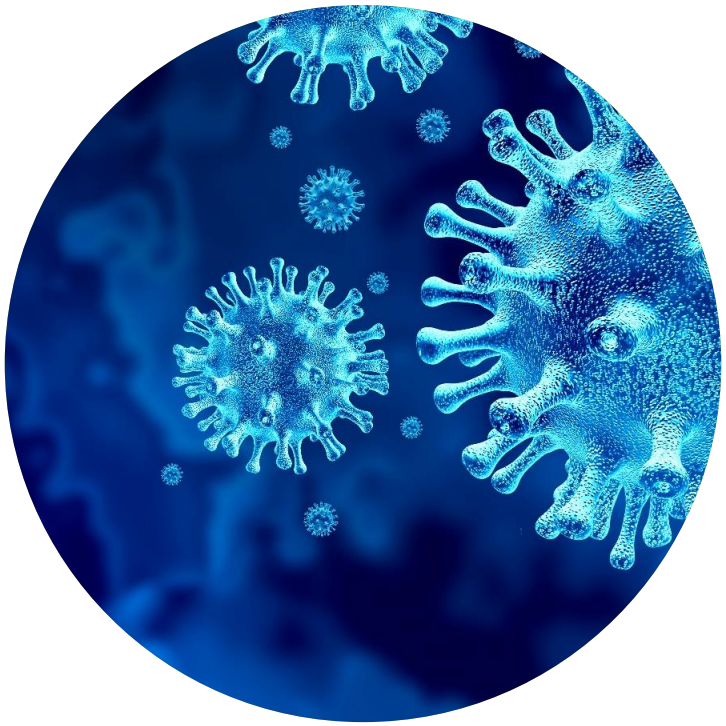
ACTION STEP CONSIDERATIONS FOR LIFE SCIENCES AND MEDICAL DEVICE COMPANIES AMIDST COVID-19 PANDEMIC



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COVID-19 SUPPORT

McDermott's multi-disciplinary team launched our Coronavirus Resource Center to help our clients weather the business impacts of this unprecedented public health crisis and map out a strategy for these uncertain times. Updated multiple times a day in near real time as developments unfold, the resource center addresses every implicated legal and regulatory issue relevant for the life sciences industry and beyond.

Visit the Resource Center at www.mwe.com/coronavirus to access our insights, FAQs, live and on-demand programming, and other guidance.

COVID-19 CONSIDERATIONS

Life Sciences and Medical Device Companies

The impact of Coronavirus (COVID-19) on life science and medical device companies has been unique. Not only have these businesses been required to set up emergency management systems practically overnight to maintain normal business operations, but the sector is expected to make significant contributions to the fight against COVID-19 across the globe.

With new challenges arising each day, as well as regulatory changes and mounting pressure on the healthcare ecosystem, we are closely tracking, digesting and advising life sciences clients on COVID-19-related issues across virtually every area impacted by this crisis. We are currently advising life sciences, healthcare and technology companies as they adapt their products and services and indeed their facilities and distribution channels to aid in the pandemic response, maintain commercial viability, implement risk mitigation strategies, and navigate highly complex regulatory hurdles and compliance obligations.

FDA CONSIDERATIONS

The US Food and Drug Administration (FDA) regulatory landscape has rapidly evolved in response to the COVID-19 pandemic, with the agency issuing new guidance documents and enforcement policies almost daily in an effort to respond to the public health emergency. The FDA has issued a slew of guidance and policy documents outlining considerations on various topics, including diagnostic tests, non-invasive remote monitoring devices, ventilators and other respiratory devices, and personal protective equipment (PPE). Key considerations related to FDA-regulated matters include:

