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Legal Aspects of Pandemic Recovery

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Richard Cheng's Background

Richard Y. Cheng is a partner at DLA Piper, based out of its Dallas office. He is a member of the health care industry sector and the corporate practice group. Richard provides legal representation and advises on corporate transactions, health care operations, regulatory issues, compliance matters, and administrative appeals. In addition, he regularly advises clients on Stark Law, Anti-kick back, HIPAA, FCA, EKRA, HITECH Act, OIG exclusions, civil monetary penalties (CMPs). Medicare-related transactions (e.g. CHOWs), licensure surveys, formation of management services (MSOs), group purchasing organizations (GPOs), managed care organizations (MCOs) payment matters and appeals before administrative law judges with the Office of Medicare Hearing and Appeals, Department Appeals Board, Civil Remedies Division and State Office of Administrative Appeals.

Richard was selected by his peers in 2015, 2017 through 2020 as a *D Magazine* Best Lawyer and as a Thomson Reuters SuperLawyers Rising Star in 2015 through 2017. Richard earned his occupational therapy degree from Texas Tech University Health Sciences Center, Juris Doctor degree from Nova Southeastern University, Graduate Certificate in Public Health from the University of Texas Health Sciences Center and earned a M.B.A. at University of Memphis Fogelman College of Business & Economics.

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Presentation Overview

- Current legislative climate and the CARES Act
- Healthcare fraud statistics
- Potentially problematic conduct
- Sanctions
- Civil and administrative statutes
- Criminal statutes
- Anti-kickback
- Responding to government inquiries
- Protective measures

Legislative History

- **Coronavirus Preparedness and Response Supplemental Appropriations Act:** Passed 03.06.20 for $8.3B in emergency funding for federal agencies to respond to the coronavirus outbreak; $6.2B to HHS ($3.4B to Public Health and Social Services Emergency Fund – research of vaccines; $1.9B for CDC response efforts, SBA, FDA and waiver for telehealth)
- **Families First Coronavirus Response Act (FFCRA):** Passed 03.18.20; work force driven; focused on FMLA leave, sick leave and identify tax credits
- **CARES Act:** Passed 03.27.20; largest major legislative initiative to address COVID-19; broken into mandatory (Div. A) and discretionary (Div. B) spending and programs
  - Encourages the use of telehealth in home health care; subject to reimbursement limitations
  - Suspends the 2% Medicare sequestration, effectively boosting reimbursement rates for providers during an eight-month period
  - Creates a $100 billion health care fund for recovering COVID-19 costs
  - Increases Medicare reimbursement to providers for taking care of COVID-19 patients

Privacy and Cybersecurity Issues During the Pandemic

- **The Situation:** The global spread of COVID-19 has prompted the workforce to **migrate from the office to remote-working environments** and businesses to adopt new data collection, use, and disclosure practices to address the outbreak's effect on the organization

- **The Issues:** Responses to the pandemic are giving rise to cybersecurity and data privacy concerns

- **Looking Ahead:** In response to these concerns, federal authorities are taking action to encourage, and in some instances to require, organizations to monitor and respond to these evolving cybersecurity and data privacy issues

Factors for Privacy and Cybersecurity Risks

- Malicious actors attempting to exploit weaknesses due to reduced IT staffing
- Use of personal devices and unsecure public and home networks
- Increasing number of ransomware attacks: Encrypted files in network
- Data drain: Exfiltrating data to their home computers; causes security, privacy and contractual term violations
- Contracts or customer privacy agreements in place mandating how it will handle sensitive data: Major issue
- Regulators (e.g., HHS OCR) are suspending enforcement of certain security and privacy regulations: “Good faith” standard
- Exception under HIPAA for infectious disease and emergency

Privacy and Cybersecurity Tips

- Back up data
- Logging: Track exfiltration of information
- Two-factor authentication (2FA)
- Password management took
- Delete old data: Could take up PII
- Lockout
- Anti-virus software
- Training
- Have a plan

