



KEY COVID-19 CONSIDERATIONS FOR HOSPITALS AND HEALTH SYSTEMS



**McDermott
Will & Emery**

mwe.com

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 healthcare 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

HOSPITALS AND HEALTH SYSTEMS

The impact of Coronavirus (COVID-19) on hospitals and health systems is unprecedented. On the frontlines combatting the pandemic, the industry is also facing a financial crisis and a rapidly evolving regulatory and legal landscape. The need to make thoughtful but quick decisions has never been greater.

On the legal and regulatory front, McDermott's multidisciplinary team is closely tracking and analyzing developments related to COVID-19 to provide thoughtful, practical advice to help our clients in these turbulent times. Based on this ongoing work, and the industry's business and operational priorities, we have created this guide to highlight some of the most critical issues for hospitals and health systems to consider. This high-level format is designed to allow legal teams, management, board members and others at your organization to quickly digest the latest developments, view more detailed summaries and analysis at the links provided, and take appropriate actions.

CARES ACT IMPLICATIONS

The [Coronavirus Aid, Relief, and Economic Security \(CARES\) Act](#) creates new funding opportunities for healthcare providers and makes adjustments to existing payment mechanisms that provides likely support and relief measures for hospitals and health systems.

- Current programs include add-on payment for inpatient hospital discharges, a program [providing accelerated or advance Medicare payments](#) (see timeline [here](#)) that can help with cash flow pressures, and temporary suspension of Medicare sequestration.
- There is also a \$100 billion [Public Health Fund for Healthcare Providers](#) and Other Grants to Healthcare-Related Businesses. Payment of these initial funds is conditioned on the provider's acceptance of [the Terms and Conditions - PDF](#). If a provider receives payment and does not wish to comply with the Terms and Conditions, the provider must contact the Department of Health & Human Services (HHS) within 30 days of receipt and then remit the full payment to HHS. Hospitals should carefully evaluate the terms and conditions before certifying or deploying the funds. See our [analysis](#) and state-by-state [breakdown](#) for more information.
- Other [federal loan opportunities](#), including [small business support](#), may be available and of interest to you and your physicians, suppliers and industry partners.

CMS ACCOMMODATIONS AND WAIVERS

In response to COVID-19, the Centers for Medicare and Medicaid Services (CMS) has waived a broad range of regulatory requirements to ensure that hospitals and health systems have greater flexibility in fighting the pandemic.

- Hospitals and health systems should consider their operational plans in light of the CMS [blanket waivers](#) and [Interim Final Rule with Comment \(IFC\)](#), which provide an extraordinary level of regulatory flexibility in a broad range of areas, including capacity expansion for hospitals (e.g., significant flexibility for deploying alternate sites to provide care), reduction of burdensome paperwork requirements, much greater flexibility for the provision of telehealth services, and relaxation of certain professional licensure requirements. Learn more about these changes [here](#).
- More complete information about the scope of the regulatory waivers, important process changes and documentation best practices can be found [here](#). Click [here](#) for specific information regarding conversion of ambulatory surgical centers. For a list of regulatory flexibilities issued by CMS, please see the hospital tab of the McDermottPlus [tracker](#).
- Of note, the blanket waivers include the [waiver of certain Stark law requirements](#). These waivers allow hospitals to increase and preserve capacity, but require (among other elements) that any arrangement protected by a waiver "must be solely related to COVID-19 Purposes." A COVID-19 purpose includes "[a]ddressing medical practice or business interruption caused by COVID-19 to maintain the availability of medical care and related services for patients and the community." The breadth of this purpose and the degree to which it is permissible to help generally with the unprecedented financial disruption is probably the primary interpretive issue under the waiver.
 - The Office of Inspector General (OIG) also issued a Policy Statement indicating that it will not prosecute arrangements under the Anti-kickback Statute (AKS) that satisfy the Stark waivers that relate to compensation exception requirements. This means that meeting at least one of the COVID-19 Purposes is critical to understanding the AKS risk of an arrangement.

ADDITIONAL RESOURCES

Please see our listing of federal programs and funding opportunities [here](#). We also invite you to [sign up](#) to receive updates to our comprehensive McDermottPlus COVID-19 [Guidance Tracker](#), which logs timely health policy guidance and developments from federal agencies that would implement congressional or administrative directives.