- Assess the regulatory status of products, including enforcement discretion and availability of expedited pathways and emergency authorities for FDA-regulated products
- Engage proactively with FDA if developing COVID-19-targeted products of a type not previously addressed by the agency, or if considering a clinical validation approach not previously addressed by the agency.
- Consider potential impact of restrictions on personnel and material movement on key service providers (e.g., CROs) and supply chain (e.g., contract manufacturers, component manufacturers), including (but not limited to) the need to notify FDA of shortages and potential shortages of certain drugs, biologicals, and medical devices
- Conduct an audit of operations, prioritizing facilities to maintain and which to close, and communicating short- and long-term plans to employees
- Ensure compliance with ongoing regulatory requirements, while taking steps to mitigate product and other litigation liabilities
- Build increased flexibility into product review and commercialization timeless; as critical agency resources are increasingly diverted to COVID-19 efforts, timelines for "normal" agency action may be impacted.
- Assess impact on clinical trials and clinical supply and proactively engage with FDA, IRBs and trial sites to discuss protocol deviations, changes to informed consent and other impacts
- Consider impact of potential key reimbursement stakeholders (e.g., CMS, third-party payers, coding authorities, technology assessment organization) delays on financial projections.

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FDA SEEKS TO IMPROVE VENTILATOR ACCESS, RELAXES REMS REQUIREMENTS DURING COVID-19

FDA UPDATE: FDA ENFORCEMENT POLICY, NON-INVASIVE REMOTE MONITORING DEVICES

FDA OFFERS LABORATORIES, MANUFACTURERS NEW FLEXIBILITY TO EXPEDITE COVID-19 TESTING

FDA UPDATE: COVID-19 TESTING, VACCINE DEVELOPMENT AND OTHER IMPACTS

FDA ISSUES FAQS ON 3D PRINTING OF MEDICAL DEVICES, ACCESSORIES, COMPONENTS AND PARTS DURING THE COVID-19 PANDEMIC

FDA OPENS SUBMISSIONS FOR COVID-19 IND APPLICATIONS

FDA ISSUES ENFORCEMENT POLICIES FOR FACE MASKS AND RESPIRATORS; EMERGENCY USE AUTHORIZATION FOR VENTILATORS

Given the rapid change of developments, we encourage you to check the Health Law section of the **Coronavirus Resource Center** for real-time updates.

COVID-19 CONSIDERATIONS

Life Sciences and Medical Device Companies

CLINICAL TRIAL CONSIDERATIONS

- Evaluate the potential use of remote monitoring and telehealth visits to maintain clinical trial protocol continuity, especially for immunocompromised subjects or sites encountering physician shortages impacting investigator or research team availability.
- Engage proactively with institutional review boards (IRBs) for previously approved studies to identify any necessary adjustments to protocols, including anticipated accrual, changes to subject enrollment procedures, and impact on analysis plan or statistical methods.
- Identify electronic consenting solutions for current or future studies to minimize the need for in-person visits while social distancing continues to be warranted.
- Evaluate investment in the development of state-of-the-art digital health tools as an outgrowth of a medical device business in anticipation of COVID-19 as a potential inflection point that will permanently transform healthcare delivery.
- Note that assessment of whether certain clinical decision support tools related to or sponsored by life sciences companies may become subject to FDA regulation due to their association with FDA-regulated products.
- Understand the HIPAA and privacy normative environment of healthcare provider customers of digital health tools, as reliance on digital health technologies becomes more pronounced as public health officials seek to minimize in-person interaction.
- Consider reimbursement codes for certain remote monitoring technologies.

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FDA OFFERS GUIDANCE ON CLINICAL TRIALS DURING COVID-19 PANDEMIC

SUPPLY CHAIN AND COMMERCIAL CONSIDERATIONS

- Identify and mitigate any potential supply chain disruptions caused by factory closures, travel restrictions or employee shortages due to illness or quarantine.
- Consider short-term changes to the supply chain model to avoid disruption (e.g., replacement suppliers or vendors, other production alternatives).
- Evaluate and consider the impact of vendors' ability to deliver and customers' ability to pay on time.
- Consider implications of missed targets on ability to achieve overall projections outlined in the current business plan and update the business plan accordingly.
- Assess implications for the potential delay of business expansion or consolidation and ability to obtain subsequent rounds of financing.
- Consider the impact on working capital of disruption to supply chain and replacement of existing company vendors
- Evaluate the feasibility of repurposing existing capacity to alternative manufacturing activities

