BOIES SCHILLER FLEXNER

Insights: Health Care

Companies in the health care industry are on the front lines of responding to the COVID 19 pandemic. Health care companies—broadly defined to include hospitals and health care systems, insurers, pharmacies, and medical device and product manufacturers and distributors—face a number of legal challenges arising out of the pandemic, from evolving regulatory guidance to potential risk in contracts, collaboration, public disclosures, and more. The analysis below highlights key legal issues and questions that companies in the health care industry may face.

1. Evolving Regulatory Guidance

As the regulatory landscape shifts, companies in the health care industry should maintain awareness of evolving guidance and put in place policies that accurately reflect current regulations and mitigate litigation risk. Major changes in regulatory guidance in the health care industry include the following:

- The Department of Health and Human Services has updated guidance on Emergency Medical Treatment and Labor Act ("EMTALA") waivers, altering requirements for hospitals and health care providers with respect to medical screenings and patient transfers.[1]
- Mandatory coverage for COVID-19 testing and related products and services has been expanded. High deductible health care plans can cover COVID-19 testing pre-deductible and still qualify as high deductible plans.[2]
- Some states such as California have mandated waiver of cost-sharing requirements and elimination of balance billing for COVID-19 testing.[3]
- The Centers for Medicare and Medicaid Services has approved pre-authorization waivers for some states.[4] Some states are also considering mandating elimination of pre-authorization requirements.
- Relaxation of telehealth requirements for Medicare beneficiaries under certain circumstances.[5]
- Relaxation of restrictions on telehealth prescribing requirements for controlled substances. Controlled substances may be written based on a telehealth visit without a prior in-person session between the prescriber and patient if the telehealth visit is conducted using audio-visual two-way interactive technology, the prescriber is registered with the Drug Enforcement Administration and acting within the scope of her practice and according to applicable laws.[6] Prescribers should be mindful of the potential for drug-seeking behavior and safe opiod prescribing practices.

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[1] Emergency Medical Treatment and Labor Act (EMTALA) Requirements and Implications Related to Coronavirus Disease 2019 (COVID-19), Ref: QSO-20-15 Hospital/CAH/EMTALA, https://www.cms.gov/files/document/qso-20-15-emtala-requirements-and-coronavirus-0311-updated-003pdf.pdf-1 (Mar. 9, 2020)

[2] *High Deductible Health Plans and Expenses Related to Covid-19, Notice 2020-15*, https://www.irs.gov/pub/irs-drop/n-20-15.pdf (last accessed Mar. 27, 2020)

[3] *Governor Newsom and Commissioner Lara Waiver Consumer Cost-Sharing for COVID-19 Testing,* http://www.insurance.ca.gov/0400-news/0100-press-releases/2020/release025-2020-2.cfm (Mar. 5, 2020)

[4] *CMS Approves Medicaid Section 1135 Waivers for 11 Additional States in Response to COVID-19*, https://www.cms.gov/newsroom/press-releases/cms-approves-medicaid-section-1135-waivers-11-additional-states-response-covid-19 (Mar. 23, 2020)

[5] *Medicare Telemedicine Health Care Provider Fact Sheet*, https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet (Mar. 17, 2020)

[6] *COVID-19 Information Page*, https://www.deadiversion.usdoj.gov/coronavirus.html (last accessed Mar. 27, 2020)

- Relaxation of requirements surrounding HIPAA and patient privacy requirements, including for telehealth services.[7] While the use of Facetime, Facebook Messenger, Google Hangouts, and Skype can be used without penalty during COVID-19, public facing applications such as Facebook Live and TikTok cannot be used.[8]
- Relaxation of out of state licensing requirements for providers, counseling requirements, refill limits, and work from home restrictions, among other issues.
- New or newly applicable price gouging laws prohibiting inflated prices (see below)

2. Issues Facing Specific Health care Sectors

Health care Systems/Hospitals

COVID-19 poses complex challenges for health care systems and hospitals in treating patients (both with and without COVID-19), protecting employees, and preventing spread even as they face unparalleled demand for medical supplies, limited resources, and a shifting regulatory landscape. Key considerations for health care systems and hospitals may include the following:

