency (HERA) in order to facilitate future measures relating to the pandemic.

ITALY

1. THE IMPACT OF COVID-19 ON THE PROVISION OF HEALTHCARE AND LIFE SCIENCES

The COVID-19 emergency has had a deep impact on the healthcare sector in Italy including:

- Increased use of digitalisation, in particular, the spread of telemedicine and the digitalisation of prescriptions for medicines and services to be supplied and paid for by the National Health Service (NHS).
- Introduction of certain derogations to the requirements for placing certain medical devices onto the market.
- Provision of special rules concerning the performance of clinical trials for medicines to be used to treat COVID-19 and all other medicines, in particular aimed at implementing digital services and remote clinical trials.
- Simplification and acceleration of procurement rules governing the purchase of goods and services, including public healthcare facilities, by public entities.

2. OWNERSHIP OR EQUIVALENT RESTRICTIONS IN RELATION TO THE PROVISION OF HEALTHCARE SERVICES

In Italy, there are no specific ownership or equivalent restrictions in relation to the provision of healthcare services.

Healthcare facilities, including hospitals, may be owned by public or private investors.

Healthcare facilities must meet specific requirements to be authorised to operate and must fulfil additional conditions to operate within the NHS and treat patients at the NHS's expense.

3. REIMBURSEMENT OF PUBLIC OR NATIONAL HEALTHCARE SERVICES AND AWARD OF CONTRACTS

The Italian healthcare system is mainly public. The NHS was created to provide universal and uniform healthcare coverage to the entire Italian population and it is financed by general taxation. The relevant responsibilities and powers are shared between the central government (the Ministry of Health) and the Italian regions.

In December each year, the Italian Parliament approves the annual Budget Law (Legge Finanziaria), which determines the amount of financing for the NHS. This health funding is then allocated among the regions, mostly on an age-adjusted capitation basis, which finances the Regional Health System (RHS) of each region. Thanks to this financing system, most healthcare services are provided free of charge to patients, and the regions reimburse the cost to the

healthcare facilities. Healthcare facilities that intend to operate within the NHS/RHS must be accredited by the competent Italian region, and must enter into agreements with the local health authorities specifying the terms and conditions of the provision of healthcare services to patients at the RHS's expense.

Public healthcare facilities must tender for the procurement of medicines and services. Exceptionally, under certain conditions, direct negotiation of agreements with private parties is also permitted.

4. DRUG APPROVALS AND REIMBURSEMENT

No medicines may be placed on the Italian market without a marketing authorisation (MA) from the Italian Medicines Agency (AIFA) or the European Medicines Agency (EMA), according to the centralised procedure provided for by Regulation (EC) No. 726/2004. To receive an MA in Italy, the applicant must be established in the European Union and have an appointed representative in Italy. Under the national MA procedure, the AIFA issues its decision on the authorisation within 210 days of the application being filed (although this period is suspended if additional documents are required). In exceptional circumstances, the authorisation may be granted on the condition that the applicant fulfils additional obligations (often related to the safety of the medicine), which are then assessed annually.

For certain categories of products, such as certain homeopathic medicines, herbal medicines and follow-on products (generic and biosimilar medicinal products), the authorisation procedure is simplified. For example, if the request for MA concerns a generic version of a reference medicine which has been authorised for at least eight years in Italy or the European Union, the applicant is not required to provide the results of the pre-clinical and clinical trials. In the case of biosimilar medicines, the applicant is required to provide the results of pre-clinical or clinical trials related to the aspects that, for the peculiar characteristics of these products, vary compared to the reference medicine (e.g., raw materials or production processes). The results of other tests contained in the reference medicine's dossier are not required.

The MA is valid for five years from its publication in the Official Gazette and can be renewed following a re-evaluation of the risk-benefit balance. After the first renewal, the MA is valid for an unlimited period unless the AIFA/EMA decides, on justified pharmacovigilance grounds, to proceed with one additional five-year renewal. The MA will lose its efficacy if the medicine is not placed on the market within three years of the MA issuance, and if the medicine has not been marketed for three consecutive years (sunset clause).

Following the issue of the MA, and upon the request of the MA holder, negotiations start with AIFA to assess whether the medicine can be reimbursed by the NHS, and if it can, to set the relevant price. In certain cases, the negotiation procedure may be launched by AIFA. Negotiations between the MA holder and AIFA shall be conducted according to criteria set out by law, which include (inter alia) the added therapeutic value and therapy costs of the new medicine compared to medicines those already distributed for the same indication. The last step to allow a medicine to be supplied at the RHS's expense is the inclusion of such medicine onto the "Prontuario Terapeutico" of each region.

5. DEVICES CERTIFICATION AND REIMBURSEMENT

The placing of medical devices on the market in Italy is permitted only for devices bearing the CE mark.

The procedure and requirements for obtaining the CE mark vary depending on the class of the relevant device and are set out in the EU Medical Devices Regulation 2017/745 (MDR), that will become applicable on 26 May 2021 and replace the national legislation implementing the Directive 93/42/EEC.

In addition, all medical devices to be placed on the Italian market shall be notified to the Ministry of Health and reported in a dedicated register (Banca dati dei dispositivi medici) that is publicly available. Finally, to be purchased by public entities (i.e., at the NHS's expenses) medical devices must also be included in another register, called the Repertorio generale dei dispositivi medici, governed under Ministerial Decrees 21 December 2009 and 23 December 2013 (for IVDMD).

There is no statutory reimbursement scheme for medical devices in Italy. Only medical devices purchased by public healthcare facilities (following tender) and provided to patients by such facilities are re-imbursed by the RHS. To be purchased by public healthcare facilities at the RHS's expense, medical devices are allocated to certain existing categories of homogeneous products. If they do not fall within existing categories, specific "Health Technology Assessment Procedures" are performed to prove their additional value for patients.

6. REGULATION OF AI AND SOFTWARE AS A MEDICAL DEVICE

There are no specific laws in Italy applicable to artificial intelligence. The use of artificial intelligence in healthcare raises many issues, including classification of the relevant application as a medical device, data protection and responsibility issues that are currently regulated according to the general principles of Italian/EU law.

The MDR, under Rule 11, provides new classification rules for "software as a medical device". Under the MDR, software as medical device is generally assigned a higher class of risk.

In order to provide clarifications and examples to manufacturers, the European Commission's Medical Devices Coordination Group published new guidance in October 2019 on the qualification and classification of software as a medical device under the MDR.

7. TELEMEDICINE AND TELECONSULTATION

Italian law does not specifically regulate telemedicine and teleconsultation.

In 2012, the Ministry of Health issued the National Guidelines on Telemedicine (endorsed in 2014 by the regions' representatives), which provides for the main regulatory framework for the provision of such services.

Moreover, in the last few months several Italian regions have enacted specific resolutions to regulate the requirements and conditions allowing for the provision of certain telemedicine services (especially tele-visits) at the RHS's expense.

8. ANTI-KICKBACK RULES AND INCENTIVES TO DOCTORS

Both the applicable law and the professional codes of conduct of pharmaceutical industry associations forbid kickbacks and incentives to physicians and other healthcare professionals (HCPs). Such actions are subject to criminal sanctions.

Cooperation between HCPs and pharmaceutical companies is, however, permitted in compliance with applicable legal and ethical regulations.

The Italian Parliament is discussing a bill which requires pharmaceutical and medical device manufacturers to publicly disclose all payments to, or agreements with, HCPs (called the "Sunshine Act"). However, the legislative procedure has not been finalised to date.

9. MERGER AND FOREIGN INVESTMENT CONTROL

Foreign investment control regulations were introduced in Italy for the first time in 2012, and granted the Italian Government authority to impose conditions on, or veto, transactions involving Italian companies carrying out strategic business, regardless of state interest in such business.

The healthcare sector was drawn into the abovementioned regulations for the first time in 2019, when, "critical infrastructure, whether physical or virtual, including … health" and "critical technologies and dual-use items, including artificial intelligence, robotics, semiconductors, cybersecurity, aerospace, defense, energy storage, quantum and nuclear technologies, as well as nanotechnologies and biotechnologies" were mentioned (via citation of Art. 4, letters a) and b) of EU Regulation 2019/452) amongst sectors subject to foreign investment control.

Recently, based on certain measures issued during the COVID-19 outbreak, the foreign investment control regime in the healthcare sector has been further expanded to include Italian target companies operating in the field of manufacturing, import, and wholesale distribution of medical, medical-surgical, and individual protection devices.

In Italy, the control of the concentration of undertakings for competition purposes is enforced by the Italian Competition Authority (Autorità Garante della Concorrenza e del Mercato) according to Law no. 287/1990. In particular, a proposed concentration of undertakings must be notified to the ICA prior to its implementation if certain thresholds concerning the annual turnover achieved in Italy are exceeded by the undertakings concerned in the transaction.

10. FORTHCOMING AND ANTICIPATED CHANGES IN HEALTHCARE AND LIFE SCIENCES LAW

Recent changes in policy and legislation that may affect investments in the healthcare and life sciences sectors focus on the following areas:

- Negotiation of medicine prices. The Ministry of Health set out new criteria for the price negotiation between MA holders and AIFA on 1 August 2019. This was published in the Italian Official Gazette and became applicable on 24 July 2020, replacing the previous regulation.
- Introduction of the payback mechanism in the medical devices sector. The payback is a mechanism applied by Italian law requiring companies to refund to the NHS certain sums proportional to the quantity of products sold to the NHS. In 2015, this mechanism, (originally concerned with pharmaceutical products only), was extended to medical devices, but it has not yet been applied, because certain implementing measures are still outstanding. Last year, some of these measures were taken and the application of the payback mechanism to the medical devices sector is expected in the near future.

AUSTRIA

1. THE IMPACT OF COVID-19 ON THE PROVISION OF HEALTHCARE AND LIFE SCIENCES

The pandemic has had a significant effect on healthcare and life sciences in Austria. Some of the changes in law and policy are only likely to be in force during the pandemic, for example: new compliance rules in the procurement of medical protective equipment, provision of certain COVID-19-related medical services for (specialised) physicians and paramedics, no supervision by physicians in certain COVID- 19-related medical services, no CE mark for standard face-masks, strict behavioural rules and testing requirements for staff members in hospitals.

Telemedicine, however, has experienced a boost, which will outlive the pandemic. Although it has not been explicitly regulated (neither before nor during the pandemic), it has now been largely accepted that physicians do not have to provide their services in person in every case but can do so remotely.

2. OWNERSHIP OR EQUIVALENT RESTRICTIONS IN RELATION TO THE PROVISION OF HEALTHCARE SERVICES

Full medical care may be provided only by physicians (Ärzte) or dentists (Zahnärzte) in private practices or hospitals (Krankenanstalten). Physicians may cooperate in the form of a group practice (Gruppenpraxis) or in a primary healthcare unit (Primärversorgungszentrum). Only doctors admitted to practice may hold an ownership interest in a group practice or primary healthcare unit. Outpatient clinics (Ambulatorien) are considered hospitals. There are no limitations as to who may become a shareholder of a hospital, but legislation may set out regulations with respect to notification requirements and/or compliance with a "fit and proper" test.

3. REIMBURSEMENT OF PUBLIC OR NATIONAL HEALTHCARE SERVICES AND AWARD OF CONTRACTS

More than 99 percent of the Austrian population is medically insured in the statutory health insurance system (SHI). SHI covers "adequate and appropriate" (ausreichend und zweckmäßig) medical and other healthcare for patients insured in the SHI. Under SHI:

- Any treatment by outpatient physicians with a contract with one or more statutory health insurers (Kassenverträg) is covered.
- Treatment by physicians without Kassenverträg (private physicians – Privatärzte) is covered to the extent the treatment is considered "adequate and appropriate", and coverage is capped at the amounts fixed in the Kassenverträge.
- Treatment in hospitals is covered to the extent the treatment is considered "adequate and appropriate". Patients might have to bear costs for food.
- The services of all other care providers and facilities (e.g., nursing care providers and facilities) are covered by SHI if these services are part of a so-called benefits catalogue (Leistungskatalog) of the respective health insurer or may be covered on a case-by-case basis.

In most healthcare sectors there are no public procurement proceedings for awarding permissions or entering into agreements with SHI funds. Generally, any provider who meets the legal requirements is admitted, yet is subject to the same conditions as any other comparable provider in the relevant region. Formal public procurement tenders usually only take place where there is no free choice of providers, e.g.,

for certain drugs such as drugs intended for use in surgeries.

4. DRUG APPROVALS AND REIMBURSEMENT

Marketing authorisation for drugs is substantially regulated by EU law. Under certain conditions, drugs may be authorised in a centralised EU procedure handled by the European Medicines Agency (EMA).

Orphan drugs and most biologics must be authorised through the EMA. The marketing authorisation granted by the European Commission is valid throughout the European Union, and therefore also in Austria.

Drugs can also be authorised by the competent Austria authority (Bundesamt für Sicherheit im Gesundheitswesen – BASG) if the drug is only to be authorised in Austria, or if several EU Member States work together to grant authorisations in several Member States. Most marketing authorisations for drugs require preclinical and clinical testing, but there are exemptions to this rule (e.g., bibliographic authorisation). Expedited approval procedures are also available, such as Conditional Approval or the PRIME procedure.

Like most EU Member States, Austria regulates drug distribution and pricing to a certain extent. Drugs to be reimbursed automatically by SHI are listed in the Reimbursement Code (Erstattungs- kodex). Drugs are included in the Reimbursement Code by a decision of the Umbrella Organisation of the Social Insurance Providers (Dachverband der Sozialversicherungsträger) following an application and negotiations on efficiency and pricing.

5. DEVICES CERTIFICATION AND REIMBURSEMENT

Before being placed on the market with a CE mark, a medical device must undergo a conformity assessment procedure to confirm that it complies with the essential requirements of the EU Medical Devices Directive. The type of conformity assessment procedure to be used depends on the medical device's risk class. Medical devices of higher than Class I risk Classes (IIa, IIb and III, in vitro diagnostics devices for self-testing) are subject to certain conformity assessment procedures by a notified body.

New EU Regulations on medical devices were adopted in 2017 and will become applicable from 26 May 2021 (for medical devices) and 26 May 2022 (for in vitro diagnostic medical devices), respectively. The new legal framework extends the scope of the medical devices regime to certain products that do not have a medical purpose. It also modifies the risk classification system. Under the new Regulations, it will become more difficult to place medical devices on the EU market, but still less challenging than placing a drug on the market.

There is no statutory reimbursement scheme for medical devices in Austria. Reimbursement by SHI is largely subject to individual negotiation.

6. REGULATION OF AI AND SOFTWARE AS A MEDICAL DEVICE

Under certain conditions, AI and software are considered to be a medical device (SaMD) and are therefore subject to the requirements of EU Medical Device Directives and the Austrian Medical Devices Act (and soon the EU Medical Devices Regulations). Currently, SaMD is often classified as a low-risk device (Class I, with exceptions) and therefore is

subject to a basic conformity assessment procedure without involvement of a notified body.

The use of artificial intelligence in healthcare is also subject to restrictions regarding medical services, restrictions on advertising and statutory and non-statutory anti-corruption provisions.

7. TELEMEDICINE AND TELECONSULTATION

Telemedicine and teleconsultation are permissible if certain requirements are met. There is certainly a strong interest in the market for these services, but regulations are strict. Due to the COVID-19 pandemic, there has been greater reliance on telemedicine and authorities have been more receptive to the use of telemedicine as part of patient care.

Telemedicine has been explicitly included in the current government programme.

8. ANTI-KICKBACK RULES AND INCENTIVES TO DOCTORS

Statutory and professional rules forbid kickbacks and incentives to physicians and other healthcare professionals. Such actions are illegal under professional rules and may be sanctioned under recently enacted criminal law.

Cooperation between different healthcare providers and sectors, however, is permitted and even promoted by the competent public authorities to improve the service quality and reduce costs.

9. MERGER AND FOREIGN INVESTMENT CONTROL

Companies in the healthcare sector may qualify as critical infrastructure within the meaning of Sec. 25a of the Austrian Foreign Trade Act (Außenwirtschaftsgesetz). The acquisition of a participation of 25 percent or more of the business of such an undertaking (asset deal) by non-EU/EEA/Swiss nationals may require prior approval by the Austrian Ministry for Economic Affairs (currently the Federal Ministry for Digital and Economic Affairs).

10. FORTHCOMING AND ANTICIPATED CHANGES IN HEALTHCARE AND LIFE SCIENCES LAW

No currently pending or anticipated changes in the relevant provisions.

DENMARK

1. THE IMPACT OF COVID-19 ON THE PROVISION OF HEALTHCARE AND LIFE SCIENCES

COVID-19 has affected various aspects of the Danish healthcare system, including:

- Extraordinary measures for clinical trials.
- Implementation of a faster process for review and approval of vaccines and medicines against COVID-19.
- Implementation of virtual and digital solutions for consultations within the healthcare sector.
- Development of healthcare technology to better combat the challenges of COVID-19 (e.g., oxygen robot monitors supplying oxygen based on a patient's current condition and robotic room disinfection systems).
- Introduction of measures to counteract problems regarding supply, including granting authorisation to the Danish Medicines Agency (DMA) to regulate the prices of medicines and medical devices as necessary and the introduction of less stringent

language requirements for labelling and instructions for use of CE marked face masks.

- Development of various projects that aim to mitigate the adverse health effects of the COVID-19 pandemic in Denmark.

2. OWNERSHIP OR EQUIVALENT RESTRICTIONS IN RELATION TO THE PROVISION OF HEALTHCARE SERVICES

In Denmark, the public healthcare system operates across three levels (i) the state, (ii) the regions and (iii) the municipalities. The state holds overall regulatory and supervisory functions in healthcare. The regions are responsible for hospital care, including emergency care, psychiatry, and for health services provided by general practitioners and specialists in private practice, while the municipalities are responsible for certain other health and social services. These include disease prevention and health promotion, rehabilitation outside of the hospital setting, home nursing, school health services, and other services for elderly people.

In addition, municipalities co-finance regional rehabilitation services and training facilities.

Apart from the public healthcare system, Denmark has a number of private hospitals and health clinics. There are no particular restrictions on the ownership of private hospitals or clinics in Denmark.