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QUARANTINING DEAL RISK IN THE COVID-19 ERA: A BUYER'S CHECKLIST

HEALTHCARE BOARD COVID-19 OVERSIGHT CHECKLIST

COVID-19 CONSIDERATIONS FOR US AND EUROPEAN PUBLIC COMPANIES

FORCE MAJEURE AND COVID-19: FREQUENTLY ASKED QUESTIONS

COVID-19 CONSIDERATIONS

Life Sciences and Medical Device Companies

RESTRUCTURING CONSIDERATIONS

- The COVID-19 crisis will quickly lead to financial distress at many companies, including some of your suppliers and customers.
    - Identify key suppliers, customers and other business partners (e.g., joint venture partners) and establish clear lines of communication to proactively identify and resolve issues. Determine whether it would be possible to replace key suppliers if one or more current suppliers were unable to continue to provide goods and/or services.
    - Stay alert for distressed M&A opportunities. Prices for assets, especially in chapter 11 bankruptcy sales, are likely to be depressed and will represent opportunities for purchasers that are able to transact.
- Even healthy businesses will be stressed by the COVID-19 crisis, whether due to supply chain disruptions, manufacturing disruptions, reduced demand, difficulty maintaining a stable workforce, etc.
    - Operate business to maximize cash flow and liquidity, and build a "cash bridge" through the crisis.
        - Minimize unnecessary spend, including monitoring and minimizing purchasing so that inventory levels are optimized.
        - Many businesses find that creating a 13-week cash flow budget of direct cash inflows and outflows, updated every 2-4 weeks, is a helpful tool in monitoring and managing liquidity.
    - Stay in front of potential financing issues, so they can be addressed proactively, before they become a crisis.
        - Review existing debt service obligations and assess ability to make upcoming principal and interest payments, and the resulting impact on liquidity.
        - Identify any near-term debt maturities (e.g., next 9-12 months) and consider options to address. Lenders will be busy in the coming months as companies seek to restructure the terms of their financing, including to obtain covenant relief and/or the suspension of events of default, so it will be important to open the lines of communication before the situation becomes critical.
        - Identify potential covenant defaults, including those resulting from operational disruption, so they can be appropriately managed.
        - Review current access to revolving lines of credit and delayed-draw term loans and consider drawing down prior to next reporting period (while being mindful of impact on any applicable financial covenants).
    - Review material contracts and leases to identify and mitigate potential contractual issues arising from delays in production or failure to fulfill outstanding orders (e.g., events of default, notice requirements, applicability of force majeure provisions) and any related consequences of a breach.
- The Company's Board should work closely with management to manage the COVID-19 crisis.
    - Increase frequency of Board meetings to ensure Board members are fully apprised of the rapidly-evolving situation.
    - Board should engage in contingency planning and develop plans for various scenarios, including a significant reduction or temporary cessation of business.
- Assess restructuring options as a means to manage delays in capital infusions and suppliers who may no longer be able to deliver.
    - Associated considerations include:
        - Evaluating affiliate obligations if looking to restructure
        - If lacking capital for next stage of research, can you sell or otherwise monetize intellectual property to move forward?

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FINANCIAL AND COMMERCIAL CONSIDERATIONS FOR SUCCESSFULLY NAVIGATING COVID-19