- Maintain awareness of reporting obligations to public health authorities regarding COVID-19 cases for both patients and employees and privacy protections restricting disclosure. Hospitals and health care systems in particular are likely to have increased likelihood of OSHA-recordable illnesses for employees who are more likely to contract COVID-19 at work.
- Assess rights and obligations in requiring employees to report temperatures or symptoms or other personal data.
- Assess risks in reducing or shifting duties of medical providers to expand testing and treatment capacity. This could include work reassignments and lessening responsibility for charting and documentation.
- Evaluate rights and obligations in rationing test kits and other medical supplies.
- Evaluate right to turn away patients and any obligations or risks in doing so. Health care systems and hospitals may consider canceling elective procedures, even if not required to do so, while weighing the financial impact of canceled or deferred procedures.
- Evaluate risks from implementing mandatory do-not-resuscitate orders.
- Assess procedures for preventing spread of COVID-19 within facilities to reduce risk of malpractice, wrongful death, negligence, and other claims. This includes patients who are seeking testing for COVID-19 but who may not have the disease, as well as patients seeking or undergoing treatment for other medical issues.
- Assess how best to manage the risk of litigation and class actions by patients and employees due to COVID-19, including any restrictions on litigation or arbitration in employment agreements.
- Provide clear guidance as to when experimental treatments may be prescribed and ensure that informed consent is obtained and documented.

[7] *FAQs on Telehelath and HIPAA during the COVID-19 nationwide public health emergency*, https://www.hhs.gov/sites/default/files/telehealth-faqs-508.pdf (last accessed Mar. 27, 2020)

[8] Also note that Facebook has been involved in a number of privacy-related complaints, including exposing user health data. It has launched privacy features for health and under a settlement with the FTC must also disclose health data use, in addition to paying a $5 billion penalty.

- Maintain awareness of the potential for counterfeit or fraudulent personal protective equipment ("PPE") or other medical equipment, use of which could jeopardize patient and employee safety and contribute to an outbreak and lead to litigation.

Insurers

Insurers should carefully assess the potential business and financial impact of COVID-19 due to evolving regulatory guidance, high demand for services, and increased volume of claims and patient questions, among other issues. Key considerations may include:

- Evaluate potential for claims-related disputes due to balance billing, billing errors, failure to comply or delay in complying with regulatory guidance, and restrictions on seeking covered treatment.
- Assess the extent to which additional communications and guidance or other steps can decrease the likelihood of claims of bad faith denials.
- Assess the extent to which relaxed documentation requirements for medical providers may increase litigation risk in disputes over claims or billing.

Pharmacies

- In addition to a relaxed regulatory framework in many areas, commercial partners for pharmacies, such as pharmacy benefit managers, are relaxing contractual requirements including mail-order restrictions, signature logs, and refill timing, quantity, and limits. Pharmacies should carefully review guidance from contractual partners to ensure compliance.
- Pharmacies should assess potential for supply chain disruption and drug shortages. At least one manufacturer has already alerted the FDA of an active ingredient shortage due to COVID-19.[9]
- Pharmacies should also assess rights and obligations to restrict physical access to the pharmacy by non-essential persons.

Drug, Medical Device, and Health Product Manufacturers/Distributors/Retailers

The outbreak of COVID-19 has generated significant demand for products that can prevent, mitigate, and treat COVID-19. Business that make or sell drugs, medical devices, and other health products should evaluate litigation risk due to marketing and sales practices for such products, including:

- **False Advertising:** Assess accuracy and defensibility of claims regarding product characteristics, especially with respect to preventing, mitigating, or treating COVID-19. A putative class action has already been filed against Vi-Jon Inc., the manufacturer of Germ-X hand sanitizer, for allegedly falsely claiming that Germ-X provides "Coronavirus/Flu Prevention" despite a previous FDA Warning Letter issued to Purell that there are no well-controlled studies supporting a representation that alcohol-based hand sanitizers provide clinical reduction in infection of disease of the flu or other viruses. David v. Vi-Jon Inc., No. 20-cv-0424 (S.D. Cal.)