3. REIMBURSEMENT OF PUBLIC OR NATIONAL HEALTHCARE SERVICES AND AWARD OF CONTRACTS

The Danish healthcare system is based on a principle of free and equal access for all citizens.

In Denmark healthcare services are financed mainly by general taxes and are supported by a system of central government block grants, reimbursements and equalisation schemes.

All residents in Denmark have access to the public healthcare system with a national health card, and most services are provided free of charge. Danish legislation ensures that diagnosis and treatment is provided within certain time limits and establishes a free choice of hospital for patients. Citizens in need of hospital care may, within certain limits, freely choose any public (and some private) hospitals.

The regions provide primary care mainly through general practitioners and specialists operating in private clinics under agreements between the Regions' Salary and Rate Commission (RTLN) that acts for the five regions, the Organisation of General Practitioners in Denmark (PLO) and the Association of Specialist Doctors (FAPS). Hospital care is provided at hospitals owned and operated by the regions and some private hospitals contracted by the regions.

Amgros (the regions' joint procurement body) secures the supply of medicines and hearing aids to public hospitals and hearing clinics through efficient procurement and tendering procedures. Amgros also develops and conducts tendering procedures for selected medical devices.

The Danish regions established the Medicines Council to ensure fast and homogeneous use of new and existing medicines across hospitals in the regions and to support Amgros in price negotiations and calls for tender; The Medicines Council evaluates new medicines and issues recommendations and treatment guidelines to the regions. The hospital administrations usually adhere to this advice and guidance, and the Medicines Council is considered critical to hospital access to medicines.

4. DRUG APPROVALS AND REIMBURSEMENT

Medicines must be approved by the European Medicines Agency (EMA) or the DMA and must be included on the medical register before marketing can commence. The applicant for and holder of a marketing authorisation must be established or represented in Denmark or another EU/EEA country. Generic medicines may be authorised using an abridged procedure.

Medicines are pharmacy-reserved unless determined otherwise. As such, medicines can, as a starting point, only be dispensed at pharmacies on prescription.

The regions purchase the medicines used for treating patients at hospitals from the hospital pharmacies under framework supply agreements secured by Amgros. Medicines at the regional hospitals are provided free of charge to patients. Patients treated in the primary care sector must purchase their own medicine at private pharmacies.

The pricing of pharmacy-reserved medicines is the same at all pharmacies and generally determined by the manufacturer/importer. The pharmacy sale price is calculated using the pharmacy purchase price as determined by the manufacturer/importer plus a percentage and a fixed amount. No price approval is required by the authorities.

Reimbursement of medicines purchased by patients in the primary care sector is determined by the DMA based on recommendations made by the Medicines Reimbursement Committee. Generally, the DMA will consider reimbursement based on an application from the company that brings the medicine onto the Danish market.

Several types of reimbursement may be granted under section 152 of the Danish Health Act. Pre-approved reimbursement means that medicines that have achieved "general reimbursement" when they are marketed in Denmark, may be prescribed by physicians directly to patients at reimbursed prices.

There are three types of general reimbursement:

- General reimbursement for prescription-only medicines: all citizens receive reimbursement from the Danish regions. The reimbursement is automatically deducted from the price charged at the pharmacy.
- Conditional reimbursement for prescription-only medicines: granted only in certain cases. In order to obtain reimbursement, it may be a condition that the medicine is prescribed to certain patient groups or for the treatment of specific diseases.
- Conditional reimbursement for over-the-counter medicines: reimbursement is only granted if the medicine is dispensed on prescription to certain categories of person, e.g., persons suffering from a specific disease.

A doctor may apply to the DMA for individual reimbursement of medicines that are not generally reimbursed on behalf of an individual patient.

5. DEVICES CERTIFICATION AND REIMBURSEMENT

The Danish Act on Medical Devices constitutes the main regulatory framework for the monitoring, pricing and reimbursement of medical devices, and implements the EU directives on medical devices.

Medical devices are not to be authorised by the DMA but must be CE marked before placement on the market. The DMA supervises medical devices marketed in Denmark.

For medical devices in Classes II and III, a Notified Body must be involved in the documentation and certification process. A Notified Body is a private

entity authorised by the relevant authorities to review and assess whether a manufacturer's technical documentation meets the legal requirements. If the requirements are met, the Notified Body issues a certificate allowing the manufacturer to place a CE mark on the product. As for medical devices in Class I, the manufacturer is usually responsible for the certification process.

For medical devices there is no system under which companies may apply for general reimbursement of costs. However, if certain requirements are met, end users have the right to full or partial reimbursement of costs for medical devices from the municipalities of Denmark.

6. REGULATION OF AI AND SOFTWARE AS A MEDICAL DEVICE

According to Danish legislation the definition of a medical device includes software and apps that have a medical purpose and are intended to be used for diagnostic or therapeutic purposes. If considered to be a medical device, such software and apps are subject to the requirements of the EU medical device directives (from May 2021/2022 the EU Regulations).

Software and apps are assessed in Denmark by the DMA based on the Danish executive order on medical devices and on the basis of the EU Commission's Guidelines on the Qualification and Classification of stand-alone software.

The majority of apps that are CE marked as medical devices are currently classified as Class I.

7. TELEMEDICINE AND TELECONSULTATION

Denmark is viewed as a frontrunner in relation to telemedicine with unique nationwide projects.

Denmark does not have legislation that deals with telemedicine and teleconsultation specifically. The current legal framework for eHealth in Denmark is found primarily in the Danish Health Act, the Authorisation Act, the Act on the Processing of Personal Information and the Act on Medical Devices as well as supplementary executive orders.

Several telemedicine projects are currently being pursued. For example, the agreement between the RTLN and PLO provides that General Practitioners will be reimbursed for telemedicine services and are obliged to offer it. The parties provide a solution which enables patients to schedule video appointments to be carried out using the My Doctor-app (Min Læge).

Other solutions such as AI-driven platforms have been introduced to facilitate remote treatment for patients.

8. ANTI-KICKBACK RULES AND INCENTIVES TO DOCTORS

The interaction of healthcare professionals (HCPs) with the industry is primarily regulated by Danish national rules regarding advertising, economic advantages, and affiliations between HCPs and the healthcare industry. Industry standards are set out in ethical codes issued by the Ethical Committee for the Pharmaceutical Industry (ENLI) and the Association for the MedTech Industry (Medicoindustrien). The ethical codes are only applicable to companies which have submitted to the authority of the industry organisations.

Under Danish legislation regarding promotion of pharmaceuticals and medical devices, economic advantages must not be offered or given to individual HCP's for advertising purposes or otherwise to promote the sale of a medicinal product or a medical device unless such a gift is of insignificant value and can be used in the HCP's business. Other

modifications to the prohibition on economic advantages permit payment for services as well as hospitality and sponsorship. Pharmaceutical and medical device companies may provide financial support in the form of payment of the reasonable costs of dining, travelling and accommodation when an HCP attends educational and promotional activities with a scientific or professional purpose.

The legal framework regarding transparency for pharmaceutical and medical devices companies' relationships with HCPs is provided in the Danish Health Act and the specific rules are set out in an executive order.

The Danish rules regarding affiliation means that an HCP's affiliation with a pharmaceutical or medical device company must be reported and disclosed to the DMA. Affiliation includes any professional or financial relationship with a pharmaceutical company. Generally, all types of relationship are covered by the rules, as well as activities for which the HCP does not receive payment. Information about financial support will be published on the DMA's website for a period of two years.

9. MERGER AND FOREIGN INVESTMENT CONTROL

At present, Denmark does not have legislation that specifically governs foreign direct investments (FDI).

The Danish Government has emphasised the need for an FDI regime, which can balance the need for security and public order whilst still ensuring an open economy with the ability to attract foreign investments.

Denmark is expected to introduce its first FDI regime in the course of 2021. It is the expectation that the Danish FDI regime will apply to specific sectors and potentially also across all sectors, as has been the trend in other jurisdictions.

10. FORTHCOMING AND ANTICIPATED CHANGES IN HEALTHCARE AND LIFE SCIENCES LAW

The Danish regions have decided to establish a Treatment Council which shall assess the price of treatments and health technology against the benefit or impact for patients. The object of the Treatment Council shall be to provide recommendations regarding the use of medical devices and health technology. Commentators generally expect the Treatment Council to be similar to the Medicines Council, but with some alterations. It is expected that the Council will be operational as of 2021.

NETHERLANDS

1. THE IMPACT OF COVID-19 ON THE PROVISION OF HEALTHCARE AND LIFE SCIENCES

The COVID-19 pandemic has had a significant effect on the Dutch healthcare system. The rise in infections has led to a prioritisation of COVID-19 related healthcare services at the expense of 'regular' healthcare. In an effort to minimise infections there has also been a significant rise in teleconsultation both by general practitioners and hospitals.

There have been shortages of equipment and consumables, including several types of medical device, in vitro diagnostics, face masks and other PPE, testing equipment and respiratory equipment. Several market initiatives by non-traditional players have aimed to alleviate these shortages. For some types of medical device, the requirement of a CE mark was temporarily relaxed at EU level. A nationwide

consortium, under the direction of the Ministry of Health, oversaw the joint purchase of COVID-19 related PPE for hospitals, nursing homes and others in order to ensure quality and sufficient stock.

2. OWNERSHIP OR EQUIVALENT RESTRICTIONS IN RELATION TO THE PROVISION OF HEALTHCARE SERVICES

A healthcare provider must obtain a licence to provide healthcare services. These services are reimbursed by either healthcare insurers (basic healthcare) or the Dutch state (long-term care).

Healthcare professionals must be registered in accordance with the Individual Healthcare Professions Act.

For specific forms of healthcare, a provider with a licence is not allowed to distribute profits. Sub-contractors fall outside this prohibition.

3. REIMBURSEMENT OF PUBLIC OR NATIONAL HEALTHCARE SERVICES AND AWARD OF CONTRACTS

All residents in the Netherlands must take out basic healthcare insurance. Healthcare insurers have a duty of care which means that they cannot refuse to provide basic insurance for any individual. In order to provide for affordable, high quality, timely and accessible healthcare, insurers conclude annual contracts with healthcare providers to ensure basic care for their clients. In most situations, the invoices are paid directly to the providers. Insurers receive monthly premiums and, depending on the insured population, compensation from the government. Under certain circumstances, insured individuals must pay deductibles. Academic hospitals receive additional contributions from the government. If insured individuals receive non-contracted care, insurers are not obliged to fully reimburse the costs.

Healthcare providers also contract separately with insurers for long-term care on an annual basis. An independent institution decides whether there is a need for long-term care. The coverage is fully paid by public money raised through taxation.

4. DRUG APPROVALS AND REIMBURSEMENT

A registration and marketing authorisation (MA) is required to stock, sell, distribute, deliver, make available within or import drugs into the Netherlands.

If the centralised procedure for obtaining an MA via the European Medicines Agency (EMA) does not apply, the Dutch Medicines Evaluation Board (MEB) is responsible for registering drugs and delivering the MA for marketing the drugs in the Netherlands.

The MEB decides whether a drug must be available by prescription only from a doctor or specialist (PO) or whether a drug is available without prescription over-the-counter (OTC). OTC drugs are divided into three categories: (i) pharmacy-only drugs (PH) with a relatively mild potential risk, (ii) Pharmacy and Drugstore only drugs (PDO) with a relatively low potential risk, and (iii) General Sales drugs (GS) with very low risk that are also available via sales channels such as supermarkets or service stations.

The Ministry of Health, Welfare and Sports (MoH) determines the maximum allowable prices for drugs biannually. When purchasing drugs, pharmacists may not pay more than the maximum prices.

Dutch healthcare insurers will only reimburse a registered drug if it is included in the Drug Reimbursement System. The MoH and the Healthcare Institute of the Netherlands decide together which drugs fall within the standard healthcare insurance coverage and whether they are either fully or partially reimbursable. OTC drugs are not reimbursable.

5. DEVICES CERTIFICATION AND REIMBURSEMENT

In order to place a medical device on the Dutch market, it must comply with the requirements of the Medical Devices Directive, the Dutch Medical Devices Decree and the In Vitro Diagnostic Medical Devices Decree. The Health and Youth Care inspectorate is the relevant authority.

For marketing purposes in the Netherlands, a medical device must comply with the essential requirements of Annex I of the Medical Devices Directive (and as from 26 May 2021 with the MDR) and labels and instructions must be in the Dutch language. If the medical device complies with the essential requirements and the correct procedures have been followed, the medical device must bear the CE mark confirming its conformity. Class I device manufacturers can assess the conformity of the product themselves. Medical devices Class IIa, IIb and III must be inspected by an independent and accredited organisation that is designated by the government (notified body).

Manufacturers have to be established in the Netherlands or must have an authorised representative in the Netherlands and must register with Farmatec if they supply: (i) a Class I medical device, (ii) a custom-made medical device, or (iii) an in vitro diagnostic medical device in the Netherlands.

There are various laws and regulations in the Netherlands for reimbursement of medical devices. Most medical devices are reimbursed based on the Dutch Health Insurance Act. This Act describes which medical devices qualify for reimbursement under basic healthcare insurance cover. Healthcare insurers assess whether a new medical device is covered by basic healthcare insurance and, therefore, if it qualifies for reimbursement. Healthcare insurers may set additional conditions for reimbursement, such as a requirement for their grant of permission prior to use. Healthcare insurers also assess whether a device has been proven to be effective.

6. REGULATION OF AI AND SOFTWARE AS A MEDICAL DEVICE

AI and big data in healthcare and the legal and ethical questions that they raise are hot topics in the Netherlands.

E-health apps are considered to be medical devices and must comply with the Medical Devices Regulation (MDR) from 26 May 2021.

The GDPR and the Dutch Processing of Personal Data in Healthcare (Additional Provisions) Act regulate the use of software and medical apps in the healthcare sector and the associated use of medical and non-medical data.

7. TELEMEDICINE AND TELECONSULTATION

In the Netherlands, the government is encouraging the healthcare sector to expand telehealth. As such, the MoH published an Assessment Framework 'Deployment of e-health by healthcare providers' in 2018, which provides standards and related assessment criteria with respect to telehealth.

In principle, teleconsultation is reimbursable by Dutch healthcare insurers, provided that certain conditions are met. Dutch law is rather restrictive in relation to online prescriptions. It is prohibited for a prescriber to prescribe drugs to any individual if the prescriber has not met the individual in person, does not know the individual or does not have access to the individual's medical history. The MoH has noted that the prohibition regarding prescriptions does not apply to healthcare professionals who are established in other

EU Member States. This view is in line with the EU E-Commerce Directive and the EU Cross-Border Healthcare Directive.

8. ANTI-KICKBACK RULES AND INCENTIVES TO DOCTORS

Dutch inducement rules prohibit the promising, offering or giving of money, valuable services or goods with the 'apparent purpose' of promoting prescribing, providing or using a drug or the sale of a medical device. Exceptions apply, for instance, for gifts of limited monetary value that can be used for professional practice. There are detailed rules for calculating fines for infringements, which take into account the size of the undertaking.

Undertakings with registered offices outside of the Netherlands can be fined if they infringe the inducement rules and the infringement has a manifest effect in the Netherlands.

Under the applicable self-regulatory framework on financial relationships between the industry and medical professionals, payments to healthcare professionals (excluding general practitioners) exceeding EUR 500 must be notified in a transparency register.

9. MERGER AND FOREIGN INVESTMENT CONTROL

Apart from certain utilities sectors, the Netherlands has a liberal policy towards foreign investment. There is no general requirement for prior approval of investments made by foreign legal entities or foreign natural persons in the healthcare sector.

A new bill on foreign investment control is pending which is intended to have retroactive effect from 2 June 2020 onwards. The bill includes a filing obligation for any acquirer where the target is of particular importance for the continuity or resilience of 'critical infrastructure'. Critical infrastructure may relate to the healthcare sector.

If a proposed merger or acquisition involves a healthcare provider that employs 50 or more individuals that provide healthcare, a prior notification to the Dutch Healthcare Authority (NZa) is mandatory. The NZa is also the designated regulator capable of taking measures if a healthcare provider or healthcare insurer has significant market power.

Mergers in the healthcare sector are subject to lowered turnover thresholds for notification to the Dutch Competition Authority (ACM). A transaction has to be notified if: (i) the worldwide turnover of all undertakings concerned is more than EUR 55 million, and (ii) at least two of the undertakings achieve a turnover of more than EUR 10 million in the Netherlands.

10. FORTHCOMING AND ANTICIPATED CHANGES IN HEALTHCARE AND LIFE SCIENCES LAW

In June 2020, the Dutch Senate adopted a bill changing the licencing system for healthcare providers and their sub-contractors to enhance the enforcement of applicable rules and regulations. It has not yet been announced exactly when the new rules will enter into force.

A bill has been announced that seeks to amend the applicable rules and regulations on the integrity of healthcare providers and their directors, including their capacity to distribute profits.

A bill on the digital exchange of data in healthcare is being prepared. In October 2020, the bill was sent to the Council of State for advice.

A bill that aims to transfer statutory duties relating to "concentration of undertakings" control and the

control of significant market power from the NZa to the Netherlands Authority for Consumers and Markets (the Dutch competition regulator) has been submitted to the House of Representatives. The bill would also amend the thresholds for prior mandatory notification. The proposed thresholds are that at least one of the undertakings involved has achieved a turnover of at least EUR 7 million in the preceding calendar year through the provision of healthcare and that at least one of the other undertakings involved had a general turnover of at least EUR 500,000 in the preceding calendar year.

In March 2020, a member of the House of Representatives submitted a bill proposing a Transparency Register Healthcare Act for financial relationships between the pharmaceutical industry and medical professionals. The bill proposes to legally anchor the existing obligation under the self-regulatory framework (see section 8 above). The bill has yet to be voted on by the House of Representatives.

Members of the House of Representatives have proposed an amendment to the Healthcare Quality, Complaints and Disputes Act to increase the involvement of healthcare employees in decisions made by healthcare institutions that affect the way in which healthcare is provided. The proposal has been published for public consultation.