COVID-19 CONSIDERATIONS

Life Sciences and Medical Device Companies

ANTITRUST CONSIDERATIONS

- Increased flexibility for competitor collaborations under the new Federal Trade Commission (FTC) and Department of Justice (DOJ) Statement:
  - In recognition of the need for increased flexibility for industry and government cooperation, FTC and DOJ issued a **Joint Antitrust Statement Regarding COVID-19,** providing that the agencies will respond to COVID-19-related requests for advisory opinions and business review letters within an expedited seven days of receipt of all information.
  - FTC and DOJ reminded industry that many types of collaboration are unlikely to raise competitive concerns, so parties likely can proceed without consultation with FTC / DOJ. These areas include: 1) collaborative research and development (unless combining two of very few developers); 2) sharing general "know-how" and clinical best practices; 3) joint purchasing arrangements; and 4) petitioning the government or jointly engaging in lobbying efforts, which are protected under the *Noerr Pennington* doctrine.
  - Other collaborative conduct, falling outside those low risk areas, may also be permissible in responding to the crisis, and can be presented to the FTC and DOJ through the expedited business review letter process.
- Other certain emergency government powers are also available to permit conduct that would be viewed as anticompetitive under normal circumstances:
  - **Defense Production Act of 1950** and the **Pandemic and All-Hazards Preparedness Act (PAHPA)** have provisions for antitrust immunity for agreements made under the supervision and in cooperation with the federal government. The DOJ/FTC are ready to assist where parties are working with FEMA, HHS or other government agencies to pursue such agreements, although the statutory requirements for this immunity create burdensome conditions that may not be practical.
  - The agencies have stated that they also will process filings expeditiously that are made under the **National Cooperative Research and Production Act**. This act applies to certain joint ventures for research and development or production as well as standards development organizations. The act remains unaffected, but the agencies have indicated they will review submissions more quickly.
- With respect to price gouging and discrimination risks in dynamic market situation, if your company produces or sells items such as hand sanitizer, face masks or medical equipment that may be in higher demand or experience supply issues as a result of the COVID-19 pandemic, it will be important to consider that government and private plaintiffs may scrutinize pricing or supply decisions after the fact as potential violations of the antitrust or consumer protection laws.
  - Many states have price gouging laws that make it unlawful to raise the price of products in response to demand shocks created by a crisis. These statutes have significant monetary penalties, and some treat price gouging as a criminal offense.
  - Also be aware that communications with competitors, even over topics unrelated to the products they sell, such as HR or workplace policies in response to the coronavirus, may still pose antitrust risks if they include competitively sensitive information, such as employee compensation.

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FTC, DOJ ISSUE ANTITRUST STATEMENT ON COVID-19 RESPONSE COLLABORATIONS

CLEAN HANDS CAN STOP MORE THAN COVID-19: ANTITRUST RISKS IN TIMES OF SUPPLY AND DEMAND SHOCKS

COVID-19 CONSIDERATIONS

Life Sciences and Medical Device Companies

WORKFORCE MANAGEMENT CONSIDERATIONS

- With life sciences companies often being determined to be essential services, companies need to take proactive steps to keep workplaces healthy, safe and compliant with regulations, and to develop a communications plan with employees:
    - Communicate with employees about coming or not coming to work
    - Follow latest guidelines of the CDC and state and local authorities
    - Follow existing workplace health and safety policies
    - Consider implementing additional policies relevant for this pandemic
    - Implement remote work where possible and limit in-person work to essential positions
    - Consider other work accommodations
    - Educate staff on proper hygiene and social distancing
    - Communicate procedures to be followed in the event of exposure
    - Identify appropriate compensation structures.
- A dedicated COVID-19 team (ideally represented by the major in-house business and legal teams) must stay current on all developments and:
    - Ensure regular communication with employees, particularly during remote work situations.
    - Ensure employees understand the resources available to them, including medical benefits, employee assistance programs and prescription drugs.
    - Consider the potential need for longer-term measures, such as:
        - Staff augmentation
        - Cost-cutting measures
        - Furloughs
        - Reductions-in-force.