COVID-19 CONSIDERATIONS

HOSPITALS AND HEALTH SYSTEMS

COMPLIANCE

When the dust settles, the use of government dollars dedicated to stimulating the company and actions taken under loosened regulatory restrictions will likely come under increased scrutiny. Hospitals and health systems should [practice good compliance hygiene](#) now to stave off potential False Claims Act claims and other alleged violations of federal and state rules and regulations. Providers should consider the following measures to ensure they have a road map of the action that they took and why—precisely the kind of road map that will prove useful to reduce exposure from government investigations and whistleblowers. Read more [here](#) about potential regulatory scrutiny and mitigation steps.

- 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) or submitting a question to CMS or OIG. Disclosure of the issue, even if there is no response from the agency, can be used to defeat an accusation that an improper intent or purpose existed.
- Make information accessible to employees and contractors regarding 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.

STATE ACCOMMODATIONS

States are moving aggressively to modify or waive regulations or issue executive orders in areas such as medical facility and professional licensure, reimbursement, standards of care, malpractice immunity, employment, tax and insurance. States also are offering their own funds and grants applicable to hospitals and health systems. McDermott is tracking multi-state developments, some of which can present tension with their federal counterparts, and can advise on these nuances as they unfold.

TRIAGE

One of the most sensitive and nuanced areas to navigate amid COVID-19 is related to triage and related issues that will arise if the need for medical equipment, supplies, or trained personnel outstrips available supply. In preparing for such contingencies, consider the following high-level issues.

- Rapidly-evolving state-by-state crisis standards of care to guide triage decision-making.
- Potential legal, compliance, claims, and operations risk vectors around care rationing issues, including private lawsuits, regulatory scrutiny, employee/union dissent, and public relations issues.
- Decision-making structures and lines of authority designated in advance by the board and executive leadership to make resource allocation decisions, handling appeals from those decisions, and ensure appropriate documentation in real-time.
- Legal immunities provided by the PREP Act and similar state laws.
- Reasonable steps that can be taken under the circumstances to honor the civil rights of all patients when drafting contingency plans for resource and workforce shortages to manage the risk of scrutiny and challenge from HHS OCR in light of recent [guidance](#) on disability and age discrimination issues related to crisis standards of care.
- Advance planning for what guidance, direction, and/or support will be offered to patients and their family members whose care is curtailed through rationing decisions.
- Support structures for workforce members and leaders who must make or carry out care rationing decisions.



COVID-19 CONSIDERATIONS

HOSPITALS AND HEALTH SYSTEMS

TELEHEALTH EXPANSION

CMS has taken a [series of actions](#) designed to increase access to and use of telehealth services, and to provide flexibilities for providers to complete certain administrative requirements virtually. As hospitals increasingly engage with patients through telehealth and look to telehealth in their pandemic response, it is important to note the following:

- Congressional and CMS action has expanded reimbursable Medicare telemedicine services, changed the payment rate for certain telehealth services, and waived specific requirements and restrictions related to the use of telemedicine.
- [States](#) continue to individually evolve their licensing and reimbursement policies.
- Funding opportunities may be available for telehealth expansion through several vehicles.
- Misunderstandings and confusion persist due to regulatory complexity and past messaging inconsistencies. To help you maintain legal compliance and maximize reimbursement, we have provided a [comprehensive roundup](#) of these developments.
- There are both short- and long-term considerations in service contract negotiations. While many federal and state changes are temporary, new frameworks and new modes of interaction between industry stakeholders will fundamentally change how hospitals and health systems, patients, and digital health solutions interact in the health ecosystem.
- Regulators with oversight of telehealth use have issued waivers to promote utilization. The OIG [clarified](#) that its copayment waivers also extend to hospitals or entities that bill on behalf of a physician or practitioner pursuant to a reassignment to that hospital or entity of the physician's or practitioner's right to receive payments. The HHS Office for Civil Rights exercised its enforcement discretion to [waive](#) certain HIPAA requirements.

CORPORATE GOVERNANCE AND BOARD-LEVEL CONSIDERATIONS

The role of the board of directors remains a key aspect of corporate governance in times of crisis, and communication and oversight are more important than ever. Best practices include:

- Setting an expectation of enhanced director engagement during the crisis
- Managing the board/management dynamic
- Establishing a culture of imagination regarding risk oversight
- Maintaining functioning board and committee meeting, including [virtual meetings](#), and information flow protocols
- Ensuring appropriate pandemic-related education for board members
- Clarifying lines of authority for critical [mission-based organizational decisions](#), including the formation of a clearly defined [executive committee](#)
- Following heightened director conduct guidelines when the organization is approaching financial distress
- Establishing special responsibilities of the audit committee regarding financial statement integrity
- Recognizing the board's workforce culture obligations (e.g., workforce safety)
- Involving the general counsel in addressing unique crisis-related legal issues.