POLAND

1. THE IMPACT OF COVID-19 ON THE PROVISION OF HEALTHCARE AND LIFE SCIENCES

Several changes in the Polish healthcare system have occurred as a result of the pandemic, including:

- Removal of regulatory obstacles regarding telemedicine and vast use of all e-health related solutions aimed to substitute face to face contact with healthcare professionals (e-consultations, e-prescriptions, e-sick notes).
- Increased legislation to avoid shortages of COVID-19 diagnosis and treatment products, medical devices, drugs and biocides and limiting access to seasonal flu-vaccines to high-risk patients only (in both public and private sector).
- Use of fast track regulatory procedures by the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (URPL) aimed at accelerating the authorisation of new products related to the COVID-19 pandemic.
- Establishment of new healthcare facilities and adaptation of non-healthcare facilities (e.g., stadiums) as temporary COVID-19 hospitals.
- Decrease of treatments not directly linked to treatment of COVID-19, particularly in oncology, cardiology and neurology.
- Introduction of incentives for doctors and other healthcare professionals involved in the treatment of COVID-19 patients aimed at increasing the efficiency and capacity of the system, including: increasing salaries, simplifying the recruitment of foreign medical staff from outside the EU, delegating trainee doctors to work in infectious diseases hospitals and increasing the working age of men in medical professions.
- Introduction of new regulations on public procurements for services, supplies or construction works necessary to fight the pandemic in case of rapid and uncontrolled spread of the disease or if required for the protection of public health.

2. OWNERSHIP OR EQUIVALENT RESTRICTIONS IN RELATION TO THE PROVISION OF HEALTHCARE SERVICES

There is no strict differentiation between the private and the public sector in Poland's healthcare market. Currently, the private sector dominates the provision of services in primary care, outpatient care, rehabilitation and long-term care, while hospitals remain the domain of the public sector. However, this changes for highly specialised single specialty hospitals, e.g., hospitals for eye surgery.

Healthcare service providers have a highly differentiated ownership structure. Primary medicine (first contact doctors) and dentistry are almost exclusively provided by individual doctors and dentists. The same applies to the plastic surgery sector and aesthetic dermatology.

Healthcare institutions operate as companies, state-funded establishments (e.g., military healthcare) and independent public healthcare providers (mostly hospitals). Public healthcare institutions may be established by the State Treasury or by local government (provincial authorities). Public entities must hold at least 51 percent of the shares in a healthcare provider established as a company and must maintain a voting majority.

The shares of a medical university clinic may only be held by the university (minimum of 51 percent of the shares), the State Treasury and/or the local government.

3. REIMBURSEMENT OF PUBLIC OR NATIONAL HEALTHCARE SERVICES AND AWARD OF CONTRACTS

More than 80 percent of the Polish population is medically insured under the statutory health insurance system, which covers both outpatient and hospital care. However, the private insurance sector is growing significantly and currently covers over 3 million people, which is an increase of 13.1 percent compared to last year.

The largest payer for services offered in private hospitals is the National Health Fund (*Narodowy Fundusz Zdrowia*) (NFZ), which in 2016 accounted for 62 percent of private hospital revenues, with patients financing 35 percent and insurers only 3 percent of private hospital revenues.

In order to render publicly financed medical services, healthcare facilities are required to sign contracts with regional NFZ branches. The content and pricing mechanisms of these contracts and the award processes are strictly regulated. As a rule, public and private healthcare facilities are treated equally in terms of access to contracts with NFZ.

Contracts with NFZ are concluded for a relatively short period (usually from one to five years). In principle, this should work to new market players' advantage, but in practice, it creates instability and lack of predictability for future operations.

NFZ conducts detailed inspections of the beneficiaries of public funds and in some cases refuses to pay for services, in particular those exceeding their allocated quota.

4. DRUG APPROVALS AND REIMBURSEMENT

Marketing authorisations for some advanced drugs are issued centrally by the European Medicines Agency (EMA). For all other drugs, the Polish Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (URPL) issues marketing authorisations for Poland using one of the EU procedures (DCP or MRP) or using the national procedure.

Marketing authorisations for innovative drugs require full pre-clinical and clinical testing. A limited number of studies are required to register generic products. Such registration can take place after the expiry of the applicable data exclusivity period (generally eight years from the issuance of the first marketing authorisation within the European Union, plus two years of market exclusivity, which can be extended by a further year when new indications have been added).

Pricing for drugs available only on prescription is strictly regulated and depends on the outcome of reimbursement and price negotiations between marketing authorisation holders (or their representatives, where marketing authorisation holders are seated outside the European Economic Area) and the Minister of Health. The Minister of Health issues a list of the reimbursable drugs every quarter.

Poland's distribution system for drugs (and medical devices) is strictly regulated via licensing (applicable to wholesale distributors and pharmacies), permitted distribution methods (upstream distribution is prohibited), and detailed obligations relating to the reporting of title transfers and physical movement of products throughout the supply chain.

5. DEVICES CERTIFICATION AND REIMBURSEMENT

In Poland, there is legislative work in progress on a new national law on medical devices aimed to supplement the MDR. It is expected that the law will enter into force in May 2021, but it is still in the legislative stage and its final shape is not yet known.

The reimbursement system applicable to medical devices differs from the one applicable to drugs. From a hospital perspective, purchase of equipment is part of the total annual budget and thus a part of overall spending on its operation. Patients that purchase medical devices prescribed by a doctor have their payments reimbursed in arrears, but the regulatory framework is about to be simplified (to allow e-prescriptions).

6. REGULATION OF AI AND SOFTWARE AS A MEDICAL DEVICE

A significant number of Polish start-ups are developing medical software. The main regulatory obstacles are: lack of certainty concerning the status of medical data and the possibility of secondary use. These issues are currently being discussed in Poland, but have not been resolved by any specific legislation.

As a rule, medical software can be classified as a medical device (SaMD), which is subject to the requirements of EU medical device directives and the Polish Medical Device Act of 20 May 2010, concerning the notification procedure before the URPL.

The new EU Medical Device Regulation (2017/745) (MDR) is in force from May 2021, replacing the Medical Devices Directive. The regulation provides for changes in the classification of medical devices and in the rules for assessment of the risk connected with placing products on the market. The MDR extends the scope of the medical devices regime to certain products that do not have a medical purpose.

As a rule, under the MDR, it will become more difficult to place medical devices on the EU market, but it will still be less challenging than marketing a drug.

7. TELEMEDICINE AND TELECONSULTATION

The principal regulatory obstacles to telemedicine have been removed.

The pandemic has significantly accelerated development of the telemedicine and e-health sector in

Poland. The introduction of e-prescriptions, e-referrals and e-sick notes has facilitated, to a large extent, cooperation between patients and doctors. Limited access to medical facilities has put more emphasis on the use of remote medical advice. At the start of the pandemic, probably more than 80 percent of medical consultations took place remotely.

8. ANTI-KICKBACK RULES AND INCENTIVES TO DOCTORS

Professional rules forbid doctors and other healthcare professionals from receiving kickbacks and incentives. Under certain circumstances, providing and accepting incentives, or exceeding the allowance threshold, can be treated as a criminal offence.

Cooperation between the private and the public sector exists and is encouraged as a method of improving service quality and reducing costs. Such cooperation is a well-established practice in the field of clinical trials.

9. MERGER AND FOREIGN INVESTMENT CONTROL

Public founders must hold at least 51 percent of shares in the healthcare provider established as a company and must maintain a majority of votes.

The shares of a medical university clinic may only be held by the university (minimum 51 percent of shares), the State Treasury and/or the local government.

10. FORTHCOMING AND ANTICIPATED CHANGES IN HEALTHCARE AND LIFE SCIENCES LAW

On 29 March 2019, NFZ published its strategy for the years 2019–2023. Its main goals for the four-year period include: supporting service providers in building efficiency (for example, through development and implementation of a system for accreditation and digitalisation) and a focus on innovation.

It is expected that further developments in the Polish healthcare sector will be spurred on by means of private- and public-sector partnerships. This will require predictability, stability and openness. I1. The private healthcare market in Poland is forecast to continue to grow. According to data provided by the Polish Chamber of Insurance for first half of 2020, Poles spent almost half a billion zlotys (approximately 225 million Euros) on health services and insurance.

SPAIN

1. THE IMPACT OF COVID-19 ON THE PROVISION OF HEALTHCARE AND LIFE SCIENCES

The pandemic has affected many aspects of the Spanish healthcare system, including:

- The adoption of urgent/emergency procurement procedures to ensure rapid letting of contracts to source essential supplies and equipment.
- New ways of home delivery of medicines for chronic and high-risk patients.
- Adoption of technology at an accelerated rate, including greater use of telemedicine, precipitating a fall in the number of face-to-face appointments and a rise in appointments conducted remotely by telephone, email and video.
- A new way of conducting clinical trials remotely.
- Emergency controls over stock of certain essential medicinal products and medical devices.
- Substantial use of medical devices for diagnosis.

2. OWNERSHIP OR EQUIVALENT RESTRICTIONS IN RELATION TO THE PROVISION OF HEALTHCARE SERVICES

Spain has no specific corporate restrictions on the type of legal entity that may develop medical care centres (i.e., outpatient or inpatient medical facilities).

As a general principle, only registered doctors may provide medical services and only registered pharmacists may dispense drugs.

Both the legal entity rendering medical services and the healthcare practitioner must be authorised and registered in Spain in order to render these services, but no specific type of company is required.

3. REIMBURSEMENT OF PUBLIC OR NATIONAL HEALTHCARE SERVICES AND AWARD OF CONTRACTS

In 2018 a new law was passed that ensured the provision of universal healthcare services by the National Healthcare System (NHS). The NHS is primarily composed of hospitals fully sustained by public funds. Private hospitals generally render services for insured patients and for self-pay patients.

Private hospitals (inpatient and outpatient) can become public health providers through public procurement proceedings that award public services to private providers (Contratos de Concesion de Servicios). These contracts may include both the management of hospital beds and other types of services.

Public procurement processes take place for drugs, medical devices, and medical inpatient and outpatient services, including services for clinical labs, home respiratory therapies and home care services.

Reimbursement for medical services (inpatient and outpatient) is carried out according to the terms of the corresponding tender launched by the regional healthcare systems. Those terms usually include both availability and demand-based payments.

4. DRUG APPROVALS AND REIMBURSEMENT

Drugs must be authorised before they can be placed on the Spanish market. Marketing authorisations are granted through four different procedures substantially regulated by European law. The Spanish Agency of Medicinal Products and Medical Devices (AEMPS), as well as the respective European Members drug agencies, are in charge of granting national marketing authorisations for drugs in Spain and can do so under the national, mutual recognition or decentralised procedures. The latter two procedures allow for the grant of coordinated authorisations in several EU Member States.

Some drugs (such as orphan drugs and most biologics) must be authorised by a centralised EU procedure handled by the European Medicines Agency (EMA), and this authorisation is valid throughout the European Union.

Marketing authorisations for innovative drugs require pre-clinical and clinical testing. Although national authorities are free to set the prices of drugs and to designate the treatments they wish to reimburse under their social security systems, the European Directive on drug pricing aims to ensure that national pricing and reimbursement decisions are made in a transparent manner. Once a drug has its marketing authorisation, national authorities decide whether to provide and reimburse it on the NHS, and set its price. If the authorities refuse to make the drug available on the NHS, the marketing authorisation holder is free to set the price and must notify the authorities accordingly. Authorities may impose a different price for any public interest reason.

5. DEVICES CERTIFICATION AND REIMBURSEMENT

The manufacture, import (from non-EU countries), grouping or sterilisation of medical devices is subject to administrative authorisation from the AEMPS.

Medical devices imported from other EU countries can be used in Spain. However, they can only be placed on the Spanish market if they meet the requirements set out in the regulations. To import devices from non-EU countries, a specific authorisation from the AEMPS is required.

Only CE-marked medical devices can be marketed or put into service in Spain. This is not applicable to custom-made devices or to devices under clinical research.

A CE marking can only be placed on products where there is evidence that they comply with the essential requirements set out in applicable regulations and which have followed the applicable evaluation procedures. These procedures which differ depending on the nature of the product. Devices that already have CE marks according to the rules applicable in other EU countries benefit from a presumption of conformity in Spain. However, if the Spanish health authorities consider that a device, used for its intended purpose, may compromise the health or safety of patients, they can take measures to withdraw it from the market or restrict its commercialisation under the safeguarding clauses included in applicable EU directives.

A CE mark on Class I products is directly set by its manufacturer. However, for other categories, a CE mark must be accredited by the notified bodies who carry out the corresponding evaluation procedures. In Spain, currently, the notified body is the AEMPS.

Any entity that places Class III, Class IIb or Class IIa devices on the market, or puts them into service in Spain for the first time, must report this activity to the AEMPS. Any subsequent changes to the information that has been reported to the AEMPS (or the relevant regional authorities) must also be reported.

Any entity established in Spain that is responsible for the initial commercialisation of Class I devices or custom-made devices in the EU must be registered with the AEMPS.

Distributors of medical devices must communicate such activity to the regional authorities where they are established.

The introduction of medical devices to the NHS is subject to public procurement proceedings.

6. REGULATION OF AI AND SOFTWARE AS A MEDICAL DEVICE

Under certain conditions, medical software is considered a medical device (SaMD) and is therefore subject to the requirements of EU medical device directives and related Member State laws. SaMD may be classified under different medical device categories depending on its functionality and risk level, and will be required to comply with the attendant obligations. If SaMD is aimed at helping or supporting a diagnosis, it is considered a Class IIa medical device, and it must undergo conformity assessment procedures carried out by a notified body and must receive a CE mark in order to be placed onto the European and Spanish markets.

It is worth noting that Regulation 2017/745 sets forth the same classification and requirements (applicable from May 2021) as rule 11 of its Annex VIII. Innovative devices, such as AI chatbots or similar devices, may be subject to individual negotiation for exclusivity reasons if the market lacks the specific know-how, tools or means to ensure that the right technology is procured.

7. TELEMEDICINE AND TELECONSULTATION

COVID-19 has lead to an exponential increase in the telemedicine and teleconsultation sector in Spain. Currently, despite the lack of specific legal framework, public and private healthcare institutions practice a degree of telemedicine, either through the monitoring of patients, triage or virtual consultation. The activity displayed by regional health authorities and the support and impetus from the industry could lead to further developments in telemedicine and teleconsultation. Regional regulations can be expected in the near future, followed by a national framework.

8. ANTI-KICKBACK RULES AND INCENTIVES TO DOCTORS

Spanish law adopts an incompatibility regime that prevents those with the power to prescribe or authorise the dispensing of drugs from having a direct economic interest in the marketing of drugs and medical devices. In addition, kickbacks and incentives to physicians and other healthcare professionals are forbidden and may be sanctioned under criminal law.

Industry codes and certain laws issued by regional authorities promote (albeit with strict rules) cooperation between different healthcare providers and the drug industry to improve data collection, drug safety and efficacy, and quality of service.

9. MERGER AND FOREIGN INVESTMENT CONTROL

The National Markets and Competition Commission (CNMC) is the authority entrusted with the enforcement of merger control and has the final decision on the majority of merger control cases.

In 2020, the Spanish government introduced a new screening mechanism for certain investments made in Spanish companies by non-EU and non-EFTA investors, which may require prior authorisation from the Spanish Council of Ministers. The sectors affected by the restrictions include: critical infrastructure, critical technologies, supply of critical inputs, sectors with access to sensitive information, media, and other sectors that may affect public security, order or health.

The screening mechanism applies to direct and indirect investments in Spanish companies made by non-EU and non-EFTA investors, even when investments are made through legal entities incorporated in the EU if those are beneficially owned by non-EU and non-EFTA residents (i.e., when non-EU and non-EFTA residents ultimately possess or control, directly or indirectly, more than 25 percent of the share capital or voting rights of the investor, or otherwise exercise control, directly or indirectly, over the investor).

10. FORTHCOMING AND ANTICIPATED CHANGES IN HEALTHCARE AND LIFE SCIENCES LAW

New laws on telemedicine and teleconsultation can be expected in the near future to regulate and improve the telemedicine and teleconsultation market.

Spain is also facing rising demand for integrated patient services (drug supply and healthcare services) and a significant increase in the wellbeing industry for the prevention and prediction of illnesses.

In addition, there is constant pressure over prices for new drugs which may lead to shortage in specific drugs (including orphan drugs).

SWITZERLAND

1. THE IMPACT OF COVID-19 ON THE PROVISION OF HEALTHCARE AND LIFE SCIENCES

Amongst the notable effects of the pandemic on healthcare and life sciences in Switzerland is an emergency regime for the supply and marketing of essential medical goods. The Swiss Federal Counsel recently lifted restrictions to allow for rapid antigen testing outside of laboratories and closed systems to reflect the need for increased testing capacity. The legislation and implementing regulation enacted to tackle the so-called special situation has imposed obligations on manufacturers, distributors, and laboratories to report their current stocks of COVID-19 testing kits and allows for emergency procurement and allocation of testing capacities.

As part of the logistical reorganisation of the healthcare system, specific COVID-19 healthcare units, inter-hospital patient transfers and closer collaboration between public and private hospitals have been implemented.

Additionally, efforts to develop teleconsultation (in particular video consultation) and telemonitoring for COVID-19 patients as well as the launching of digital tools (e.g., contact tracing apps) have gained momentum. The increased use of digital platforms during the pandemic will likely have a lasting and enabling effect on telemedicine.

2. OWNERSHIP OR EQUIVALENT RESTRICTIONS IN RELATION TO THE PROVISION OF HEALTHCARE SERVICES

There are no ownership or equivalent restrictions pertaining to the operation of inpatient or outpatient medical care facilities. However, physicians practicing under the umbrella of a legal entity (usually a limited liability company or stock corporation) in outpatient care must themselves hold a professional license to practice and perform healthcare services personally under their own professional responsibility.

Hospitals or other inpatient service providers require an operating licence granted by the canton in which they operate. The requirements are laid down in the cantonal legislation.

3. REIMBURSEMENT OF PUBLIC OR NATIONAL HEALTHCARE SERVICES AND AWARD OF CONTRACTS

Costs of healthcare services are reimbursed by mandatory public health insurance, which is available to all Swiss residents and offered by private health insurers. In addition, non-compulsory supplementary private health insurance is widespread.