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EMPLOYMENT-SPECIFIC PROVISIONS OF THE CARES ACT
H.R. 6201: FAMILIES FIRST CORONAVIRUS RESPONSE ACT
IMPACT OF THE CARES ACT ON EXECUTIVE COMPENSATION

TAX CONSIDERATIONS

- Assess the impact of various tax provisions of the CARES Act, including the ability to carry back net operating losses (NOLs) incurred in 2018, 2019 and 2020, and the higher threshold for claiming interest expense deductions.
- Design tax-efficient assistance to employees through the company's existing employee assistance funds or by constructing a new program to take advantage of the disaster relief payments under IRC section 139.
- Evaluate any changes to supply chain manufacturing and design contingent supply chain arrangement that optimize subpart F planning.
- Evaluate potential tax legislation that incentivizes increased manufacturing capacity in the United States in response to reduced supply from China and IP inbounding relief.
- Confirm options for delayed filing and payments of various tax returns and taxes from the federal, state and local tax perspective.
- Assess the IRS People First Initiative, effective April 1, 2020, that temporarily adjusts or suspends key compliance programs, including any ongoing examinations and appeals.

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CURVE-FLATTENING TRAVEL IMMOBILITY LEADS TO CROSS-BORDER TAX CHALLENGES FOR COMPANIES AND EMPLOYEES
IRS TO TEMPORARILY ADJUST OPERATIONS AND KEY COMPLIANCE FUNCTIONS
IRS SIGNIFICANTLY EXPANDS COVID-19 TAX DEFERRAL RELIEF

COVID-19 CONSIDERATIONS

Life Sciences and Medical Device Companies

INTERNATIONAL CONSIDERATIONS

- Pharmaceutical companies should assess the effects of COVID-19 on their upcoming and ongoing clinical trials and should review the guidance **published by the EMA and the local regulatory bodies for the European Union** and the **Managing clinical trials during Coronavirus (COVID-19)** document published by the MHRA for the UK.
    - This provides guidance in respect of paperwork for trials that have been halted, restarting paused clinical trials, reducing participant monitoring visits or replacing in-person visits with phone calls, and reporting serious adverse events and annual safety reports.
- Existing pharmaceutical legislation provides for a number of procedures to ensure rapid market access for drugs in particularly sensitive cases. At the EU level, these procedures include, in particular, the **Priority Medicine (PRIME) system**, which enables accelerated assessment and granting of conditional approval for priority medicines. In addition, specific guidance has also been adopted in most European countries to facilitate trials in relation with the Coronavirus treatment or diagnostic.
    - The European Medicines Agency (EMA) currently offers free scientific advice for the benefit of companies developing vaccines or therapeutics against COVID-19. These companies are invited to contact EMA at 2019-ncov@ema.europa.eu.
- The MHRA is working closely with the Department of Health and Social Care and other healthcare partners on COVID-19, and is prioritizing certain fields, including supporting and authorizing the development of vaccines and the launch of clinical trials for new medicines, and managing the supply of medicines and healthcare products. Guidance can be found here. In addition, the MHRA has also provided advice for medical devices clinical investigations (both for ongoing and new applications), which can found here.
- Pharmaceutical companies should keep an eye on the production networks and supply chains relevant to them and, where possible, ensure that they do not depend exclusively on individual suppliers.
    - If there is a risk of a supply bottleneck in a specific case, e.g., owing to a contract manufacturer having to reduce or discontinue its activities, pharmaceutical companies should review their rights under the respective contracts in order to at least limit adverse commercial effects.
- European government also expanded the list of medicines that cannot be parallel exported or hoarded. Pharmaceutical companies should examine to what extent their drugs are affected by the restrictions.
    - The current list of restricted medicines is available here for the UK, and similar restrictions exist in France and Germany.
- The European commission has invited the Member states to **review foreign investments** in strategic healthcare infrastructures, including vaccines and personal protection.