See our [Healthcare Board COVID-19 Oversight Checklist](#) for more comprehensive details and our continued [updates](#) on this topic.

DATA SHARING AND COLLABORATIONS

All kinds of data sharing and collaborations are emerging in the wake of the crisis, including requests by public health authorities either directly or via providers' business associates for real time information on infections, bed and equipment availability, and collaborations among providers and other stakeholders for tracking caseloads, searching for testing options, treatment and vaccine solutions, and evaluation of co-morbidities. When engaging, consider the following evaluation and implementation steps:

- Who on your team is charged with evaluating these activities, including what other aspects of the crisis they are managing
- Evaluate the purpose of the data sharing arrangement and the data types to be shared and with whom
- Evaluate the applicable [HIPAA](#), state and GDPR pathways and associated intellectual property aspects
- Consider the vehicle by which the data will be shared and security protocols for data transmission and storage
- Consider the parties who will have access to the data and the specific uses of the data
- Consider the associated costs of the data collection, storage and evaluation processes, whether payment to data contributors and downstream users is involved, and the purposes and amount of such payments
- Consider the term of the data collaboration and the handling of submitted data and aggregated data upon conclusion.



COVID-19 CONSIDERATIONS

HOSPITALS AND HEALTH SYSTEMS

EMPLOYMENT AND WORKFORCE MANAGEMENT

First and foremost, consider [proactive steps](#) to update processes around exposure plans, staff testing requirements and occupational health needs, identification of essential and backup staff and communications with employees. In addition, create and communicate a safety protocol and attendance policy for employees to follow regarding COVID-19 exposure or potential exposure, symptoms, and positive test, in accordance with CDC and other guidelines.

- Due to the unknown severity and duration of the COVID-19 crisis, including the deepening economic slowdown, the human and financial resources of hospitals and health systems continue to be under considerable stress. Rapid decision-making is required on a wide range of [executive and physician employment issues](#), including compensation adjustments, retention arrangements, hiring decisions, and procedural changes needed to make these types of decisions with greater speed and with the possibility of a potential shortage of decision-makers.
 - As organizations evaluate the magnitude of their financial challenges, preservation of cash flow is paramount. As a result, the immediate focus has been on deferral or delay of salary increases, incentive awards and other compensation and benefit arrangements, even if previously approved by the compensation committee or board. Depending on the duration and severity of the crisis, pay and benefit programs are likely to be revisited in coming months with an eye to making significant changes.
 - Two more immediate action items are (a) to assure that executive incentive arrangements contain sufficient discretion for the compensation committee to make a wide variety of adjustments, such as changing goals, recognizing performance under crisis conditions, or delaying payment of approved awards until the crisis abates, and (b) to have emergency leadership succession plans in place and ready to activate.
- In order to protect your organization and fully understand the available options should a workforce restructuring event become necessary, consider the following:
 - With respect to temporary furloughs and permanent layoffs, audit the business impact, review employee agreements and applicable minimum wage and antidiscrimination statutes, determine any final payment obligations and assess union-related ramifications.
 - Develop and maintain a post-crisis management plan, including reinstatement of employees placed on unpaid non-medical leave to ensure compliance with employment contracts and company policies.
- A dedicated COVID-19 team (ideally including the key business leaders and representation from in-house legal and human resources) should stay current on [all developments](#).
- For employees who are working remotely, regularly communicate telework-focused policies, requirements (particularly for non-exempt employees) and resources available to facilitate teleworking.
- There are also numerous newly enacted and forthcoming federal and state laws and accommodation measures, including the [employment](#) and [executive compensation](#) implications of the CARES Act, the [Families First Coronavirus Response Act](#), [the Employee Retention Tax Credit and deferral of Employer Social Security Tax](#).