Depending on the method of treatment (inpatient or outpatient), the reimbursement scheme varies significantly. As a general rule, the applicable tariff structures are negotiated between the tariff partners, i.e., representatives of health insurers and professional associations (the so-called primacy of negotiation, Verhandlungsprimat). The reimbursement scheme for costs of outpatient treatment is separated into the services performed by healthcare professionals and the reimbursement of the prescribed medicinal products. Patients are free to choose their physician, save where they have adhered to a specific insurance model offering only limited choices (e.g., HMO schemes). The services of hospitals and other inpatient service providers are only reimbursable by public health insurance if the institutions are listed by the canton in which they operate. Treatments are reimbursed in the form of a flat fee designed to cover the costs of all reimbursable services provided by the hospital, including the costs of medication. All listed

public and private hospitals are subject to public procurement proceedings.

4. DRUG APPROVALS AND REIMBURSEMENT

The distribution of medicinal products in Switzerland requires a marketing authorisation issued by the Swiss Agency for Therapeutic Products (Swissmedic). The marketing authorisation holder must have its registered address, registered office or a branch office in Switzerland. There is no mutual recognition of EU marketing authorisations. However, if a medicinal product or procedure is already authorised in a country having equivalent medicinal product control, the results of examinations carried out for this purpose will be considered. In specific situations (e.g., medicines containing known active ingredients), a simplified procedure applies. Certain formulations produced by pharmacies do not require a marketing authorisation.

The data protection period for new medicinal products is 10 years. An additional protection period of three years applies to new indications, new modes of administration, new preparation forms or new dosages, and may be extended to 10 years for new indications when a significant clinical benefit can be expected, and the indication is supported by extensive clinical studies. A 10-year data protection period may be granted for medicinal products designed for pediatric use. Important orphan drugs are eligible for a 15-year data protection period.

Costs for medicinal products prescribed by a physician in outpatient treatment are reimbursed based on the maximum price set out in the positive specialty list (LS). In addition to reimbursement of listed medicinal products, public health insurance will exceptionally reimburse the costs of unlisted medicinal products that are either authorised by Swissmedic or imported from a country featuring an equivalent market authorisation scheme.

5. DEVICES CERTIFICATION AND REIMBURSEMENT

In contrast to medicinal products, medical devices do not require a marketing authorisation in Switzerland but may be placed on the market if the manufacturer is able to demonstrate that the device has undergone the prescribed conformity assessment procedures. The type of conformity assessment procedure to be used depends on the medical device's risk class. The current regime closely mirrors the EU directives on medical devices and is deemed equivalent by virtue of a mutual recognition agreement (MRA) between Switzerland, the EU and its member states. In anticipation of the impending application dates of the new EU medical devices regulations in May 2021 and 2022, the Swiss regulator enacted certain amendments reflecting the European provisions on, inter alia, the registration of notified bodies and interim exceptions.

Medical devices qualify for reimbursement under the Swiss social health insurance regime if they are listed on the lists: of aids and equipment (MiGeL), of laboratory analyses (Analysenliste), or included in the lists for dental treatments, preventive medical care or maternity services issued by the Swiss Federal Department of Home Affairs (FDHA). The lists are exhaustive positive lists, meaning that non-listed aids and equipment, analyses, dental and preventive care or maternity services are not covered by the social health insurance regime, unless they are included in the applicable tariffs for inpatient or outpatient treatment.

6. REGULATION OF AI AND SOFTWARE AS A MEDICAL DEVICE

Swiss medical device regulations are harmonised with the corresponding EU/EEA regulatory framework by

virtue of a mutual recognition agreement. Accordingly, in line with the EU regulatory framework, medical software is considered a medical device if it is intended by the manufacturer to be used, inter alia, for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of a disease.

Applications that conduct medical analyses based on automated processing of data, including solutions employing artificial intelligence, are therefore deemed medical devices.

Use of AI by medical practitioners is still in its infancy and, whilst the use of intelligent medical software is making progress, it is not yet established in clinical practice and there is currently limited use in hospitals. Physicians tend to use medical software to support and verify diagnoses. Arguably, however, physicians are obliged to inform patients about digital innovations.

7. TELEMEDICINE AND TELECONSULTATION

Telemedicine is an established practice in Switzerland and is generally permissible under Swiss law. Since there is no specific legal regime governing telemedicine in Switzerland (apart from a few dispersed cantonal provisions, some with restrictive regimes), telemedicine is subject to the same rules and principles as conventional forms of healthcare. The Swiss Federal Supreme Court confirmed the admissibility of teleconsultation as long as the counselling physician is in a position to take adequate measures depending on the health of the patient.

8. ANTI-KICKBACK RULES AND INCENTIVES TO DOCTORS

Under Swiss law, it is prohibited to grant, offer or promise material benefits to persons who prescribe or dispense medicinal products or to their employers. Under a legislative amendment due to take effect in 2022, this provision will include medical devices. As of 2020, enhanced transparency requirements apply with respect to any rebates or reverse payments granted on medicinal products and medical devices. All discounts and reimbursements must be recorded on the files, invoices and accounting documents of the supplying and purchasing parties. An exemption is provided for certain OTC medicinal products and Class I medical devices. Further, healthcare providers must in principle pass on to the patient (or the insurer paying directly, as the case may be) all direct and indirect discounts or other benefits (e.g., referral fees and kick-backs) granted by the supplier of a medicinal product or medical device that is subject to reimbursement by public health insurance. Subject to conditions stipulated under the applicable ordinance, healthcare providers and insurers may agree not to pass on parts of the discount in order to improve treatment quality.

9. MERGER AND FOREIGN INVESTMENT CONTROL

There are no foreign investment control restrictions in the Swiss healthcare sector. The largest private hospital group in Switzerland is owned by the South African entity Mediclinic International plc.

10. FORTHCOMING AND ANTICIPATED CHANGES IN HEALTHCARE AND LIFE SCIENCES LAW

The major legislative change currently underway in Switzerland relates to the adoption of the new EU Regulations on medical devices, which will apply from 26 May 2021 (for medical devices) and 26 May 2022 (for in vitro diagnostic medical devices), respectively.

For cohesion, the adopted legislative amendments in Switzerland will also be implemented in stages. The main provisions (marketing requirements, market surveillance etc.) will come into force on 26 May 2021. The date of entry into force of the in vitro diagnostic medical device provisions will remain unchanged at 26 May 2022. It is still unclear if the mutual recognition agreement in place between Switzerland and EU/EEA will be amended accordingly.

Other ongoing projects include a proposal to loosen regulation on cannabis for medical use by repealing the need for patient-specific derogations, the reform of legislation on genetic testing, and the introduction of a certified electronic health record system in 2021.

DIGITAL HEALTH 2020 YEAR IN REVIEW AND 2021 LOOK AHEAD

INTRODUCTION

The digital health marketplace exploded in 2020 as all but the most essential in-person services were put on hold to stave off the spread of COVID-19. This transition toward digital care spurred:

- **TEMPORARY LEGAL AND REGULATORY CHANGES** as federal and state laws and regulations were reshaped to break down longstanding barriers to digital care adoption and implementation to respond to COVID-19
- **PROPOSED LEGISLATION in** the federal and state legislatures addressing a range of matters highlighted during the pandemic response
- **HEIGHTENED ENFORCEMENT** activity and new compliance considerations
- **INNOVATIVE TRANSACTIONS** to capitalize on demand and expand access to care

Digital health providers, technology developers, investors and all industry stakeholders should take a proactive approach to successful navigate this rapidly changing environment in 2021.

LEGAL AND REGULATORY CHANGES

TEMPORARY PANDEMIC RESPONSE

Lawmakers, executives and regulators across jurisdictions and agencies took drastic measures in light of the COVID-19 public health emergency, including expanding access to Medicare reimbursement for telemedicine and e-health encounters, mandating insurance coverage for telemedicine visits and loosening licensing requirements for domestic and intra-state care. For the most part, these measures will terminate when the COVID-19 public health emergency ends, which the current administration has suggested is likely to last through the end of 2021.

While the pandemic response may be temporary, it has reignited an interest to digital health and telemedicine in particular. This has resulted in a mass of legislation introduced on the subject.

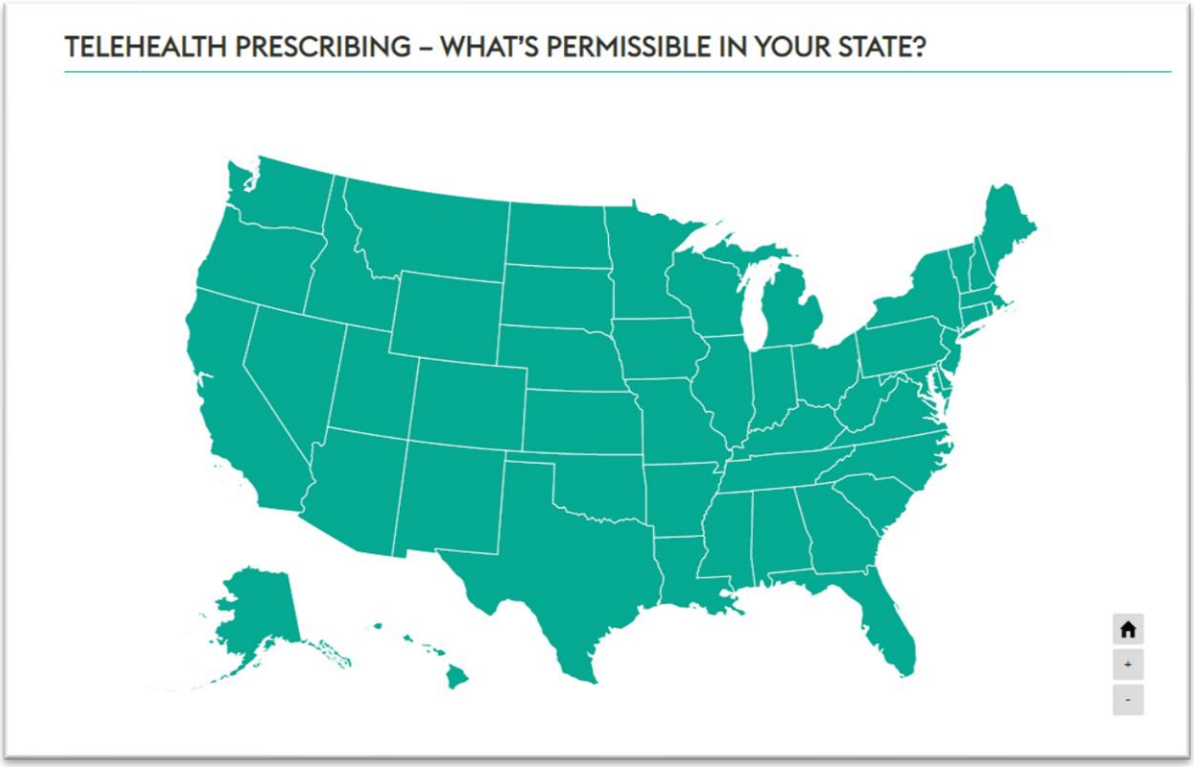
STATE-BY-STATE PATCHWORK REMAINS COMPLEX

At the state level, the laws governing digital health, including remote patient monitoring (RPM) and telehealth use, and reimbursement for such care, maintained their patchwork status. This ongoing complexity, particularly against the backdrop of heightened telehealth demand and an increased need to track and share healthcare data to combat the COVID-19 public health emergency, made it all the more crucial for healthcare providers to closely monitor their states' laws, regulations and declarations of public health emergencies. Hospitals, health systems, PPMs and others with multi-state operations, physicians and nurse practitioners licensed to practice in different states, traveling doctors and nurses and even patients who relocated during the public health emergency all faced hurdles when trying to understand when, where, how and under what circumstances telehealth and RPM could be used.

State-by-state regulations will continue to evolve throughout 2021 and lawmakers, the Federation of State Medical Boards, healthcare providers and patients themselves advocate for care solutions that enable providers to safely and cost-effectively provide care that meets patient needs.

Healthcare providers, insurers, technology companies and dealmakers alike should keep a close eye on evolving regulations. The future of reimbursement parity for virtual care and telemedicine, the sophistication of healthcare technology, physician training, permitted modalities of care and more will impact collaboration and investment opportunities and the outlook for innovation in the years to come.

STAY IN THE KNOW: VISIT MCDERMOTT'S TELEHEALTH TRANSFORMATION PAGE



ENFORCEMENT OUTLOOK

EXPECT AN UPTICK IN 2021 AS TELEHEALTH USE EXPANDS, WAIVERS EXPIRE AND CARE COORDINATION LAWS BECOME EFFECTIVE

In recent years, the government has increasingly focused on alleged healthcare fraud schemes involving telehealth services. September 2020 saw the largest national healthcare fraud and opioid enforcement action in the DOJ's history (the Takedown). The Takedown involved coordination with the US Department of Health and Human Services Office of Inspector General (OIG) and other federal and state law enforcement agencies and resulted in cases against more than **345 defendants** in **51 judicial districts**.

The government charged the defendants with participating in healthcare fraud schemes involving more than **$6 billion in alleged losses to federal health care programs**, with the vast majority of alleged losses ($4.5 billion) stemming from arrangements involving alleged "telefraud."

According to the DOJ press release, a recently announced National Rapid Response Strike Force led the initiative focused on telehealth. The National Rapid Response Strike Force is part of the Health Care Fraud Unit of DOJ's Criminal Division Fraud Section, and its mission is to "investigate and prosecute fraud cases involving major health care providers that operate in multiple jurisdictions, including major regional health care providers operating in the Criminal-Division-led Health Care Fraud Strike Forces throughout the United States."

The Takedown is an example of the government's continued and growing focus on telehealth services arrangements. Although the alleged fraudulent practices are not representative of the broader community of telehealth providers that deliver necessary care to patients conveniently and efficiently, the government's actions offer insights that can help legitimate telehealth providers further enhance their ongoing compliance practices. As telehealth becomes an increasingly common method for delivering healthcare, current telehealth providers and those organizations considering expanding into telehealth services, as well as individual healthcare providers who may provide telehealth services through another company, should consider these five issues when reviewing their existing telehealth programs or before establishing a new telehealth service line or entering into arrangements with third parties to provide telehealth services.

CHECKLIST: 5 COMPLIANCE AREAS FOR TELEHEALTH PROVIDERS TO WATCH


TELEHEALTH AND ENFORCEMENT
5 COMPLIANCE CONSIDERATIONS WHEN OFFERING TELEHEALTH SERVICES

The Regulatory Sprint to Coordinated Care saw several long-awaited Final Rules published – the US Department of Health and Human Services Office of the National Coordinator for Health Information Technology (ONC) information blocking prohibition and the Centers for Medicare and Medicaid Services and Office of Inspector General final rules amending the regulations to the physician self-referral law (Stark Law) (Stark Rule) and the Anti-Kickback Statute (AKS) and Beneficiary Inducement Civil Monetary Penalty Law (CMPL) (collectively, AKS Rule).

Due to the COVID-19 public health emergency, the compliance date for ONC's information blocking prohibition was pushed back to April 5, 2021, at which point certified health IT developers must not engage in practices that constitute information blocking and actors, including healthcare providers, cannot engage in practices that are known to or are likely to interfere with access, exchange or use of electronic health information (EHI), unless the practices are required by law or are covered by one of the eight exceptions established by ONC. For healthcare providers, the provider must also know that the practice is unreasonable for it to constitute prohibited information blocking. In December 2021, the ONC final rule requires certified health IT developers to submit testing plans to their certifying

bodies to test a subset of certified health IT functionality in the setting(s) where the certified health IT modules are (or will be) marketed.

DIG DEEPER: VISIT MCDERMOTT'S REGULATORY SPRINT RESOURCE CENTER

TRANSACTIONS

SPOTLIGHT ON INNOVATION: WHAT'S NOW AND WHAT'S NEXT

According to Rock Health, digital health deals and overall funding increased significantly in 2020. The year saw a 28% increase in mergers and acquisitions from 2019, an influx of first-time investors in the digital health sector and increased valuations for digital health companies.

From our analysis, we found four legal and business factors that drove a spike in digital health transactions in 2020:

- reduced burden of care delivery
- reimbursement parity for telehealth and RPM
- enhanced focus on data sharing and privacy
- expansion of digital care into new healthcare sectors

LET'S GET TO WORK: LEARN MORE ABOUT COLLABORATIVE TRANSFORMATION

Notable deals and collaborations driving innovation in 2020 included, among others:

- Teladoc and Livongo's $18.5B merger, which combined telehealth and remote patient monitoring into one cohesive platform
- Verizon's collaboration with healthcare providers, using 5G technology to optimize their technologies for better care delivery.
- Lyft's launch of a healthcare division to facilitate access to care
- Microsoft and Nuance Communications' collaboration to bring clinical intelligence into exam rooms so providers can focus more on patient care
- Novartis and Propeller Health's co-packaged asthma medicine and digital health tool, which provides remote health data providers and empowers patients in the EU to take an active role in their own care.

Looking forward into 2021, digital health collaborations that address population health and monitor co-morbidities, ease administrative burdens and reduce friction when sharing data between providers and patients are likely to be successful as we move toward efficiency and improved care. In fact, UnitedHealthcare and Optum's $13B purchase of healthcare technology company Change Healthcare, announced in January 2021, is already one example this year of leveraging digital health tools for improved reimbursement efficiencies.

In terms of sector and platform-specific investment opportunities, behavioral health, provider-side substance abuse digital health solutions, and remote primary care physician practice management are three areas that will see demand in the year ahead as providers and patients continue to demand virtual care services. Overall, 2021 has ample room for positive disruption from established healthcare players and new market entrants who can understand healthcare's unique and complex regulatory landscape, proactively manage compliance and tap into unmet patient and provider needs.

MANAGED CARE SPOTLIGHT: 2020 YEAR IN REVIEW AND 2021 OUTLOOK

The past year saw significant developments in managed care regulation at the federal and state levels and we anticipate the rapid pace of change will continue through 2021. We break down the most significant legal developments affecting health plans in 2020 and explored what to expect in 2021, including the impact of managed care regulations on a broad range of industry subsectors, from plans and providers to vendors and pharmacy benefit managers.