Health Care Fraud

- Federal government (DOJ) recovered over $3.054 B in False Claims Act (FCA) cases, with $2.605 B from healthcare cases alone (85% of FCA cases)
- Since 1986, when Congress amended the FCA, DOJ has recovered more than $62 billion under the statute
- 10th consecutive year in FCA recovery exceeding $2.0 billion
- Government paid out $198 M to relators in healthcare qui tam cases
- Direct file cases up 18.7% in 2019
- Recovered money for Medicare, Medicaid and TRICARE
- Texas OAG MFCU recovered $$140,893,436.69 in 2019
- Texas HHSC OIG executed 48 settlement agreements for a total recovery of $6,098,716.04

Health Care Fraud Enforcement 2019

- Targeted industries: Drug and medical device manufacturers, managed care providers, hospitals, pharmacies, hospice organizations, laboratories, and physicians
- Two of the largest recoveries in the healthcare industry this past year came from settlements with opioid manufacturers
- Data analytics continue to identify possible bad actors. Agents are now able to obtain and analyze billing data in real-time.
- 636 new qui tam matters in FY 2019, a drop from 2018 at 646 and 681 in 2017

COVID-19 Health Care Fraud Enforcement

- On 03.16.20, the US AG issued a memorandum on fraud in connection with COVID-19: FBI established a COVID-19 Working Group comprised of representatives from all 56 FBI field offices and 500 total participants from the DOJ and FBI to combat the criminals undermining our nation during this crisis.

- As of 05.28.20, the FBI Internet Crime Complaint Center (IC3) received nearly the same amount of complaints in 2020 (about 320,000) as they had for the entirety of 2019 (about 400,000). Approximately 75% of these complaints are frauds and swindles.

- **PP:** EINs were already used for fraudulent loan applications; fraudulent websites claiming to facilitate PPP loans, which gather all the personally identifiable information necessary to apply for a PPP loan

COVID-19 Health Care Fraud Enforcement

- **Advance Fee and Business Email Compromise (BEC) Schemes:** Prepays a purported seller or a broker for goods, and then receives little or nothing in return; BECs use a legitimate email or one nearly identical to one known and trusted to redirect legitimate payments to bank accounts controlled by the fraudsters

- **Money Mules:** Jeopardizes financial security and compromises PII

- **Health Care Fraud:** Collect and use PI to bill federal health care programs and/or private health insurance plans for tests and procedures the individual did not receive and pocket the proceeds. Scammers are selling fraudulent at-home test kits while others are even going door-to-door and performing fake tests for money.

Contract Dispute Issues During COVID-19

- Contracts usually contain provisions addressing unforeseeable events that prevent or impede performance (e.g., COVID-19)
- **Excusing performance**: Contract may contain a *force majeure* clause that relieves liability if certain unforeseeable events beyond the party's control ("acts of God" or governmental actions) prevent performance
- "Material adverse event" or other form of "hardship" can provide grounds to re-negotiate or terminate; "impossibility of performance"
- Dispute rests on the "un-foreseeability" and are fact-specific (e.g., duration of the effects of the event; key is on the "triggering event"
- Are there commercially reasonable alternatives to minimize effects?
- Giving notice within a "reasonable" time period and it may be a condition to excuse performance

Contract Dispute Tips During COVID-19

- Material Adverse Effect (MAE): Know what is in your contract; make sure allocating pandemic risks when drafting MAEs
- *Force Majeure* Notices: Party seeking to excused their obligations; can challenge if not really prevented from performing, or the event is not a for covered event; recipients should ask questions to assess events associated with the alleged "covered event" and respond
- Re-negotiating Contract: Define carefully what is considered a covered event and define its *force majeure,* and be specific
- Plan and understand your court: Is it using Zoom for hearings? Is it taking depositions in person?
- Speed up: TRO vs. lifting TROs

Family First Coronavirus Response Act (FFCRA) Key Developments

- Confirms that there is **no entitlement to leave** where the employer (ER) does not have work for the employee (EE); such as where the business has temporarily closed
- Clarifies that mass “shelter-in-place” or “stay-at-home” orders: Considered a government quarantine or isolation order under FFCRA
- Clarifies the treatment of **affiliated entities for purposes of calculating the number of EEs**; separate corporations are generally treated as separate entities, unless they meet the joint ER test under the Fair Labor Standards Act (FLSA) or integrated enterprise test under the Family and Medical Leave Act (FMLA)
- Clarifies that an EE who is advised to self-quarantine because the EE may be particularly vulnerable to COVID-19 (even where there is no reason to believe the employee has or may have COVID-19 at the time) is **eligible for leave**
- Clarifies both EE and ER documentation requirements