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LEGAL IMPLICATIONS OF COVID-19 FOR PHARMACEUTICAL AND MEDICAL DEVICE COMPANIES IN THE UNITED KINGDOM

LEGAL IMPLICATIONS OF COVID-19 FOR PHARMACEUTICAL AND MEDICAL DEVICE COMPANIES IN FRANCE

LEGAL IMPLICATIONS OF COVID-19 FOR PHARMACEUTICAL AND MEDICAL DEVICE COMPANIES IN GERMANY

PRIVACY IN A GLOBAL PANDEMIC: ANALYSIS OF COVID-19 GUIDANCE BY DATA PROTECTION AUTHORITIES

COVID-19 CONSIDERATIONS

Life Sciences and Medical Device Companies

GOVERNMENT STRATEGIES CONSIDERATIONS

- Think through the creative ways you can sustain key relationships with the government.
- Create a tangible plan for managing expenses and offsets available through federal relief programs for companies, investors and small business partners.
- Explore how to position your business or an integral supplier/vendor for an exemption as an essential business (or preemptive designation, as essential) amid growing state shutdown orders.
- Identify the ramifications of the recently passed CARES Act and Families First Act on federal funding and monetary support available from the federal government:
    - Closely review how the CARES Act provisions to strengthen the supply chain of devices, drugs and personal protective equipment—both immediately and in preparation for future epidemics—can support your efforts to spur production and distribution of drugs and equipment.
    - Adjust your contingency plans for back-up supplies/products to meet new, heightened standards of notifications required to be sent to the FDA when facing possible shortages or interruption in the supply chain.
    - If applicable to certain lines of your business, review small business-related provisions of the CARES Act.

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CARES ACT OFFERS RELIEF, SUPPORT FOR US HEALTHCARE SECTOR DURING COVID-19 RESPONSE

SMALL BUSINESS RELIEF IN THE CARES ACT

THE FAMILIES FIRST CORONAVIRUS RESPONSE ACT: WHAT YOU NEED TO KNOW

OVERSIGHT & COMPLIANCE CONSIDERATIONS

As the dust settles, enforcement and scrutiny will follow. For these reasons, providers should continue to practice good compliance hygiene:

- Maintain diligent, contemporaneous records regarding accounting and spending of federal funds.
- Document, in real-time, deviations from policies. Demonstrate when actions were taken to save lives or continue care delivery because there was no reasonable alternative.
- Follow government instructions. When an oral instruction or answer to a question is provided, document the details of the conversation contemporaneously, including the name of the government official.
- Adhere to proper billing and coding rules when submitting claims for COVID-19 tests and treatments.
- When possible, revise policies and procedures to address the changing circumstances of COVID-19.
- Consider seeking permission (*e.g.*, Section 1135 waivers).
- Make information accessible to employees and contractors on proper fraud, waste and abuse compliance and provide key compliance training to new providers as needed.
- Build up the internal audit function to monitor claims for appropriateness before submission and evaluate audit plans to take into account changed circumstances during COVID-19.