PROGRAM INSIGHTS

1. The Biden administration seeks to set a tone of order and predictability in its COVID-19 relief and response efforts. These efforts include a swath of executive orders on topics such as data aggregation, support for the National Guard and strategies for vaccine distribution. The acting secretary of Health and Human Ser-vices also recently sent a letter to state governors stating that the agency will likely extend the public health declaration—and its attendant regulatory flexibilities—through 2021.
2. The direct contracting model is the next step in the evolution of the Medicare accountable care organization portfolio. The model allows participating organizations to take on a greater level of financial risk, including the Centers for Medicare & Medicaid Services' version of global capitation. The direct contracting global or professional options may be particularly attractive to managed care organizations, because these options allow new entrants with low or no fee-for-service beneficiaries.
3. The coming year will likely see a continued trend toward financial risk assumption in value-based contracting. Within this trend, there are two common variations. In one, the provider or intermediary entity takes on broad financial risk for a large patient population with diverse demographics and health statuses. In the other common variation, risk sharing is focused on specific populations, such as individuals with a particular disease or significant chronic conditions.
4. Plan/provider joint venture health plans will continue to pick up steam in 2021. These arrangements allow the provider organization to have an economic interest in a health plan without having to build out administrative capabilities. In turn, the plan is able to align itself with a key provider network in one or more markets and potentially take advantage of co-branding opportunities.
5. Managed care organizations should prepare for the implementation of the No Surprises Act, which authorizes a suite of reforms to mitigate surprise billing. Signed into law on December 27, 2020, as part of the Consolidated Appropriations Act of 2021, the legislation applies to group health plans, issuers offering group or individual insurance, and providers. The implementation of the Act will involve multiple rulemakings, and the final rules likely will raise preemption questions, as many states have their own statutes and regulations regarding surprise billing.

Watch the recording and download the slides here

2020 HEALTH ANTITRUST YEAR IN REVIEW

INTRODUCTION

The health antitrust landscape saw an overall reduction in enforcement actions against healthcare companies from 2019 to 2020, but the federal and state policymaking efforts and guidelines released throughout the year, combined with the incoming Democratic administration, could have a significant impact on healthcare antitrust in 2021.

Our Health Antitrust Year in Review:

- Examines specific antitrust challenges and enforcement actions that impacted hospitals and health systems, payors and other healthcare companies in 2020;
- Offers lessons learned from these developments in the midst of the COVID-19 pandemic; and
- Provides analysis of the enforcement trends, federal guidelines and state policy updates that are likely to shape the healthcare antitrust landscape in 2021.

HOSPITALS & HEALTH SYSTEMS

Takeaways: The Federal Trade Commission (FTC) challenged three hospital and health system transactions in 2020. While the outcome of the most recent challenged transaction is pending, in one of the other two transactions, the merging parties abandoned the deal after the complaint was filed, and in the other transaction the district court refused to grant a preliminary injunction to cease consummation of the transaction pending an administrative trial. Other than various strategic, cost, timing and business reasons for why parties choose to defend a transaction or not, and the difference in case development, what lessons can be drawn from these recent enforcement actions? First, payor views—and the substantiation thereof—remain key. Parties to proposed in-market transactions should carefully analyze their historical contracting practices and network configuration. Second, geographic market definition has always been and remains critical to the antitrust analysis of these transactions, particularly in urban areas. Relevant geographic markets are analyzed first by the impact a merger may have on insurers, and second by its potential impact on patients. Detailed economic analysis is part of antitrust due diligence in preparation for proposed transactions.

MEMPHIS HOSPITALS ABANDON PROPOSED MERGER AFTER FTC ACTION

In December 2020, the FTC announced that Methodist Le Bonheur Healthcare abandoned its efforts to acquire two hospitals known as Saint Francis in the Memphis, Tennessee area. In November 2020, the FTC sued the hospitals in Tennessee federal court to temporarily enjoin the merger.

The FTC alleged a geographic market of the Memphis Metropolitan Statistical Area, and that the merger would reduce the number of hospitals providing general acute care (GAC) services from four to three. The complaint alleged the combined system would have over 50% of the market for GAC services in Memphis.

The FTC heavily cited each system's internal documents, which allegedly describe the other hospital as one of two important competitors, and which closely track each other's quality scores, advertising and brand recognition. The FTC focused on direct competition between Methodist and Saint Francis for inclusion in payor networks and for patients, and that Methodist had allegedly provided

price concessions to payors to exclude Saint Francis from narrow network products.

The FTC's economic (diversion) analysis showed that "a majority" of patients from Saint Francis would seek care from Methodist as an alternative, and a "significant fraction" of Methodist patients would seek care from Saint Francis.

FTC DENIED PRELIMINARY INJUNCTION TO BLOCK JEFFERSON/EINSTEIN MERGER

In February 2020, the FTC and Pennsylvania attorney general (AG) sought to enjoin a merger between Thomas Jefferson University (Jefferson Health) and Albert Einstein Healthcare Network (Einstein) in the Philadelphia, Pennsylvania area. In December 2020, the district court dismissed the motion for preliminary injunction to enjoin the proposed merger. The US Court of Appeals for the Third Circuit subsequently summarily denied the FTC's appeal for an emergency injunction to pause the merger pending an administrative trial.The Pennsylvania AG has since dropped his opposition to the merger, citing the parties' commitment to make investments in the community.

The FTC alleged two different geographic markets for GAC services and another geographic market for inpatient rehabilitation services. Specifically, the FTC alleged that the merger would give Jefferson Health control over 60% of the market for inpatient general acute care services in North Philadelphia and 45% of the market for those services in Montgomery County, as well as 70% of the market for inpatient rehab acute care services in the Philadelphia area. The court did not agree with the FTC's geographic markets and held that while Einstein "aspires to compete" with Jefferson, Jefferson actually competes with four other hospital systems, some of which were left out of the FTC's geographic market definitions.

The FTC also offered expert economic analysis and witness testimony from two of the four major commercial insurers in the region. Notably, the district court found the FTC's insurer-witness testimony to be unpersuasive because it contradicted the insurers' own documents, and was not unanimous, in that only two of four insurers in the Philadelphia area testified. The court further held that the expert economist should not have relied substantially on that testimony in his geographic markets analysis. The court found that FTC failed to prove that commercial insurers would be forced into paying more for hospital services as a result of the merger. The court noted that the Philadelphia area is somewhat unique in that there a small group of large insurers with bargaining leverage vis-à-vis hospital providers.

FTC SUES TO BLOCK HOSPITAL MERGER IN NORTHEAST NEW JERSEY

In December 2020, the FTC filed an administrative complaint challenging a proposed merger between Hackensack Meridian Health, Inc. (HMH) and Englewood Healthcare Foundation. The FTC also filed suit in New Jersey federal district court to temporarily enjoin the transaction. The FTC argues that the merger would give HMH control of 50% of the inpatient GAC hospitals in Bergen County, New Jersey. The FTC complaint alleges that HMH is the largest healthcare system in New Jersey and the largest provider of inpatient GAC services in Bergen County, and operates two hospitals within 10 miles of Englewood. The FTC further alleges that Englewood is the third-largest provider of inpatient GAC services in Bergen County, that Hackensack and Englewood provide similar services, and that the acquisition would allow Hackensack to demand higher rates from insurers which would result in passed-down cost increases to subscribers.

PAYORS

Takeaways: If finally approved by the court, the proposed Blues plans' subscriber settlement may change the competitive dynamic in the healthcare services insurance markets. Employers would be able to request bids from and providers may negotiate rates with multiple insurance providers even under the same umbrella. Insurance licensees may be able to make inroads into new markets and offer new products.

BLUES PLANS TO SETTLE SUBSCRIBER CLASS ACTION FOR $2.7B

In a class-action lawsuit brought by both providers and subscribers, a federal judge in the US District Court for the Northern District of Alabama gave preliminary approval to a settlement agreement with the subscriber class of plaintiffs. The plaintiffs accused 36 Blue Cross member firms across the country of conspiring to allocate markets and limit competition for insurance coverage. The firms allegedly agreed not to compete with other states' Blue Cross licensees, giving each state's member firm a geographic monopoly over Blue Cross health insurance coverage. As a result, member firms allegedly raised premiums on subscribers and negotiated lower reimbursements to healthcare service providers.

Prior to the subscriber settlement, the court ruled that the *per se* rule applies in this litigation, meaning that the plaintiffs need only prove an anticompetitive market allocation/price fixing agreement, without having the additional burden to prove anticompetitive harm on a specific market. *Per se* illegal agreements are those that are so inherently anticompetitive on their face that no further analysis of their effect on markets is necessary.

The subscriber settlement includes a $2.67 billion damages award and certain injunctive relief, including the abolition of Blue's "National Best Efforts" pact, which required members to derive a minimum of two-thirds of their revenue from Blue-branded services. The settlement also eliminates the Blue Card program, which required states to treat members of another state's program as in-network, eliminating incentives to compete for those members.

Provider plaintiffs are still seeking class certification from the court.

An ongoing class action against Delta Dental in the US District Court for the Northern District of Illinois in large part mirrors the allegations in the Blue Cross litigation. The plaintiff class of providers allege that Delta Dental Association and its state entities divided markets and fixed reimbursement rates to dentists below competitive levels. The Delta Dental court has likewise ruled that the *per se* rule applies.

CRIMINAL ENFORCEMENT

Takeaways: The Department of Justice (DOJ) has brought several criminal charges against healthcare companies in the past couple of months, including for wage-fixing, nonsolicitation/no-poach agreements and market allocation. General counsels (GCs) and human resources (HR) professionals should emphasize company-wide training and familiarity on how the sharing of nonpublic wage and employment term information with competitors can lead to antitrust violations for individuals as well as the company. Enforcement agencies, as well as private plaintiffs, can challenge agreements as anticompetitive irrespective of whether they challenge any underlying transaction. The federal government, as well as state AGs, is ramping up criminal enforcement in healthcare markets. Healthcare organizations should consider their internal corporate compliance programs and education.

JUSTICE DEPARTMENT OBTAINS FIRST-EVER WAGE-FIXING INDICTMENT

On December 9, 2020, a jury in the US District Court for the Eastern District of Texas indicted Neeraj Jindal, the former owner of a therapist-staffing company, for conspiring over a 5-month period to fix physical therapist and therapist assistants' wages below competitive levels in the Dallas-Fort Worth area. Jindal and his co-conspirators allegedly shared nonpublic information on wage rates, and as a result paid lower rates to therapists and assistants. It is notable that Jindal also was charged with obstructing a separate FTC investigation into the alleged wage-fixing. This is the first indictment from DOJ of an individual for a wage-fixing agreement, so it remains to be seen whether the obstruction charge tipped the scales in the DOJ's decision to pursue criminal charges against an individual in a wage-fixing case.

As a reminder in 2016, the Antitrust Division and FTC jointly announced updated enforcement guidelines that emphasize that wage-fixing and no-poach agreements are illegal on their face, and that wage information sharing between competitors can give rise to wage-fixing. Even innocent information sharing may bring civil liability.

More recently, in 2019, the Justice Department announced a Procurement Collusion Strike Force, an interagency group dedicated to prosecuting antitrust violations, like price-fixing and bid-rigging, by firms contracting with federal, state, and local government agencies.

These steps make it clear that the Justice Department will continue to pursue wage-fixing and no-poach and price-fixing and bid-rigging enforcement actions.

$100M CRIMINAL MARKET ALLOCATION SETTLEMENT

DOJ brought criminal charges against an oncology practice alleging an illegal market allocation agreement with another oncology practice. The DOJ alleged that from 1999 to 2016, the practice agreed to treat cancer patients with chemotherapy, while the other practice would handle radiation treatment in three southwest Florida counties, and that the two practices agreed not to hire or solicit each other's employees. Under a deferred prosecution agreement with DOJ, the oncology group paid the maximum fine of $100 million to the DOJ and $20 million to the state of Florida as part of a separate civil consent decree with the Florida Attorney General. The group also agreed not to enforce noncompete agreements against any employees in the three counties. The DOJ also indicted the former CEO of the one oncology practices.

The DOJ's actions are a reminder that it will aggressively pursue antitrust violations that diminish competition and maintain higher prices for healthcare services. Violators not only face the prospect of criminal liability and imprisonment, but also debarment from participating in federal healthcare programs. Likewise, the Florida Attorney General's consent decree also shows that the DOJ is not the only antitrust enforcer violators must fear. Lastly, the DOJ and Florida Attorney General actions followed an earlier private civil antitrust class action suit against the practices that resulted in its own multi-million dollar settlement against similar allegations.

VERTICAL MERGERS

Takeaways: In analyzing the potential harm of a vertical transaction, the antitrust enforcement agencies will ask whether the parties, after they have merged, will have the ability or incentive to foreclose rivals. So, for example, if a hospital system acquires an ambulatory care provider in the same geographic area, will the merged entity have the ability to force payors into an exclusive arrangement that limits the payors' ability to contract with other hospitals or ambulatory care providers? Or, will the

merged entity have the ability to cherry-pick profitable cases and refer less profitable cases to other entities? In a vertical merger between an insurer and a pharmacy, the concern is that insurer enrollees could use only the payor's pharmacy, or have to pay higher fees to use a different pharmacy. Either end result forecloses retail pharmacy competition.

VERTICAL MERGER GUIDELINES FINALIZED

The FTC and DOJ released their final Vertical Merger Guidelines in June 2020. These Guidelines address mergers between different firms along the supply chain. The guidelines codify existing theories of potential harm, and identify potential efficiencies and price benefits from vertical integration.

FEDERAL AND STATE POLICY & ENFORCEMENT

Takeaways: With Xavier Becerra nominated to Secretary of the Department of Health and Human Services (HHS), states pursuing antitrust enforcement in the health systems marketplace will be likely to receive support (e.g., briefs, public statements, parallel federal enforcement actions) from the federal government. Moreover, the injunctive relief included in the settlement terms of a lawsuit Becerra joined as California Attorney General could very well lead states to pass tighter transparency regulations and price controls.

XAVIER BECERRA, CALIFORNIA ATTORNEY GENERAL WHO JOINED THE LAWSUIT AGAINST SUTTER HEALTH, NOMINATED AS HHS SECRETARY

President-Elect Joe Biden has nominated Xavier Becerra, the California Attorney General, for HHS Secretary. Now that the Democrats have secured control of the Senate, Mr. Becerra is likely to be confirmed.

Mr. Becerra has a history of challenging healthcare provider transactions and practices, including Sutter Health's contracting practices. For example, Mr. Becerra joined a class action lawsuit against Sutter Health that resulted in a $575 million dollar settlement (which is pending court approval). That case challenged Sutter's contracts with payors, which, among other things, prevented the payors from using steering and tiering to reduce costs, and clauses that required payors to contract with all Sutter Health facilities. If the landmark settlement receives final approval, it may serve as a guide for other states pursuing enforcement actions against hospital systems.

Mr. Becerra also has a history of being a strong proponent of the Affordable Care Act, and, as a US Congressman, supported its passage. If confirmed, Mr. Becerra's first and largest priority will be leading a comprehensive vaccination program for Americans.

As California Attorney General, Mr. Becerra has focused on monitoring companies' compliance with coronavirus safety measures.

PRICE TRANSPARENCY AND ANTITRUST ENFORCEMENT

The new Centers for Medicare & Medicaid Services (CMS) price transparency rules are likely to shape private antitrust litigation. The rules require hospitals to provide their prices in an Excel or other machine-readable form with all items and services online, as well as in a consumer-friendly format. The prices to be disclosed include: (1) the chargemaster price; (2) discounted cash price; (3) payor-specific negotiated price; (4) the lowest charge a hospital has negotiated with a payor; and (5) the highest charges a hospital has negotiated with a payor. We

may also see an uptick in litigation against healthcare providers from competing providers and other payors learning about providers' rates.

CALIFORNIA BILL TO EXPAND THE CALIFORNIA ATTORNEY GENERAL'S REVIEW OF HEALTHCARE TRANSACTIONS DELAYED

California Senate Bill (SB) 977 failed to pass in the 2020-2021 legislative session. The bill would have given the California Attorney General the ability to review and prohibit certain healthcare system transactions exceeding $500,000. It specifically targeted alleged anticompetitive practices and over-consolidation in the healthcare industry. The bill would have required the California Attorney General to deny consent to acquisitions that did not have a substantial likelihood of "clinical integration," as defined in the bill, or of increasing the access to services for an underserved population. The bill also provided for the creation of a Health Policy Advisory Board dedicated to analyzing healthcare markets and transactions.

The bill was opposed by a number of hospitals, physician groups, and the American Investment Council, the private equity trade and lobbying group. Opponents argued that the bill gave the Attorney General too much power, and that it would make it hard for smaller facilities and providers to stay in business or to merge with larger systems if they go out of business.

COLLABORATIVE TRANSFORMATION

INTRODUCTION

The country is in the midst of a challenging and transformational time. The healthcare industry is no exception, and in many ways is both at the center of and leading that transformation.

The pandemic has accelerated trends we already were seeing, and forced health business leaders to reconsider old assumptions. These rapid changes, driven by unprecedented challenges, present bold and exciting opportunities for unexpected partners to come together to improve care, lower costs and expand access to care.

We expect in 2021 to see even more shifts in the marketplace as federal and state regulators, healthcare providers, investors, technology developers and others respond to these pressures and opportunities, and come together to better serve patients, break down barriers and drive healthcare innovation.

With these opportunities come novel and complex legal and business considerations that health industry players must keep in mind as they forge a path forward in 2021, and come back stronger than ever from the crises of 2020.

In these videos, we explore the following areas driving Collaborative Transformation in the year to come:

- Digital Health
- Private Equity Investing
- Federal Healthcare Policy Changes
- Hospital and Health System Innovation

2020 REVISITED: RESHAPING HEALTHCARE THROUGH COLLABORATIVE TRANSFORMATION

COLLABORATIVE TRANSFORMATION: 2021 OUTLOOK

TOP HEALTH POLICY ISSUES OF 2021

As the US healthcare system grapples with the ongoing COVID-19 pandemic, the Biden administration is setting the tone for future relief efforts and rolling out its broader healthcare policy priorities—many of which differ considerably with those of its predecessor. The coming year will likely see major regulatory and legislative actions, and stakeholders should be closely anticipating and monitoring key policy trends that may affect their business objectives and strategies. Here are the top health policy issues to expect this year.

COVID-19 RELIEF. Not surprisingly, the Biden administration came out of the gate early and aggressively on a next COVID-19 relief and stimulus package. In the first quarter of 2021, the House and Senate put pen to paper on their respective aspirations for COVID-19 relief. Vaccine distribution and deployment, as well as provider financial recovery will remain key issues through 2021. We expect Congress to be back to the negotiating table later this year on health care related relief proposals.