FFCRA

- Created two new emergency paid leave requirements in response to the COVID-19 global pandemic through 12.31.20
  - The Emergency Paid Sick Leave Act (**EPSLA**): Entitles certain EEs to **take up to two (2) weeks of paid sick leave**
  - The Emergency Family and Medical Leave Expansion Act (**EFMLEA**): Amends the FMLA, permits certain **EEs to take up to 12 weeks of expanded family and medical leave**, 10 of which are paid, for specified reasons related to COVID-19
- FFCRA covers private employers (ERs) with fewer than 500 EEs and certain public ERs

FFCRA Benefits

- **Two weeks (up to 80 hours) of paid sick time at the EE's regular rate of pay** where the EE is unable to work because the EE is isolated or quarantined (pursuant to Federal, State, or local government order or advice of a health care provider), and/or experiencing COVID-19 symptoms and seeking a medical diagnosis; or

- **Two weeks (up to 80 hours) of paid sick time at two-thirds the employee's regular rate** of pay because the EE is unable to work because of a bona fide need to care for an individual subject to isolation or quarantine (pursuant to Federal, State, or local government order or advice of a health care provider), or to care for a child (under 18 years of age) whose school or child care provider is closed or unavailable for reasons related to COVID-19, and/or the EE is experiencing a substantially similar condition as specified by the Secretary of Health and Human Services, in consultation with the Secretaries of the Treasury and Labor; and

- **Up to an additional 10 weeks of expanded paid FMLA leave at two-thirds the employee's regular rate of pay** where an employee, who has been employed for at least 30 calendar days, is unable to work due to a bona fide need for leave to care for a child whose school or child care provider is closed or unavailable for reasons related to COVID-19. The Guidance makes it clear that for these 10 weeks of paid leave, employers must include whatever hours the employee typically works during the period (including overtime hours). **ONLY for EEs employed continuously for at least 30 days prior to 04.01.20**.

FFCRA Requires Employers to Provide Two Weeks of Paid Sick Leave When the EE:

1. Is **unable** to work because the EE is subject to a government quarantine or isolation order related to COVID-19;
2. Has been **advised** by a health care provider to self-quarantine due to concerns related to COVID-19;
3. Is **experiencing** COVID-19 symptoms and seeking a medical diagnosis;
4. Is unable to work because of a **need to care** for an individual subject to a government quarantine or isolation order related to COVID-19 **or** who has been advised by a health care provider to self-quarantine due to concerns related to COVID-19;
5. Is unable to work because of a **need to care** for the employee's son or daughter whose **school or place of care is closed**, or whose childcare provider is unavailable, due to COVID-19 related reasons; or
6. Is experiencing a substantially similar condition, as specified by the Secretary of Health and Human Services.

Comparison: EPSLA vs. EFMLEA

- By comparison, EFMLEA can be used only where the EE is unable to work (or telework) due to a need for leave to care for the son or daughter of such EE if the school or place of care has been closed, or the child care provider of such son or daughter is unavailable, due to a public health emergency.

FFCRA Covered Employer Assessments: Covered Employers

- The Employer (ER) includes: (i) all EEs who are on leave; (ii) all temporary EEs who are jointly employed by the ER and another ER, regardless of the payroll on which these EEs are maintained; and (iii) all day laborers supplied by a temporary employment agency. Independent contractors under the FLSA are not included.

- Two Ways to Calculate EEs: (i) **Joint ER** - EEs of separate corporate entities are not counted together unless the corporate entities are joint ERs under the FLSA; (ii) **Integrated employer test** - Under the FMLA (common management, interrelation between operations, centralized control of labor relations, and degree of common ownership or financial control), all of their EEs count toward this threshold.

Questions: Covered Employers

- At what point in time should employers take a count?
  - **ANSWER:** ERs should count their EEs when the EE's leave is to be taken. This means if an ER is hovering around 500 EEs, it will need to keep a close watch on its EE count. If, at the time the EE needs leave, and the ER has 500 or more EEs, but then the headcount subsequently drops and the EE still needs the leave, the ER is now a covered ER and will need to comply. The reverse is not true.