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PREPARING FOR THE AFTERMATH OF COVID-19: THE INVESTIGATIONS

PRECAUTIONS FOR HEALTHCARE PROVIDERS SOURCING PERSONAL PROTECTIVE EQUIPMENT FROM FOREIGN SUPPLIERS

COVID-19 CONSIDERATIONS

Life Sciences and Medical Device Companies

TELEHEALTH CONSIDERATIONS

- Understand that the state and federal requirements that govern telehealth services and reimbursement are changing on a daily basis during the current public health emergency, and it is important to stay abreast of these changes for purposes of maintaining legal compliance and maximizing reimbursement.
- Balance short- and long term considerations in service contract negotiations. While many federal and state changes are temporary, there are new frameworks and new modes of interaction between industry stakeholders that will fundamentally change the digital health ecosystem.
- Recognize that collaborations and partnerships should still be understood in the context of an overall strategy:
    - Experimentation/pilot v. long-term plan (e.g., is this only for the period of the COVID-19 public health emergency or beyond?)
    - Perceived volume and type(s) of needs versus reality (e.g., limitations associated with home lab testing may limit telehealth feasibility)
    - Branding and marketing of arrangement are still important to consider in early stages
- Investigate the capabilities of your potential telehealth partner:
    - Ask around "town"
    - What is the collaborator's reputation?
    - What independent feedback is provided in references?
    - Determine stage in organizational "life-cycle" and affiliated relationships
    - Consider pros and cons of partnering with an earlier stage versus longstanding organization
    - Assess capabilities of collaborator for meeting your needs and pressure test ability to come up with back-up options to confirm such needs are met by collaborator if circumstances change
- Demonstrate your commitment to the patient/consumer journey on the front end. In a stressed time, when patients are being asked to interact and quickly engage with technology in emergency fashion, providers and plans do not have luxury to reimagine how to onboard patients. Below are questions to consider to facilitate successful adoption:
    - How are patients on-boarded?
    - How are patients trained to use and understand the technology?
    - What happens if technology is interrupted?
    - What support is provided to patients and providers?
    - Who will contact patients, e.g., caregivers/monitors?
    - How does the technology address generational issues?
- State-based regulation of providers continues to be varied.
    - Does a traditional exception (e.g., peer-to-peer) to professional licensure or state COVID-19 waiver of licensure requirements apply?
    - Has the state relaxed its practice standards in response to COVID-19?
- Monitor changing Medicare reimbursement requirements. CMS has eliminated the requirement that patients be located in an approved originating site (i.e., a rural area that is located in one of 11 permitted types of healthcare facilities).
- Consider whether Medicare virtual check-ins (short patient-initiated communications with a provider) and e-visits (non-face-to-face, patient-initiated portal communications) are an option, as these are still reimbursable in addition to the expanded telehealth benefit noted above.
- Note that the DEA announced that COVID-19 public health emergency qualifies as an exception and practitioners may issue prescriptions for controlled substances where in-person medical evaluation has not been conducted, provided certain conditions have been met.
- Ensure the security of telehealth visits and compliance with the HIPAA Security Rule (unless relying on the temporary HHS Office for Civil Rights enforcement discretion).
    - Address key security considerations such as access controls/password complexity, storage of videos and securing the transmission of data through the solution.
    - The HHS Office for Civil Rights will exercise enforcement discretion and waive penalties for HIPAA violations against health care providers providing telehealth services in good faith through everyday audio and video communications technologies such as FaceTime or Skype; telehealth encounters must involve two-way, audio-video capability (discretion applies to services provided to *all* patients – not just COVID-19 patients).