The Affordable Care Act. The new administration likely will seek to unwind several Trump administration actions related to the Affordable Care Act (ACA), and in fact the new President took steps in his first week to suspend, reverse or pause a variety of the former President's Executive Orders, regulations and guidance documents. This focus may include regulations related to marketplace navigators, short-term limited-duration insurance plans and association health plans, 1332 waivers, and Medicaid work requirements. House Democrats are already seeking to advance ACA-strengthening and expanding provisions in the COVID relief bills. These provisions may not survive this round of lawmaking, but this Congress undoubtedly will return to coverage expansion efforts throughout the year.

SURPRISE BILLING. After more than two years of competing proposals and intense lobbying, Congress passed surprise billing legislation as part of the Consolidated Appropriations Act, 2021. Beginning January 1, 2022, plans and providers may not bill patients more than in-network cost-sharing amounts in certain circumstances. The act sets out an arbitration process to reconcile disputes between plans and providers. The action now shifts to the administrative agencies charged with developing implementing regulations and guidance, due in second half of 2021.

DRUG PRICING. Although the topic of drug pricing has taken a back seat to the immediate demands of COVID-19 relief, several proposals in Congress have received bipartisan support and may gain fresh traction in 2021. President Biden likely will encourage bipartisan compromise on drug pricing as part of his administration's goal to reduce healthcare costs for patients. Measures that might see movement even in a sharply divided Congress include capping out-of-pocket costs for seniors, capping price increases or providing rebates for increases great than inflation, and using international pricing indices.

2020 FDA YEAR IN REVIEW

The US Food and Drug Administration (FDA) became a central focus of US and global attention in 2020, since the agency regulates many of the therapies, treatments and interventions necessary to mitigate and combat the COVID-19 pandemic. The agency faced many challenges in light of the inevitable politicization of a public health emergency, exercising rarely used authorities to facilitate an expedient response to the pandemic in addition to pushing forward its traditional regulatory agenda.

This Special Report reviews notable actions that shaped FDA-regulated industries and products in 2020, and it offers insights into the agency's 2021 expected actions and priorities.

COVID-19

CARES ACT

As discussed in-depth here, on March 27, 2020, President Trump signed the Coronavirus Aid, Relief, and Economic Security (CARES) Act in response to the COVID-19 pandemic. The CARES Act amended section 506C of the Federal Food, Drug, and Cosmetic Act (FDCA) to require manufacturers of (1) any "drug that is critical to the public health during a public health emergency" and (2) active pharmaceutical ingredients (APIs) used in any such drug to notify FDA of a "permanent discontinuance of the manufacture" or "interruption in the manufacture" of the drug or API, respectively. FDA previously only required manufacturers of drugs characterized as "life-supporting," "life-sustaining" or "intended for use in the prevention or treatment of a debilitating disease or condition" to report drug shortages. FDA also issued a Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act Guidance for Industry, describing how and when to notify FDA of a discontinuance or interruption in manufacturing and what information to include. The CARES Act also created a new section 506J of the FDCA, which requires medical device manufacturers to report potential shortages or supply chain disruptions.

The CARES Act established section 505G of the FDCA, which clarifies the FDA approval process for certain over-the-counter (OTC) drugs marketed without an approved drug application under section 505 of the FDCA. It also established an OTC Drug User Fee, subject to reauthorization in 2025. The new sections 744L to 744N apply to facilities identified as "OTC monograph drug facilit[ies]" and contract manufacturers of OTC drugs as well as to those that submit an OTC monograph order request. Finally, the CARES Act gives manufacturers of OTC drugs the ability to obtain 18 months of market exclusivity for their products, which could spur OTC drug innovation.

EMERGENCY USE AUTHORIZATIONS AND TEMPORARY ENFORCEMENT POLICIES

Section 564 of the FDCA allows the FDA Commissioner to allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency under an emergency use authorization (EUA) to diagnose, treat or prevent serious or life-threatening disease or conditions by chemical, biological, radiological and nuclear (CBRN) threat agents when there are no adequate, approved and available alternatives. With the COVID-19 pandemic, we saw the most expansive use of this authority ever.

Under this authority, FDA has issued hundreds of EUAs for *in vitro* diagnostic products (primarily

COVID-19 tests, discussed below), PPE and related devices, ventilators and other medical devices, and drugs and biologics (primarily for treatment of COVID-19 patients). As of the date of this writing, FDA has issued two EUAs for COVID-19 vaccines.

The Public Readiness and Emergency Preparedness (PREP) Act authorizes the US Department of Health and Human Services (HHS) to issue a PREP Act declaration, which provides immunity from liability—except for willful misconduct—for claims of loss arising out of, relating to, or resulting from administration or use of "countermeasures" to diseases, threats and conditions. The PREP Act requires that a "covered countermeasure" be a "qualified pandemic or epidemic product," which must be "approved, licensed, or cleared by the FDA" or otherwise authorized by an EUA, emergency use instructions, or used under an Investigational New Drug (IND) or Investigational Device Exemption (IDE). HHS issued a declaration under the PREP Act for medical countermeasures against COVID-19 on March 17, 2020 (most recently amended on December 9, 2020). As a result, manufacturers of COVID-19 products under an EUA have a valuable liability shield, which encourages them to produce critical medical products and supplies during a global pandemic. Relatively few court cases have been filed in the past year that test the boundaries and contours of PREP Act protections. Products liability actions arising from COVID-19 activities and products may increase in the aftermath of this unprecedented public health crisis.

TEMPORARY ENFORCEMENT POLICIES

FDA has the authority under section 701(h)(1)(C) of the FDCA and 21 CFR § 10.115(g)(2) to issue guidance documents without prior public comment when it determines that prior public participation is not feasible or appropriate. On January 31, 2020, HHS issued a declaration of a public health emergency related to COVID-19 (Pandemic Declaration), renewed most recently on October 8, 2020, and on March 13, 2020, President Trump declared a national emergency in response to COVID-19. As a result of these actions and authorities, FDA has issued dozens of guidance documents and temporary enforcement policies in which the agency effectively waives or exercises enforcement discretion over many of the traditional legal and regulatory requirements for medical products during the COVID-19 public health emergency. Depending on the risk profile of the product, many of these guidance documents and temporary enforcement policies impose performance standard and labeling, registration and listing, or ad verse event reporting requirements on product manufacturers or distributors. The agency's plans for addressing the cessation of marketing of these products after the public health emergency ends are not entirely clear. Companies that market products under these enforcement policies should develop strategies to secure required marketing authorizations or implement contingency plans to ensure compliance with applicable requirements if and when FDA withdraws or amends these enforcement policies.

CLINICAL TRIALS

FDA issued guidance on the Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency in March 2020 (updated in December 2020) in response to the challenges presented by quarantines, site closures, travel limitations, interruptions to supply chain for investigational products, study staff and subject infections and various COVID-19 protocols limiting individuals' access to physical facilities. FDA's key objectives are to maintain the safety of trial participants, comply with good clinical practice (GCP) and minimize the risk to trial integrity.

Key elements of FDA's COVID-19 clinical trials guidance include provisions instructing sponsors and investigators on how to make protocol changes to minimize or eliminate immediate hazards or to protect the life and wellbeing of research participants without obtaining prior institutional review board approval. The guidance also provides recommendations on notifying FDA and institutional review boards, and documenting protocol deviations and amendments. It provides recommendations on alternative administration of investigational products, *e.g.*, through home nursing or use of non-study personnel, such as a subject's local healthcare provider (HCP). It also allows for modifications to study monitoring and consenting procedures.

MANUFACTURING

COVID-19 has also had an impact on medical product manufacturing activities, creating delays, supply reductions, reduced staff, site closures and other challenges. In many instances, the pandemic forced manufacturers to temporarily depart from current good manufacturing (cGMP) practices. FDA's 2011 Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products guidance recommends a risk-based approach to determine which products should be prioritized and which cGMP activities can be delayed, reduced or otherwise modified. In its September 2020 Resuming Normal Drug and Biologics Manufacturing Operations During the COVID-19 Public Health Emergency: Guidance for Industry, FDA reiterates that cGMP requirements remain in effect during the COVID-19 pandemic and provides guidance on how manufacturers should return to normal operations using a quality risk-management approach. Specifically, the guidance addresses how manufacturers should identify and document deviations from cGMP and how to consider remediating products manufactured with unapproved changes to critical operations and materials. FDA also recommends that manufacturers implement a resumption plan specific to their operations and organizational needs, using a risk management approach that identifies, evaluates and mitigates factors that may affect product quality.

ENFORCEMENT

With many sellers advertising products that claim to prevent, treat, mitigate, diagnose or cure COVID-19, FDA and the Federal Trade Commission (FTC) have been actively coordinating to monitor and issue enforcement actions for fraudulent COVID-19 prevention and treatment claims. To date, FDA and FTC have issued more than 140 warning letters for fraudulent products. FDA's primary concern is that these deceptive and misleading products might cause Americans to delay or stop appropriate medical treatment, leading to serious and life-threatening harm. FDA is concerned that these products, in addition to simply not working or doing what they claim, could cause adverse effects or interact—and potentially interfere—with essential medications.

- Fraudulent products have included dietary supplements, such as vitamins, "essential oils," colloidal silver or other products with unproven health claims, including the prevention or treatment of COVID-19 or related symptoms.
- Some hand sanitizers have included lower amounts of alcohol than labeled or contain methanol, which is not approved as an OTC ingredient for hand sanitizers.
- Cannabis-derived products, including those with cannabidiol (CBD), have been mislabeled as preventing or treating COVID-19.

COVID-19 DIAGNOSTIC TESTS

In 2020, the FDA spent considerable time evaluating *in vitro* diagnostic tests (IVDs) for use in the detection, care and management of patients with COVID-19, caused by the SARS-CoV-2 virus. FDA issued EUAs for more than 300 tests, including molecular tests, antibody tests and antigen tests; held weekly stakeholder town halls; and published multiple "template" EUA submission documents to facilitate the validation and review of novel COVID-19 tests, among other efforts to facilitate access to reliable testing.

Perhaps unsurprisingly given the novel nature of the virus and the nation's evolving demand for tests, FDA's requirements for COVID-19 testing evolved over the course of the year. Specifically, whether an EUA is required to offer a test primarily depends on two factors: the type of test (diagnostic or serology), and who is offering the test (test kit manufacturer or high complexity Clinical Laboratory Improvement Amendments of 1988 (CLIA)-certified clinical laboratory). The following table summarizes the FDA's premarket regulatory requirements with respect to each test type:

LOOKING AHEAD TO 2021

The public health emergency has necessitated the manufacture and distribution of several products that FDA has assessed to be safe and effective, but which may not be optimized for the end user. Manufacturers, particularly vaccine developers, likely will continue to refine their chemistry, manufacturing and controls (CMCs) to improve shelf-life, stability, and the conditions under which products can be stored and distributed. For example, some vaccine formulations have been improved to avoid the need for extreme cold storage, and others are being developed to only require one dose rather than two or more doses for full effectiveness.

When the COVID-19 public health emergency ends or the HHS rescinds its Pandemic Declaration, FDA will need to reinstitute the traditional legal and regulatory requirements for medical products that are currently subject to enforcement discretion. FDA likely will phase in its legal and regulatory requirements using a risk-based approach. It is also possible that some products may be "downregulated," at least with respect to some regulatory requirements, as appropriate. Once enforcement discretion ends under an EUA, some manufacturers might choose to discontinue marketing their products, whereas others may pursue permanent authorizations through 510(k) clearances, premarket approvals (PMAs), new drug applications (NDAs) and biologic license applications (BLAs). Some EUAs may provide a unique opportunity to use real world data (RWD) and real world evidence (RWE) to accelerate those permanent authorizations.

A substantial number of COVID-19 tests remain under review at the FDA. While FDA has taken steps to decrease its backlog (*e.g.*, limiting itself to one round of feedback on most EUA submissions), test developers likely will continue to see substantial review times at least through the first half of 2021.

Tests currently offered under an EUA will eventually need to obtain a "full" marketing authorization from FDA to remain on the market. Initial tests are likely to be reviewed under the *de novo* classification process, while subsequent tests should be able to rely on the 510(k) pathway if the test developer can establish substantial equivalence to an authorized test. However, the timeline for this transition remains uncertain. The agency announced that it is developing guidance to help developers transfer out of an EUA-centric process, and has acknowledged that it will

approach this issue with flexibility to avoid creating testing shortages. The exact parameters of the process are yet to be determined. Interested stakeholders should monitor FDA communications on this topic to facilitate their transition into a more traditional medical device regulatory framework.

DRUGS AND BIOLOGICS

DRUGS

FDA approved 50 new drugs in 2020, which is similar to the number FDA approved in 2019. FDA approved several drugs intended to treat various cancers, including lung cancer, breast cancer, multiple myeloma and lymphoma. For infectious diseases, FDA approved drugs for treatment of Human Immunodeficiency Virus (HIV), Ebola Virus Disease and COVID-19.

Indicating support for development of gene therapy products, FDA issued six final guidances in 2020, focused on gene therapy manufacturing and clinical development. In a January 2020 statement, FDA noted that more than 900 IND applications had been submitted for ongoing clinical studies involving gene therapies, and that FDA anticipates a significant number of forthcoming gene therapy approvals. This objective, however, may have been impacted by COVID-19. In January 2020, FDA also issued a draft guidance, Interpreting Sameness of Gene Therapy Products Under the Orphan Drug Regulations, to assist industry with orphan drug development of gene therapies.

In March 2020, FDA published its final Competitive Generic Therapies Guidance for Industry. This guidance tracks the draft guidance and clarifies the FDA process that companies can follow to request a designation of a drug as a competitive generic therapy (CGT), which is a drug with "inadequate generic competition." FDA also provides information on how FDA may expedite the development and review of abbreviated new drug applications (ANDAs) for CGTs and how the agency implements the 180-day exclusivity period for certain CGT ANDA applicants. In September 2020, FDA published ANDA Submissions – Amendments and Requests for Final Approval to Tentatively Approved ANDAs Guidance for Industry, which provides clarity for ANDA applicants in preparing and submitting amendments to tentatively approved ANDAs, including requests for final approval.

As discussed here, on August 6, 2020, President Trump issued an executive order that directs FDA and other federal agencies to take actions for ensuring that there is an adequate supply in the United States of essential medicines, medical countermeasures and critical inputs (*i.e.*, the ingredients and components used to make essential medicines and medical countermeasures) in the face of chemical, biological, radiological and nuclear threats and public health emergencies, such as infectious disease outbreaks. As part of the order, FDA issued a list of such products that are medically necessary to have available in an adequate amount in the United States at all times.

In November 2020, HHS announced through a Federal Register Notice the termination of FDA's Unapproved Drugs Initiative and withdrawal of FDA's "Marketed Unapproved Drugs – Compliance Policy Guide, Sec. 440.100, Marketed New Drugs Without Approved NDAs or ANDAs." As described in HHS FAQs, the Unapproved Drugs Initiative was established through FDA guidance to reduce the number of unapproved drugs on the market by requiring manufacturers of previously unapproved drugs to undergo the FDA approval process. According to HHS, a study conducted by the Yale School of Medicine and the University of Utah found

that the Unapproved Drugs Initiative had the "unintended consequence of increasing drug prices and shortages" and did not achieve FDA's goal of obtaining more data on older, unapproved drugs. HHS also had concerns that the initiative was not established pursuant to legally appropriate notice-and-comment rulemaking procedures.

BIOLOGICS

In February 2020, FDA and FTC announced a collaboration agreement to deter anticompetitive practices for biological products, including biosimilars and interchangeable biologics, and to address false and misleading promotional activities by biologic manufacturers. The anticompetitive practices at issue include "anticompetitive reverse payment agreements, abusive repetitive regulatory filings, or misuse of restricted drug distribution programs."

In February 2020, FDA issued a final rule, in line with the requirements of the Biologics Price Competition and Innovation Act of 2009 (BPCI Act), revising the definition of the term "biological product" to include the term "protein," which means "any alpha amino acid polymer with a specific, defined sequence that is greater than 40 amino acids in size." This is a significant development for manufacturers of insulin and certain human growth hormone products, which now may be regulated as biological products. In March 2020, FDA published The "Deemed To Be a License" Provision of the BPCI Act Questions and Answers Guidance for Industry, clarifying FDA's implementation of the "transition" provision of the BPCI Act, under which an application for a biological product approved as a drug under the FDCA would be deemed a license for a biological product under Public Health Act as of March 23, 2020. In November 2020, FDA published Biosimilarity and Interchangeability: Additional Draft Q&As on Biosimilar Development and the BPCI Act Guidance for Industry, which provides information on the abbreviated pathway to market created by the BCPI Act for biologics shown to be biosimilar to, or interchangeable, with an FDA-licensed reference product. Insulin and certain hormone products can serve as FDA-licensed reference products for biosimilar or interchangeable products approved under this new abbreviated pathway. Ultimately, these efforts are aimed at potentially increasing market competition and patient access to more affordable medications. Manufacturers of these transitioning products should note that these products are no longer eligible for the exemptions for compounded drugs as of March 23, 2020.

HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS

FDA regulates human cells, tissues, and cellular and tissue-based products (HCT/Ps) solely under 21 CFR Part 1271—*i.e.*, these items do not require a BLA if they meet all the requirements set forth in 21 CFR § 1271.3. HCT/Ps are articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion or transfer into a human recipient. In July 2020, FDA reissued its Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use: Guidance for Industry and Food and Drug Administration Staff, which supersedes the 2017 version of the guidance, to clarify its interpretation of "minimal manipulation" and "homologous use." For structural tissue, "minimal manipulation" is processing that does not alter the original relevant characteristics of the tissue, and for cells and nonstructural tissues, it is processing that does not alter the relevant biological characteristics of cells or tissues. FDA states that if information does not exist to show that processing of tissues meets the definition of "minimal manipulation," FDA will

consider the processing to be "more than minimal manipulation" outside the scope of 21 CFR Part 1271.

Similarly, homologous use means the repair, reconstruction, replacement or supplementation of a recipient's cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor. FDA provides numerous examples of both minimal manipulation and homologous use, and provides a flowchart to demonstrate how manufacturers can determine whether their product is an HCT/P. Most critically, FDA extends the period of enforcement discretion for products that do not meet the definition of HCT/P to May 31, 2021, with respect to the IND and premarket approval requirements.