- What qualifies as 30 days for purposes of EFMLEA EE eligibility?
  - **ANSWER**: EE must have been on payroll (again, any time worked as a temporary employee for the employer also counts as being on payroll) for 30 days, no matter how many days he or she worked

Questions: Covered Employers

- Do temporary employees count toward an employer's total?
  - **ANSWER**: Yes. ERs are required to count all temporary EEs in their total, even if paid by a temporary services agency

  It is possible that the temporary staffing agency and the client company may have different statuses under the FFCRA. For example, if the staffing agency has over 500 EEs, it would not be covered under the FFCRA. However, if its customer has less than 500 EEs, it would be covered under the FFCRA. If the two entities are ***joint ERs of a particular worker***, the customer/ER would be obligated to provide leave to the EE under the FFCRA. The DOL states in its FFCRA Q&As, "[t]o determine whether the second ER exercises such control [to be a joint employer], the DOL would consider whether it exercises the power to hire or fire you, supervises and controls your schedule or conditions of employment, determines your rate and method of pay, and maintains your employment records." To process the paid leave and recover the tax credit, this may require the customer/joint ER to collect documentation that it would not normally keep on a temporary EE (like a leave request form).

Questions: EFMLEA

- What type of emergency leave does the EFMLEA provide?
  - **ANSWER**: FFCRA amends the FMLA to grant emergency FMLA leave when an EE is needed to care for a son or daughter when the need is related to a PHE that results in a school closure, place of care closure, or unavailability of the son or daughter's normal childcare provider. Of note, the leave offered here is the same as the leave provided for under the EPSLA's leave entitlement for school and childcare closures. The leave must be taken between April 1, 2020, and December 31, 2020. Leave provided prior to April 1, 2020, ***will not count*** as EFMLEA leave.

Questions: EFMLEA

- Is EFMLEA leave paid or unpaid?
  - **ANSWER**: It is both. The first two weeks (usually 10 days) of leave are unpaid. The FFCRA also includes EPSLA leave (for school and childcare closures) that covers the same event, which would cover the first two weeks unless the employee's EPSLA leave has been exhausted for other reasons. The EPSLA provides for leave in a much wider array of scenarios related to COVID-19 than the EFMLEA does, so it could be exhausted before an employee seeks EFMLEA leave.

  After the first two weeks of EFMLEA, the EFMLEA offers paid leave for up to another 10 weeks (depending upon need and whether the EE has already exhausted some FMLA leave for other qualifying reasons). During the last 10 weeks of leave, an ER must pay the EE 2/3 of the EE's average rate of pay (i.e., total compensation other than discretionary bonuses) over the past 6 months, subject to a statutory cap of $200 per day and $10,000 total (the aggregate maximum of all paid FMLA leave under this provision).

Question: EFMLEA

- What if an employee is furloughed? Does he or she qualify for leave?
  - **ANSWER**: According to the DOL, furloughed EEs do not qualify for leave regardless of whether the furlough started before April 1, 2020. An EE who is furloughed, even if the furlough is considered temporary, will not be entitled to take leave once furloughed. The DOL's position is that the EPSLA and EFMLEA are designed to cover hours the EE is expected to work. If an EE is not expected to work (because of a layoff, furlough, temporary business closure, or otherwise) the EE is not entitled to leave.

Questions: EPSLA

- What must eligible EEs be paid under the EPSLA?
  - **ANSWER**: If an EE is eligible for EPSLA leave due to his or her own inability to work (i.e., for reasons 1-3 in slide 17), the ER must compensate that EE for any paid sick time he or she takes at the higher of the EE's average regular rate, the federal minimum wage, or the local minimum wage. To determine the EE's average regular rate, ERs can use the FLSA methods (subject to the 6-month rule below) to determine an EE's regular rate of pay (i.e., combine his or her hourly wage or salary, plus any non-discretionary wages, such as commissions, tips, piece rates).

  An ER should look back over the past six (6) months to ***determine the EE's average regular rate***. If the EE has not been working for six months, the ER should look back over the EE's entire employment period. Once the ER determines the EE's total compensation, it can divide that number by the number of hours the EE worked to determine the EE's wages for purposes of the regular rate of pay. This amount, however, is capped at $511 per day ($5,110 in the aggregate).