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OIG CLARIFIES SCOPE OF TELEHEALTH COPAYMENT WAIVER

WAIVERS OF CERTAIN HIPAA REQUIREMENTS IN FURTHERANCE OF TELEHEALTH DURING COVID-19 PANDEMIC

COVID-19 TELEHEALTH GUIDANCE: WHAT YOU NEED TO KNOW

COVID-19 CONSIDERATIONS

Life Sciences and Medical Device Companies

DATA PRIVACY CONSIDERATIONS

- When considering privacy and data security obligations in connection with the COVID-19 pandemic, be aware that the applicable data protection regime may depend upon whether the relevant personal information arises out of interactions involving HIPAA covered entities or business associates (and is thus subject to HIPAA) or in the consumer context and may be subject to obligations under the California Consumer Privacy Act (CCPA) and guidance from the FTC.
- If an employee has tested positive for COVID-19, only share minimal amount of information necessary for each party to assess their own personal health and avoid sharing and any personally identifiable information without consent.
- Before collecting, using or sharing personal information related to COVID-19, review your existing public-facing and employee-facing privacy policies, and if necessary, make updates to ensure they cover any new purposes for disclosure, e.g., to governmental agency for public health purpose.
    - Note that most policies include exceptions for a response to a valid legal process or to protect health and safety.
- If a government agency requests health status or other personal information about your company's employees, guests or customers, be aware that privacy obligations vary among jurisdictions; CCPA and the EU GDPR impose strict new rules applicable to personal information of individuals in those jurisdictions.
- When considering use of your company's existing personal information for COVID-19-related purposes (e.g., developing new products or services) consider carefully whether the data you hold can help with any important decisions, not just provide general insights. Be sure you have a focused strategy with defined scope and goals. Where possible, consider using de-identified, aggregate data. Carefully supervise, manage and limit all users and uses and secure the data, even under time and work from home pressures.
- Be aware of significant privacy-related trust issues in the context of delivery of health care, particularly in relation to whether personal information collected in connection with care services and solutions will be combined with existing consumer data, and whether and how such information will be shared.
- If entering into Business Associate Agreements with healthcare providers or health plans, ensure that you have:
    - Conducted a HIPAA Security Risk Analysis and have written security and incident response policies and procedures that meet the requirements of the HIPAA Security and Breach Notification Rules;
    - Implemented policies and procedures to ensure that your company only uses and discloses protected health information (PHI) as permitted by the Business Associate Agreements; and
    - Established a HIPAA compliance and security awareness training program.
- If seeking to leverage data from multiple covered entities for public health purposes, consider whether or not the data will be de-identified in accordance with HIPAA, if the activity would constitute "research" under HIPAA and if you have adequate permissions in agreements with Covered Entities.
- If you determine you are a Business Associate under HIPAA, and you intend to de-identify PHI maintained within the solution for its own use, ensure to:
    - Obtain permission to use the PHI to create de-identified data; and
    - Obtain a license in the de-identified data for your own uses.

CYBERSECURITY CONSIDERATIONS

- Be mindful of the cybersecurity risks and issues that arise when increasing remote work, including bandwidth limits, increased exfiltration of data to employees' personal devices, and greater security exposure due to large numbers of remote workers, including new or inexperienced ones.
- Prepare your employees, contractors and others to identify and avoid the unique cybersecurity threats related to online communications about COVID-19 by sending security reminders on best practices to avoid cyberattacks and scams. See list of protective measures here
- Alert employees, contractors and others about overlooked privacy and cybersecurity risks such as smart home devices.
- Review incident response plan, disaster recovery plan and other security monitoring plans to ensure preparation for a security incident. Identify contingencies and backups if personnel or systems are not available.

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PRIVACY, HIPAA, SECURITY AND GDPR – COVID-19 CONSIDERATIONS

SIX TIPS FOR WORKING (CYBER) SAFELY FROM HOME DURING COVID-19

COVID-19 CONSIDERATIONS

Life Sciences and Medical Device Companies

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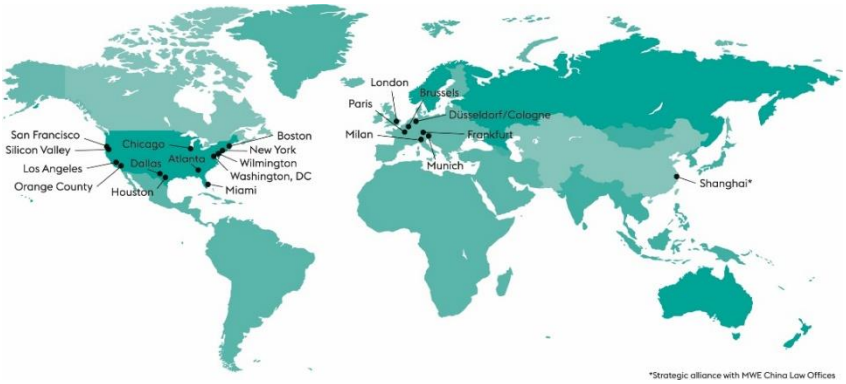

WHY MCDERMOTT – ENABLING PASSIONATE PURSUIT OF PROGRESS

McDermott's life sciences team propels you closer to your goal. Built of top lawyers with demonstrated strength across regulatory, policy, corporate, litigation, intellectual property, employment, and data privacy and cybersecurity law, we're a purpose-built team of thought leaders united by a passion for our work. For decades, we have embraced the value of focused knowledge, harnessing both the particular skills of individuals and the collective cross-border experience of our team. This makes us uniquely qualified to help you move business initiatives across the finish line when it matters and anticipate what's next.