DRUG PRICING

DRUG IMPORTATION

On October 1, 2020, HHS issued its Importation of Prescription Drugs final rule implementing sections 804(b) through (h) of the FDCA. This final rule allows states and Indian tribes to authorize commercial importation of certain prescription drugs from Canada through FDA-authorized, time-limited programs. The final rule went into effect on November 30, 2020. While the Centers for Medicare and Medicaid Services has determined that drugs imported under these "Section 804 Importation Programs" would not meet the definition of a "covered outpatient drug" under the Medicare Drug Rebate Program, they may be eligible for Medicaid federal financial participation as prescribed drugs.

Industry groups have filed a complaint against HHS in the US District Court for the District of Columbia, seeking to permanently enjoin the final rule, arguing the Secretary of HHS' certification that implementation of Section 804 "poses no additional risk to the public's health and safety and will result in a significant reduction in the cost of covered products to the American consumer" is contrary to Section 804 and unsupported by the administrative record. The complaint also alleges the final rule infringes manufacturers' First and Fifth Amendment rights. Specifically, plaintiffs allege the final rule violates their First Amendment rights by compelling manufacturers to make certain statements about the drugs with which they may disagree and which involve disputed issues of fact and opinion, and by preventing them from adding statements to their labels explaining the differences between FDA-approved drugs and drugs imported under Section 804. They also allege the final rule violates the Fifth Amendment's Takings Clause by requiring manufacturers to disclose trade secrets and other confidential information and provide samples of analytical reference standards and FDA-approved drug to importers for free.

The final rule also authorizes the re-importation of insulin products made in the United States and creates a pathway for widespread use of personal importation waivers of the prohibition of importation of prescription drugs at authorized pharmacies.

MEDICARE REBATE RULE

On November 30, 2020, HHS issued its Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Services final rule, which narrows the Anti-Kickback Statute's discount safe harbor protection for price reductions provided by manufacturers to Medicare Part D sponsors and pharmacy benefit managers (PBMs), unless the price reduction is required by law. The final rule retains the safe harbor

for rebates to Medicaid managed care organizations and creates two new safe harbors. One of the new safe harbors applies to discounts, including rebates, offered at the point-of-sale that are passed through to the dispensing pharmacy and applied to the price charged to a beneficiary, and the other applies to fees charged by PBMs to manufacturers. This final rule will go into effect January 1, 2022, to allow affected entities to make changes to their business arrangements. See our detailed discussion here.

LOOKING AHEAD TO 2021

We expect to see more regenerative medicine and gene therapy development programs in 2021 with the advent of mRNA vaccines and the associated advantages of faster production capability than traditional vaccine development. We also expect more development of new biosimilar products as a result of the FDA and FTC collaboration agreement and BPCI Act changes resulting in an abbreviated pathway to market. We likely will see more proactive development of essential medicines, medical countermeasures and critical inputs as a result of lessons learned from the shortages that occurred during the COVID-19 pandemic.

MEDICAL DEVICES

MULTIPLE FUNCTION DEVICE PRODUCTS

In July 2020, FDA issued its final Multiple Function Device Products: Policy and Considerations guidance. An analysis of the 2018 draft guidance is available here. FDA reiterated that while non-device functions or device functions subject to enforcement discretion will not be the focus of its review, FDA may assess the impact of "other functions" when assessing the safety and effectiveness of the device "functions-under-review." In their premarket submissions, manufacturers should provide information related to the impacts of "other functions" if those functions could negatively or positively affect the device function-under-review. Manufacturers also should document such impacts as part of design validation under 21 CFR § 820.30(g). FDA included a flowchart in the final guidance to help manufacturers assess whether these impacts should be documented, and included additional examples of ways in which the "other function" can affect the device function-under-review, such as impacts to memory requirements, shared programming pointers and privileges that can cause delays or interruptions. FDA also provided two additional examples of multiple function devices.

MEDICAL DEVICE INSPECTIONS

As part of the FDA Reauthorization Act of 2017, Congress directed FDA to issue guidance specifying how the agency will implement uniform processes and standards for routine device establishment inspections for both domestic and foreign establishments. On June 29, 2020, FDA issued its Review and Update of Device Establishment Inspection Processes and Standards: Guidance for Industry. Under the guidance, FDA aims to make reasonable efforts to make contact with firms to preannounce inspections. The agency also plans to maintain inspection timeframes of approximately three to six continuous business days, and make every reasonable effort to discuss all observations with the relevant responsible party or parties.

UNIQUE DEVICE IDENTIFIERS

In its July 2020 Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking: Immediately in Effect Guidance for Industry and Food and Drug Administration Staff,

FDA announced that, in response to the COVID-19 pandemic, it will not enforce the Unique Device Identification (UDI) requirements for class I and unclassified devices, other than implantable, life-supporting or life-sustaining (I/LS/LS) devices before September 24, 2022, giving an additional two-year extension to manufacturers and labelers.

COMBINATION PRODUCTS

In December 2020, FDA issued its final Requesting FDA Feedback on Combination Products: Guidance for Industry and FDA Staff. FDA provided product developers additional guidance on Combination Product Agreement Meetings (CPAMs) as a mechanism for agency feedback. The guidance includes a structured process for managing pre-submission interactions between FDA and sponsors developing combination products, and FDA and sponsor best practices to ensure that FDA feedback represents the agency's best advice based on information provided.

FDA also clarified what information sponsors should submit with a request for a CPAM and the form and content of CPAM agreements. FDA stated that any agreements made through the CPAM process will remain in effect except in the limited circumstances set forth in § 503(g)(2)(A)(iv) of the FDCA (*e.g.*, new information or updated scientific thinking) or if the sponsor changes the basis of the agreement (*e.g.*, fails to follow an agreed upon pre-clinical or clinical protocol, makes substantive changes to an endpoint, alters manufacturing process or controls, or changes the investigational plan).

DIGITAL HEALTH

DIGITAL HEALTH CENTER OF EXCELLENCE

In September 2020, FDA launched the Digital Health Center of Excellence (DHCoE) as part of the agency's efforts to modernize digital health regulatory approaches and policies, and to provide access to specialized agency expertise, technological knowledge and tools to accelerate access to digital health technology. The DHCoE is focused on:

- Empowering digital health stakeholders to advance healthcare
- Innovating regulatory approaches to provide efficient and least burdensome oversight
- Connecting and building partnerships to accelerate digital health advancements
- Sharing knowledge to increase understanding and advance best practices.

In 2020, FDA focused on the first part of its three-phase approach to the DHCoE, *i.e.*, raising awareness and engaging stakeholders through listening sessions, resource development and beginning to operationalize outcome measurements.

SOFTWARE PRE-CERTIFICATION PROGRAM

In September 2020, FDA published its Developing the Software Precertification Program: Summary of Learnings and Ongoing Activities, concluding the following about the Software Pre-Certification (Pre-Cert) Program:

- A mock Excellence Appraisal, which is intended to identify the objective criteria and methodology that FDA will use to pre-certify a company and decide whether a company can keep its precertification

status, that is reliant on remote pre-work and objective evidence, appears to be a viable alternative to a multi-day onsite visit.

- Additional exploration and testing is necessary to inform a Streamlined Review, which is intended to identify the type of information that a pre-certified company would include in its premarket submission for the FDA to review software products for safety and effectiveness before patients access them.
- Collection of real world performance data allowed for the observation of several important measures, including human factors usability engineering, and metrics that provide assurance that safety risks are managed and mitigated in a timely way.
- More testing is needed to understand how health benefits may be observed in real world performance data.

FDA will use these learnings and information to explore how the agency can develop a structured, objective and repeatable approach to assessing organizational excellence, which will help FDA identify and test parameters for ongoing monitoring of software as a medical device (SaMD) product performance. After FDA assesses and evaluates the readiness of the Pre-Cert Program, FDA will consider obtaining legislative authority to fully implement the Pre-Cert Program as a pathway for SaMD clearance or approval.

LOOKING AHEAD TO 2021

The Center for Devices and Radiological Health (CDRH) agenda for Fiscal Year 2021 includes publication of the final Clinical Decision Support Software guidance. More information on the 2019 draft Clinical Decision Support Software guidance is available here.

FDA will also launch the next phases of its three-phase approach to the DHCoE:

- Building strategic partnerships, developing resources for external stakeholders, creating a practice community, and assembling FDA and CDRH advisory groups (winter 2020 to winter 2021)
- Building and sustaining capacity, including by updating and implementing regulatory frameworks and continuing to harmonize with other regulators (winter 2021 and beyond).

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

FDA has the authority to grant a test waived status under CLIA—and to therefore make the test eligible for performance in a laboratory operating under a CLIA Certificate of Waiver—if the test is simple and has an insignificant risk of producing an erroneous result. FDA assesses whether a test has an insignificant risk of producing an erroneous result in part by evaluating whether the test produces accurate results when used by a waived user. Historically, FDA evaluated accuracy by comparing the test's performance when used by a waived user to certain statistical guardrails that may or may not be clinically relevant based on the test's intended use. The 21st Century Cures Act required FDA to use a different, potentially less restrictive comparison when evaluating a test's accuracy—*i.e.*, the test's performance when performed by a moderate complexity user. In February 2020, FDA published a long-awaited update to its "waiver" guidance document, Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices, implementing this change.

LABORATORY-DEVELOPED TESTS AND PRECISION MEDICINE

On August 19, 2020, HHS announced that FDA will not require premarket review of LDTs without first outlining its plans for such review following formal notice-and-comment rulemaking.

The announcement clarified that clinical laboratories that develop and offer LDTs may voluntarily seek approval, clearance or an EUA from FDA, but that such laboratories are not required to do so. However, laboratories that chose to run LDTs for the SARS-CoV-2 virus without FDA premarket review or authorization will not be eligible for liability protections under the PREP Act.

The announcement also clarified that clinical laboratories remain subject to regulation under CLIA, regardless of whether they elect to seek premarket review of their LDTs. State laboratory licensure requirements are also unaffected by the notice.

BACKGROUND

The FDA has long contended that it has the authority to regulate LDTs as medical devices. However, the FDA has historically exercised enforcement discretion with respect to most LDTs, which FDA defines as tests designed, manufactured and used within a single laboratory. However, with LDTs becoming increasingly complex, the FDA announced its intent to revisit its policy of enforcement discretion, and in July 2014 released draft guidance outlining its intent to regulate most LDTs as medical devices. In January 2017, the FDA announced that it would not finalize the 2014 guidance, and instead published a "discussion paper" that outlined a substantially revised approach to agency oversight of LDTs. Since then, the agency has primarily focused on responding to legislative efforts (*e.g.*, the Verifying Accurate Leading-edge IVCT Development (VALID) Act of 2020) as a mechanism to clarify its authority over LDTs.

Although the announcement was primarily positioned as relating to pandemic testing efforts, HHS's language regarding the requirement for notice-and-comment rulemaking is noticeably not limited to COVID-19 tests. Indeed, HHS intends for this announcement to apply to all tests offered as LDTs—not just tests for COVID-19. As such, this announcement appears to open the door for many types of LDTs that currently are not eligible for enforcement discretion (*e.g.*, companion diagnostics) to be offered without FDA clearance, approval or authorization. HHS has clarified that direct-to-consumer tests would not be considered LDTs under its policy.

Clinical laboratories would be prudent to consider the context in which this announcement was made before making wholesale changes to business plans. Notwithstanding the HHS announcement, FDA's LDT website remains unchanged, and the FDA website continues to link to previous guidance documents and informal statements, suggesting the agency intends to "stay the course" on its plans to regulate LDTs. The durability of this policy also remains in question, since a new Biden Administration may rescind this policy and take a position that makes it easier for FDA to exercise oversight of LDTs.

Moreover, any decisions by the executive branch concerning FDA regulation of LDTs may be short lived if Congress passes a bill to reform the regulation of laboratory tests. If enacted, the VALID Act would subject all diagnostic tests, including LDTs, to a novel risk-based oversight framework. In contrast, the Verified Innovative Testing in American Laboratories (VITAL) Act of 2020 would prohibit the

FDA from regulating LDTs and confirm a CLIA-centric framework for FDA oversight.

LOOKING AHEAD TO 2021

While the HHS announcement is a notable development, the long-term impact of the announcement on LDTs is unclear at this time. Interested stakeholders should carefully monitor future statements from HHS and the FDA for clarifications on the applicability of this policy. Stakeholders should consult with their trusted advisors to determine whether to pursue premarket review and, if applications for such review are already submitted or in process, whether to withdraw such applications or stop such efforts pending formal rulemaking by the FDA on regulation of LDTs. More generally, stakeholders should consider the impact of the presidential election and congressional appetite to enact a new regulatory framework for diagnostics as they evaluate the ramifications of this announcement for their business plans and operations.

FOOD

FDA announced a joint initiative with the US Department of Agriculture and the Environmental Protection Agency in January 2020. The platform, called the Unified Website for Biotechnology Regulation, streamlines the information from all three regulatory bodies on agricultural biotechnology products.

In October 2020, FDA published its U.S. Agent Voluntary Identification System (VIS) for Food Facility Registration: Guidance for Industry. This guidance document provides notice of FDA's establishment of a VIS in conjunction with the food facility registration database, the Food Registration Module (FFRM). The VIS allows for a streamlined US agent verification process, whereby US agents can directly provide FDA with their contact information and the name of the facilities for which they agree to serve. FDA's VIS guidance outlines several benefits to US agents and foreign facilities, including use in facilitating verification for the purposes of compliance with regulations, automatic registration number assignment when a US agent adds facility information to the VIS profile and limits to the number of unauthorized or fraudulent US agent listings.

FDA also issued several guidance documents allowing for temporary flexibility during the COVID-19 pandemic regarding nutrition labeling of certain packaged food, menu labeling requirements for chain restaurants and similar retail food establishments, and certain labeling requirements for human foods.

LOOKING AHEAD TO 2021

On September 23, 2020, FDA published a proposed rule to establish additional traceability recordkeeping requirements for entities that manufacture, process, pack or hold foods that FDA has designated for inclusion on the Food Traceability List (FTL), which is a list of specific high-risk foods identified by FDA by a risk-ranking model for food tracing. Under the proposed rule, companies would need to establish records regarding critical tracking events in the supply chain, "such as growing, shipping, receiving, creating, and transforming the foods." Where there are outbreaks of foodborne illness or threats of serious adverse health consequences or death resulting from adulterated or misbranded food, this proposed rule is intended to help FDA quickly and accurately identify the recipients of the food. Comments on the proposed rule are due by January 21, 2021.

DIETARY SUPPLEMENTS

In response to COVID-19, FDA issued guidance in May 2020 to provide a convenient way for food producing facilities, including farms and manufacturers, to voluntarily report to FDA temporary closure or reduced production. The Reporting a Temporary Closure or Significantly Reduced Production by a Human Food Establishment and Requesting FDA Assistance During the COVID-19 Public Health Emergency guidance also describes ways for food producers to engage with FDA to discuss concerns or strategies for resuming operations or addressing other challenges posed by COVID-19. The policy is intended to remain in effect for the duration of the public health emergency.

In May 2016, FDA issued a final rule amending the conventional food and dietary supplement labeling regulations. The compliance dates were initially set for July 26, 2018, for food manufacturers with $10 million or more in annual sales, and July 26, 2019, for food manufacturers with less than $10 million in annual sales. These compliances dates were subsequently extended to July 1, 2020, and July 1, 2021, respectively. In February 2020, FDA issued its revised Food Labeling: Revision of the Nutrition and Supplement Facts Labels: Guidance for Industry Small Entity Compliance Guide to provide guidance to small entities on the changes in the final rule. Topics include foods covered by the rule, nutrients that must be newly declared and changes to nutrients previously declared, recordkeeping requirements, updates to values of nutrients and formatting requirements.

LOOKING AHEAD TO 2021

Many US food producers have faced challenges in production and wrestled with the effects of COVID-19 on the health and safety of their workforce. The pandemic has also affected routine activities such as Foreign Supplier Verification Program (FSVP) requirements for food importers. FDA appears to be taking a flexible and risk-based approach to these and other programs affected by COVID-19, and seems to be actively encouraging companies to engage to address and resolve issues as they arise.

TOBACCO

WARNING STATEMENTS AND PLANS

As discussed in our 2019 Year in Review, the US District Court for the District of Massachusetts ordered FDA to publish a new proposed rule in March 2020 establishing required warnings for cigarette packages and advertisements, and the court delayed the effective date of the proposed rule following FDA's issuance of such final rule for cigarette warnings. In March 2020, FDA published a final rule, codified at 21 CFR Part 1141. On April 3, 2020, industry challenged the final rule in the US District Court for the Eastern District of Texas, and on May 8, 2020, the court granted a joint motion to govern proceedings in that case and postpone the effective date of the final rule to October 16, 2021. Under Required Warnings for Cigarette Packages and Advertisements: Small Entity Compliance Guide (Revised): Guidance for Industry, FDA encourages entities to submit cigarette warning plans to FDA as soon as possible after publication of the final rule and, in any event, within five months or 120 days after the final rule's publication date. The agency also issued the Submission of Plans for Cigarette Packages and Cigarette Advertisements (Revised) and reissued the FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and

Advertisements: Guidance for Industry. In these guidances, FDA discussed the regulatory requirements to submit cigarette warning plans, including their scope, when to submit and what information to submit.

FDA's deeming rule requires that the packages and advertisements of all cigarette tobacco, roll-your-own tobacco and covered tobacco products bear an addictiveness warning label statement. The deeming rule also requires cigar packaging and advertising to include additional health warning label statements. On July 7, 2020, the US Court of Appeals for the DC Circuit found that FDA needed to examine more closely whether the health warnings would likely affect the number of users for cigars and pipe tobacco. Specifically, the DC Circuit found that FDA violated the Family Smoking Prevention and Tobacco Control Act and the Administrative Procedure Act by failing to study whether the extensive health warnings required on cigars would actually lower the number of smokers in promulgating the regulation. The DC Circuit remanded the case, and on September 11, 2020, the US District Court for the District of Columbia vacated and remanded the health warnings for cigars and pipe tobacco. As a result, FDA will not seek to enforce the warning requirements or the labeling requirements under sections 903(a)(2) and 920(a) of the FDCA for cigars and pipe tobacco at this time.