[9] *Coronavirus (COVID-19) Supply Chain Update*, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-supply-chain-update (Feb. 27, 2020)

- **Price Gouging:** In addition to unfair or deceptive trade practice acts already in force in many jurisdictions, states have begun to announce emergency rules making price gouging illegal for certain goods needed to limit, spread, or treat COVID-19.[10] Some states also make price gouging unlawful during states of emergency, which have been declared in many states.[11] Indeed, a putative class action has already been filed against Amazon.com Inc. based on purchases of toilet paper and hand sanitizer at high prices. The claims allege that charging "unconscionable" prices after the Florida Governor declared a state of emergency violates the states' Deceptive and Unfair Practices Act. Armas v. Amazon.com, Inc., No. 2020-5653 (Fla. Cir. Ct.).

3. Miscellaneous Issues

Securities Issues for Publicly Traded Companies

The outbreak of COVID-19 creates fertile ground for the latest wave of event-driven securities litigation. Two recently filed purported class actions underscore the care that companies must exercise in issuing public statements. This is particularly important for businesses in the health care industry. Companies should carefully evaluate the potential financial and business impact of COVID-19, including the following:

- Consider the need to update risk factor disclosures, earnings guidance, and forward looking statements, especially in light of new SEC guidance encouraging such assessments.[12]
- Maintain awareness of updated guidance from the SEC regarding filing obligations, including conditional relief (consisting of a 45 day extension) for inability to comply with filing obligations due to COVID-19.[13]
- Assess rights and obligations in conducting virtual or telephonic board and shareholder meetings.
- Assess succession and contingency planning.
- Assess sufficiency of operational oversight.[14]
- Assess insider trading risk and controls.
- Assess risk of hostile or unsolicited takeovers and defensive measures like poison pills.

Collaboration and Antitrust Risk

Many companies in the health care industry may find coordinated responses and collaboration with competitors important for addressing challenges posed by COVID-19. Notwithstanding the pandemic, agreements among competitors remain illegal under antitrust and competition laws. Businesses should be

[10] *See, e.g.*, NYC Admin. Code 20-701(b), *available at* https://www1.nyc.gov/site/dca/media/pr031720-DCWP-Emergency-Rule-Price-Gouging-Illegal.page.
[11] *See, e.g.*, Fla. Stat. § 501.160.
[12] CF Disclosure Guidance: Topic No. 9, www.sec.gov/corpfin/coronavirus-covid-19 (Mar. 25, 2020)
[13] *Order Under Section 36 of the Securities Exchange Act of 1934 Granting Exemptions from Specified Provisions of the Exchange Act and Certain Rules Thereunder*, Release No. 34-88318 (Mar. 4, 2020).
[14] *See Marchand v. Barnhill*, 212 A.3d 805 (Del. 2019) (reversing dismissal and finding shareholders stated a claim that the board failed to exercise proper operational oversight regarding events that led to a listeria outbreak in the company's only product, ice cream).

wary not just of agreements on price, but also agreements to restrict supply, divide the market, exchange information, and other mechanisms that could be used to harm competition.

Competitors seeking to collaborate should seek guidance in complying with DOJ and FTC guidance on collaboration, submitting requests to collaborate, and minimizing antitrust risk in collaborating.[15] Companies should be prepared to explain why collaboration is reasonably necessary to achieve procompetitive objectives and does not result in harm to competition, among other issues, and should seek the assistance of counsel before engaging with potential collaborators.

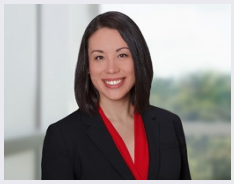
Contractual Risk

Companies in the health care industry may find that they or their counterparties are unable or unwilling to perform under their contracts due to the impact of COVID-19. Businesses should carefully evaluate contracts for the existence and scope of force majeure clauses, which commonly include disease or pandemics, and would allocate the risk of such event to the beneficiary of the obligation. Many other contractual issues are also likely to arise, from timely performance, mitigation and notice, to exclusivity arrangements, rescheduling or cancellation flexibility, and self-help or step-in rights. Businesses should seek the advice of counsel in the event contract performance issues arise.

Possible Invocation of the Defense Production Act

Invocation of the Defense Production Act could have significant implications for the health care industry. To the extent it is used, businesses should evaluate impact on their resources, supply chain, and other areas. Medical device manufacturers and suppliers in particular could be impacted by a mandatory reallocation of resources.

CONTACT



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[15] *Joint Antitrust Statement Regarding COVID-19*, https://www.justice.gov/atr/joint-antitrust-statement-regarding-covid-19 (Mar. 24, 2020).