  For EEs absent from work to care for others (reasons 4-6 in slide 17), ***ERs must compensate them for any paid sick time they take at 2/3 their average regular rate of pay***. This amount, however, is capped at $200 per day ($2,000 in the aggregate). Unlike the amendments to the FMLA in the FFCRA, the EPSLA does not contain any provision for an initial period of unpaid leave.

Questions: EPSLA

- Does unused EPSLA leave carry over to subsequent years?
  - **ANSWER**: No. Prior state and local paid sick leave requirements typically include a requirement that at least some amount of unused paid sick leave carry over from one year to the next. However, that is not the case with EPSLA leave, which plainly states carryover is not required. Further, because the act sunsets at the end of December 2020, carryover would be inapplicable.

Questions: EPSLA

- What if an employer previously provided paid sick leave?
  - **ANSWER**: EPSLA leave under the FFCRA is in addition to any paid sick leave already offered by an ER (including paid sick leave available under state and local laws). Even if an ER has a generous paid sick leave policy offering more than the 80 hours required by the Act, the Act requires ERs to offer EEs additional EPSLA leave for COVID-19 purposes.

New Development Background

- On April 14, New York State Attorney General Letitia James filed a lawsuit against the DOL in Manhattan federal court alleging that the agency exceeded its rulemaking authority with respect to:

  (1) The “work-availability” requirement,
  (2) The Final Rule’s definition of “health care provider,”
  (3) The prohibition on intermittent leave; and
  (4) The documentation requirements.

- Specifically, New York claimed that each of these four provisions either ***limited paid leave or burdened its exercise***, forcing employees to choose between taking unpaid leave and going to work even when sick, therefore contravening the purpose of the FFCRA.

New Development

On August 3, 2020, US District Court for the Southern District of New York ("SDNY") issued a decision vacating certain aspects of the DOL's regulations on the FFCRA.

- **Qualifying Absences and Work-Availability Requirement:** Work available requirement to qualify for paid leave is invalidated (applies to 1,4,5 on slide #17); EE may be entitled to leave, even if the EE is not scheduled to work.

- **EE secure ER consent for Intermittent Leave:** Invalidated requirement for an ER's consent for intermittent leave; ER must allow intermittent leave unless the EE's specific circumstances appear to create with a higher risk of viral infection

- **Definition of "Healthcare Provider":** Health care provider, emergency responder or employee (e.g., non-clinical) was overly broad; FFCRA provide that an ER of "a health care provider or an emergency responder ***may elect to exclude*** such EE from the application" of the paid sick leave and paid family leave; too broad = "no nexus whatsoever" to healthcare services

- **Documentation requirement:** EEs submit reason, duration, and source of authority supporting the leave to their ER, **prior to** taking FFCRA leave invalidated; court held that the FFCRA only requires EEs to provide notice prior to taking leave

Employer Strategies

- ERs should take stock of the SDNY's August 3rd decision and its effect on their administration of paid leave under the Act, particularly in terms of (a) determining when employees have a qualifying need for paid leave, (b) the scope of the "health care provider" exemption, if applicable, (c) handling intermittent leave requests, and (d) timing for requiring employees to submit documentation
- Monitor **potential legal challenges** to or appeals of the SDNY's August 3 decision
- Monitor for **DOL announcements** regarding possible updates to it regulations and FAQs on the FFCRA
- **Review existing workplace policies** relating to a wide host of issues, including travel, work from home, and other policies as well as existing leave policies, and assess the potential effect of the FFCRA on those policies. If necessary, implement additional policies specifically tailored to FFCRA compliance.

We’re here to help

- We are always available to assist agencies with consulting and advisory services, but especially through this public health emergency

- Visit our website:
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- Contact us directly:
  - DLA Piper 214.743.4500 richard.cheng@dlapiper.com

Pandemic Recovery Series: Next Events

- **BONUS Session** (8.11.20)
  - PPP Forgiveness EZ Form Application Training
- Session 7 (8.06.20)
  - Addressing Pandemic Psychosocial Impacts While Rebuilding Agency Operations
- For registration support, call 888.258.1894 or email info@hc-link.com
- Visit the webinar series website for more detailed information: http://www.hc-link.com/pandemic-recovery-webinar-series

Questions??