OTHER CONSIDERATIONS:

In addition to the key regulatory and legal topics highlighted above, there are innumerable short-and-long term issues impacting hospitals and health systems that will require ongoing review and action. A few include:

- When turning to unfamiliar foreign suppliers and domestic middlemen to quickly secure personal protective equipment (PPE) and medical supplies, take steps to avoid fraud, ensure compliance with Foreign Corrupt Practices Act requirements, address potential import restrictions related to US Food and Drug Administration (FDA) regulated medical devices, and follow good supply chain procurement practices. Learn more about other precautions during the PPE procurement process [here](#).
- To further address shortages, hospitals and health systems may increasingly consider obtaining critical equipment and supplies from non-traditional avenues (e.g., importing directly from international sources, working with affiliated researchers with access to [3D printers](#)). Such activities may subject your organization to FDA regulation, so before moving forward, examine the FDA regulatory status of products, including the availability of [enforcement discretion](#) and/or expedited pathways and emergency authorities. Proactive engagement with the agency to address any novel issues not clearly addressed in existing agency guidance is often productive.
- There is emerging litigation risk arising from claims brought by patients (or heirs of deceased patients) for negligent management of the COVID-19 pandemic.
- Detailed [focus](#) on liquidity and cash flow is critical to ensure continued financial viability as well as regular monitoring of financial performance and any potential concerns with compliance under debt documents. Proactive discussions with lenders and noteholders increase the likelihood of reaching an agreement regarding any necessary modifications. Consider discussions with key vendors regarding modifications to payment terms or schedule to help all parties better accommodate the current situation.



COVID-19 CONSIDERATIONS HOSPITALS AND HEALTH SYSTEMS

RESOURCE CONTACTS



CHARLES BUCK
Co-Chair, Hospitals & Health
Systems Initiative, Boston
cbuck@mwe.com
+1 617 535 4151



KERRIN SLATTERY
Co-Chair, Hospitals & Health
Systems Initiative, Chicago
kslattery@mwe.com
+1 312 984 7685



STEPHEN BERNSTEIN
Partner, Boston
Health Industry Advisory
sbernstein@mwe.com
+1 617 535 4062



EMILY COOK
Partner, Los Angeles
Health Industry Advisory
ecook@mwe.com
+1 310 284 6113



RALPH DEJONG
Partner, Chicago
Health Industry Advisory
rdejong@mwe.com
+1 312 984 6918



SANDRA DIVARCO
Partner, Chicago
Health Industry Advisory
sdivarco@mwe.com
+1 312 984 2006



DAVID GACIOCH
Partner, Boston
White Collar
dgacioch@mwe.com
+1 617 535 4478



TONY MAIDA
Partner, New York
Health Industry Advisory
tmaida@mwe.com
+1 212 547 5492



LISA SCHMITZ MAZUR
Partner, Chicago
Health Industry Advisory
lmazur@mwe.com
+1 312 984 3275



MICHAEL PEREGRINE
Partner, Chicago
Health Industry Advisory
mperegrine@mwe.com
+1 312 984 6933



FELICIA PERLMAN
Partner, Chicago
Corporate Advisory
fperlman@mwe.com
+1 312 984 3680



MICHELLE STROWHIRO
Partner, Los Angeles
Employment
mstrowhiro@mwe.com
+1 310 788 1571



PAUL THOMPSON
Partner, Washington, DC
White Collar
pthompson@mwe.com
+1 202 756 8032



DALE VAN DEMARK
Partner, Washington, DC
Health Industry Advisory
dcvandermark@mwe.com
+1 202 756 8177



ERIC ZIMMERMAN
Chair, Health Industry Advisory
Washington, DC
ezimmerman@mwe.com
+1 202 756 8148

Please contact your McDermott relationship attorney or click [here](#) to have one of our lawyers contact you to discuss your organization's coronavirus preparation.

TRANSFORMING HEALTHCARE TOGETHER

McDermott's multidisciplinary [team](#) delivers counsel to hospitals and health systems on critical initiatives intended to improve patient care and safety, provide greater operational efficiencies and reduce costs and optimize investments in technology and innovation. As the top-ranked healthcare law firm, we offer guidance on all segments of the industry, applying our knowledge of the rapidly changing business, legal and regulatory terrain to support winning strategies.

OUR SERVICES

- Antitrust
- Clinical Care
- Corporate Governance
- Data Strategies and Collaborations
- Digital Health
- Employee Benefits and Executive Compensation
- FDA Medical Device & Regulatory
- Labor and Employment
- Licensing and Accreditation
- M&A and Joint Ventures
- Litigation & Defense
- Policy & Advocacy
- Privacy, Cybersecurity, HIPAA/HITECH
- Regulatory Compliance & Defense
- Restructuring and Corporate Organization
- Tax-exemption Matters