PREMARKET SUBMISSIONS

In April 2020, FDA issued a revised Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization guidance. FDA reiterated that it intends to prioritize enforcement for the following ENDS products marketed without FDA authorization:

- Any flavored, cartridge-based ENDS products (other than tobacco- or menthol-flavored ENDS products)
- All other ENDS products for which the manufacturer has failed or is failing to take adequate measures to prevent minors' access
- Any ENDS product whose marketing is likely to promote use of ENDS to minors or that is targeted to minors

Consistent with the Further Consolidated Appropriations Act of 2020, for the purpose of this guidance, "minor" means individuals under the age of 21.

September 9, 2020 was the premarket submission deadline for certain deemed new tobacco products. FDA is reviewing submitted premarket tobacco product applications (PMTAs), substantial equivalence reports and exemption from substantial equivalence requests, and intends to prioritize enforcement of any products for which the manufacturer has not made the relevant submission.

Industry challenged the PMTA requirement for premium cigars when FDA denied requests to extend the filing deadline. The DC Circuit determined that FDA does not have the authority to change the grandfathering date for specific tobacco products, which applies once FDA deems a tobacco product subject to its regulation. The DC Circuit also determined that the PMTA deadline of September 9, 2020 was not arbitrarily or capriciously applied to substantial equivalence reports for cigar and pipe tobacco manufacturers. Industry has challenged these two holdings in ongoing litigation.

However, the DC Circuit held that FDA had not adequately considered or responded to industry concerns regarding the possibility of creating a separate, streamlined process for premium cigars,

which do not appeal to minors. The Court remanded the issue to FDA to determine whether such a streamlined process is more appropriate for premium cigars and enjoined enforcement of premarket review requirements for premium cigars. FDA must specify when manufacturers will have to submit substantial equivalence reports once it makes a decision regarding the appropriate course for premium cigars, but industry has also requested clarification on whether the injunction vacates the deeming rule with regard to premium cigars, which would require FDA to engage in notice-and-comment rulemaking.

LOOKING AHEAD TO 2021

FDA likely will be met with ongoing litigation that seeks to define the limits of FDA's authority to regulate tobacco products that primarily appeal to adults, such as premium cigars. FDA retains the broad authority Congress granted it under the Family Smoking Prevention and Tobacco Control Act of 2009, however. FDA's efforts to establish warnings for cigars that withstand First Amendment scrutiny likely will mirror its multi-year effort to establish graphic warnings for cigarettes—a process that is still ongoing.

CANNABIS

In our 2019 Year in Review, we wrote about FDA's Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds public hearing. FDA established a docket (FDA-2019-N-1482) for public comment on this hearing. In March 2020, FDA reopened the public hearing docket to facilitate information sharing indefinitely.

In March 2020, FDA also released a report to Congress summarizing the regulatory landscape surrounding CBD drugs, dietary supplements, foods, cosmetics and vape products. FDA's identified next steps included potentially adopting a risk-based enforcement policy. As discussed in detail here, in July, FDA issued its Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research, Draft Guidance for Industry. Under this draft guidance, FDA clarified that clinical research involving cannabis over the 0.3% delta-9 tetrahydrocannabinol (THC) limit requires an approved IND with cannabis from a DEA-registered source, which historically has been only the National Institute on Drug Abuse (NIDA) Drug Supply Program, in contract with the University of Mississippi. However, for clinical research involving "hemp" products under the 0.3% delta-9 THC limit, researchers may obtain cannabis from other sources. FDA further recommends that, in an IND application, companies provide qualitative laboratory data and detailed testing methods, including testing methods to evaluate the level of delta-9 THC, in particular for phase 2 and 3 studies and marketing applications, which may differ depending on dosage form. FDA also cautioned NDA applicants to not rely on published literature in place of a full toxicology program to support development of a botanical drug product for phase 3 trials and beyond.

LOOKING AHEAD TO 2021

On July 22, 2020, FDA submitted its Cannabidiol Enforcement Policy; Draft Guidance for Industry to the White House Office of Management and Budget for review. FDA has yet to issue any official statements providing additional details regarding the draft guidance. For about two years, FDA has been considering potential regulatory pathways for lawful use of CBD and hemp-derived ingredients in food and supplements, but a lack of safety data has slowed progression. The cannabis industry is eagerly

anticipating this guidance on FDA's enforcement position regarding CBD products.

Multiple federal legislative actions are pending that would increase flexibility for manufacturers of cannabis and cannabis-derived compounds and provide guidance in a space where FDA has been slow in issuing regulations. For example, HR 5587, introduced in the US House of Representatives on January 13, 2020, would amend the FDCA with respect to the regulation of hemp-derived CBD and hemp-derived-CBD-containing substances to allow them to be marketed as dietary supplements and in food. Similarly, HR 8179, the Hemp and Hemp-Derived CBD Consumer Protection and Market Stabilization Act of 2020, introduced in the House on September 4, 2020, would make hemp and hemp-derived CBD, and any other ingredient derived from hemp, "lawful for use under the [FDCA] as a dietary ingredient in a dietary supplement."

CLINICAL INVESTIGATIONS

ENHANCING DIVERSITY IN CLINICAL TRIALS

On November 9, 2020, FDA issued its final guidance on Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry, which Congress mandated under the FDA Reauthorization Act of 2017.

Pursuant to Congress' mandate, FDA addresses in the guidance:

- Broadening eligibility criteria, avoiding unnecessary exclusions for clinical trials, and applying these recommendations to trials of drugs intended to treat rare disease or conditions
- Developing eligibility criteria and improving recruitment so enrolled participants better reflect the populations most likely to use a drug.

While clinical research is critical to the development of safe and effective treatments and therapies, particularly for diseases and conditions that disproportionately affect certain groups of individuals, these same groups tend to be under-represented in clinical trials. These groups may share demographic characteristics (*e.g.*, sex, race, ethnicity, age, geographic location) or non-demographic characteristics (*e.g.*, patients with comorbidities or disabilities, pregnant women, children, or individuals with other medically complex circumstances). Lack of diversity in clinical trials limits the generalizability of a study's research findings; creates disparities in the safety, effectiveness and quality of treatments and therapies; exacerbates existing health disparities and inequalities; and decreases opportunities to deliver treatment and care to underserved populations. The COVID-19 pandemic has reinforced the need to develop medical products that are effective across multiple populations and healthcare disparities.

ELIGIBILITY

FDA recognizes that eligibility criteria exist primarily to exclude people for whom risk of an adverse event outweighs the potential benefit of participation and the resulting knowledge from the trial. Many sponsors have come to accept some common eligibility criteria without strong clinical or scientific justification, however. Many trial designs also lack reasonable accommodations for non-English speakers, patients who are unable to access transportation, or patients who work and must make site visits outside of normal business hours.

FDA's specific recommendations for inclusive enrollment include the following:

- Eliminating or modifying exclusions, such as by basing exclusions on appropriate specific measures (*e.g.*, setting a level of organ dysfunction that does not lead to unnecessary exclusion of those with milder dysfunction)
- Eliminating exclusion criteria from phase 2 studies in phase 3 protocols based on data available from completion of other relevant studies (*e.g.*, *in vitro* or *in vivo* drug-drug or drug-disease interaction studies)
- Enrolling participants who reflect characteristics of clinically relevant populations with respect to age, sex, race and ethnicity (*e.g.*, including, as appropriate, children and adolescents in confirmatory clinical trials involving adults; including women in adequate numbers to allow for analysis by sex; including racial and ethnic minorities and analyzing trial data by race and ethnicity, including differences in data attributable to intrinsic factors, such as genetics, metabolism or elimination, or extrinsic factors, such as diet, environmental exposure or sociocultural issues)
- Using enrichment strategies to increase a trial's potential to show an effect, if one exists, by ensuring that participants have a particular severity or subset of a disease or genetic marker (*i.e.*, prognostic enrichment, which enrolls participants more likely to reach study endpoints, or predictive enrichment, which enrolls participants with a specific characteristic that makes them more likely to respond to an intervention) in conjunction with appropriate marker-negative participants
- Considering re-enrollment of early-phase participants into later-phase randomized trials when studying the effectiveness of rare diseases, when medically appropriate and scientifically sound
- Making available open-label extension studies with broader inclusion criteria after early-phase studies.

ENROLLMENT

FDA also recommends that sponsors consider trial design and methodological approaches that will facilitate enrollment of broader populations, for example:

- Characterizing drug metabolism and clearance across populations that metabolize or clear the drug differently to avoid later exclusions and allow dose adjustments to optimize safety and efficacy across different populations
- Using adaptive clinical trial design to allow for pre-specified trial design changes, including altering the trial population, allowing expansion into broader populations based on interim safety data
- Considering a broader pediatric development program early, with staggered enrollment based on chronological age
- Including pharmacokinetic sampling to establish dosing in women who become pregnant during a trial to allow for continued participation and to provide information regarding drug metabolism during pregnancy
- Using data from expanded access programs to identify patients for subsequent studies.

SUBJECT RECRUITMENT AND RETENTION

FDA recommends that sponsors address practical burdens during the study design phase by reducing the frequency of required subject visits, using electronic communication and remote monitoring to replace site visits, employing home visits and providing

reasonable reimbursement for expenses associated with participation (*e.g.*, travel and lodging expenses).

The agency also recommends adopting enrollment and retention practices that enhance inclusiveness, including the following:

- Conducting public outreach and education with relevant community stakeholders, including patient advocacy groups
- Providing cultural competency and proficiency training to study staff to facilitate trust-building, decrease biased communication and behavioral practices and address patient reluctance to enroll
- Establishing sites in diverse geographic locations
- Holding recruitment events in accessible locations, during evening and weekend hours, and at trusted non-clinical locations or events (*e.g.*, places of worship, community centers, beauty salons, cultural festivals) or through social media.

With respect to patient records and consents, FDA recommends that sponsors explore agreements to facilitate exchange of medical records between sites to promote participant retention and to ease the burden on participants to gather and transfer their own records. FDA also recommends providing resources and documents in multiple languages, employing multilingual research staff or interpreters and using electronic consents or holding consenting processes in locations more accessible to participants. Finally, the agency recommends using real world data to promote more efficient recruitment of diverse populations, if patients have provided relevant permissions and consents for access to and sharing of identifiable data from their records.

LOOKING AHEAD TO 2021

FDA has expressed a commitment to exploring the effects of bias in clinical trial design and the lack of diverse population representation in product development. The guidance is an important step in the right direction because it contains practical, common sense recommendations. It remains to be seen whether guidance alone, without additional or specific regulatory authority, will encourage changes in product development and clinical research. Initiatives such as the Pediatric Research Equity Act (PREA), which gave FDA the authority to require pediatric studies in certain drug and biologic products, have encouraged greater focus on innovative trial designs for pediatric populations. While these issues are not without challenges and complexities, they continue to be a focus for FDA and industry in 2021.

ADVERTISING AND PROMOTION

ENFORCEMENT

In 2020, FDA's Office of Prescription Drug Promotion (OPDP) issued only five warning letters and one untitled letter related to prescription drug promotion. The warning letters focused on failure to present any risk information, making false or misleading claims about risk or safety and effectiveness and making claims about unapproved new uses or indications. The untitled letter was for a direct-to-consumer television advertisement, which FDA alleged made false or misleading claims and representations about the drug product's associated risks and efficacy. As previously noted, FDA issued numerous warning letters related to fraudulent COVID-19 products. CDRH did not issue any non-COVID-19-related warning letters for medical device promotion. However, it is difficult to ascertain whether the downtrend is primarily a result of the

pandemic, or if it is in line with the recent decline in FDA warning letters for advertising and promotion.

INTENDED USE RULE

As discussed in depth here, FDA published its Regulations Regarding "Intended Uses" Proposed Rule to amend its "intended use" regulations at 21 CFR §§ 201.128 and 801.4, and with the intent to clarify that the manner in which HCPs prescribe or use a product cannot be the sole basis for determining intended use. The comment period for this proposed rule closed October 23, 2020.

SOCIAL MEDIA

Both FDA and the FTC remain focused on social media influencers. FDA announced that it plans to evaluate the influence of four types of endorsers (celebrity, physician, patient and influencer) in two separate studies examining whether the presence and type of disclosure language (one direct and consumer-friendly, and one less direct) influences participant reactions. FTC requests comments on its Guides Concerning the Use of Endorsements and Testimonials in Advertising.

FTC sent a warning letter to Teami stating that because Instagram users typically see only the first few lines of a post unless they click "more," endorsers should disclose any material connection above the "more" link. Teami responded by implementing a social media policy (given to influencers or included in their contracts) that instructed influencers to include effective disclosures above the "more" button. FTC alleged in its complaint that the new policy did not result in effective disclosures. As part of its $15.2 million settlement with Teami, FTC required the company to maintain a system to monitor and review how endorsers disclose material connections. FTC noted that when it comes to social media influencers, "[a] contract provision is a fine start, but it's probably not enough," and "[a] written policy for influencers without effective monitoring and follow-through" "isn't worth the paper it's printed on."

FDA and FTC also issued joint warning letters to four companies manufacturing and marketing flavored e-liquid products. FDA determined that the e-liquids were misbranded because the social media posts at issue did not include FDA's required nicotine warning. FTC cited the companies for unfair or deceptive trade practices under the FTC Act, because the companies failed to disclose material health or safety risks in advertising.

LOOKING AHEAD TO 2021

Despite a historic low in advertising-and-promotion-related enforcement outside of COVID-19-related enforcement, the incoming Biden Administration's priorities likely will result in an uptick in warning letters and untitled letters.

ENFORCEMENT

INSPECTIONS

In March 2020, FDA announced the postponement of all domestic and foreign routine surveillance facility inspections due to the health risk posed by the COVID-19 pandemic. In July 2020, FDA stated its plan for resuming prioritized onsite domestic inspections. In the interim, FDA had continued its "mission critical" inspections and had utilized other tools, including "remote assessments and import alerts." Under its stated plan, FDA determined that prioritized domestic inspections would be pre-announced for the foreseeable future (with the exception of retail tobacco inspections). In its August 2020 Manufacturing, Supply Chain, and Drug and Biological Product Inspections During COVID-19 Public Health Emergency Questions and

Answers guidance, FDA reiterated that foreign pre-approval and for-cause inspections would remain temporarily postponed, while mission-critical inspections would continue. Mission-critical inspections are assessed based on multiple factors, including whether the product has a special designation, such as a breakthrough therapy or regenerative medicine advanced therapy, or whether the product is intended for a serious disease or condition with no adequate substitute.

WARNING LETTERS

Despite the postponement of inspections, warning letter numbers (excluding tobacco retailer warning letters) in 2020 overall were higher than in 2019 or 2018, mainly attributed to the agency's focus on ensuring unapproved and misbranded products related to COVID-19 were kept off the market. Aside from the COVID-19-related warning letters, FDA continued to focus enforcement efforts on claims that go beyond the indication for use in existing clearances or approvals, and claims that suggest a product can diagnose, prevent, treat or cure a disease or condition without clearance or approval. For example, in July 2020, FDA issued seven warning letters to dietary supplement companies making unapproved claims that their products cure, treat, mitigate or prevent hangovers. In October 2020, FDA issued five warning letters to dietary supplement companies marketing products containing cesium chloride because of significant safety concerns. These warning letters may indicate a continued agency focus on dietary supplement products.

With reference to medical devices, 2020 saw an uptick in warning letters issued by CDRH after a significant downturn in recent years. In 2015, CDRH issued 83 warning letters, a number that has decreased each year since, down to a total of 12 issued in 2019. In 2020, CDRH issued a total of 27 warning letters, but 16 of those letters were related to COVID-19, making a total of 11 non-COVID-19 warning letters.

For drugs, several warning letters issued by the Center for Drug Evaluation and Research (CDER) cited cGMP violations, suggesting a continued focus in this area. CDER also issued several warning letters to companies for the unlawful sale of opioids online to US consumers.

On November 16, 2020, the HHS Office of Inspector General (OIG) issued a special fraud alert, discussed in detail here, drawing attention to the potential fraud and abuse risks of speaker programs hosted by pharmaceutical companies. The alert encouraged pharmaceutical companies to reassess the need for in-person and virtual programs where remuneration may be paid to speakers and attendees, and encouraged HCPs to consider the risks of soliciting and receiving remuneration tied to speaker programs. OIG acknowledged that the risks posed by speaker programs depend on the facts, circumstances and intent of the parties, and provided a list of factors that may increase the enforcement risk of such programs.

LOOKING AHEAD TO 2021

Inspections will likely increase as FDA continues to adapt to the COVID-19 pandemic, whether by adopting more proactive remote inspections or resuming frequent in-person domestic and foreign inspections as COVID-19 vaccine distribution increases. FDA likely will issue more warning letters to companies claiming to prevent, treat, mitigate or cure COVID-19. We also anticipate more warning letters to e-commerce companies illegally selling products such as tramadol and oxycodone over the internet, as the opioid epidemic continues in the United States.

2021 OUTLOOK

At the close of 2020, the outgoing Trump Administration issued several last-minute executive orders and rulemakings. Because several of these rulemakings relied on exceptions from notice-and-comment requirements under the Administrative Procedure Act, industry groups and stakeholders have already challenged several Trump Administration rules (see, *e.g.*, the Drug Importation discussion above), and the incoming Biden Administration likely will spend much of 2021 assessing the impact of the Trump Administration's policies and deciding which, if any, it will carry forward.

As of this writing, President-Elect Biden has selected his picks for HHS secretary and director of the Centers for Disease Control and Prevention, but the FDA commissioner pick remains outstanding. It is unclear whether Biden will opt to retain Commissioner Hahn in the role for continuity during the early deployment of the COVID-19 vaccines, or whether he will opt for a leadership transition. The President-Elect's COVID-19 task force includes former FDA Commissioner David Kessler, who served under President George H.W. Bush and President Bill Clinton, and who remains a possible candidate. What is clear is that the national response to COVID-19 will remain a high priority for FDA, with additional vaccine authorizations likely and greater coordination with other agencies and international stakeholders.

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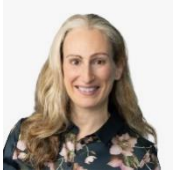

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