2020 Regulatory Update

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Grappling with Compliance and Reporting Guidelines Resulting from COVID-19 Pandemic

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PREVIEW

- While healthcare providers have been reeling from the chaos surrounding the COVID-19 pandemic, you've also had to navigate a complicated patchwork of federal and state laws and regulations targeted at containing the virus and its aftermath.

PREVIEW

- In this 2020 Regulatory Update, we will look back and walk through some of these big changes, including:
  - the Coronavirus Aid, Relief, and Economic Security (CARES) Act,
  - the Families First Coronavirus Response Act (FFCRA),
  - and the final regulations stemming from the 21st Century Cures Act.
- Since passage, each of these pieces of legislation has evolved through agency and court interpretations. This session will focus on what responsibilities – and ethical considerations – remain for providers into 2021 as we wrap up this chaotic year.

CARES ACT

CORONAVIRUS AID, RELIEF, AND ECONOMIC SECURITY ACT

CARES ACT RECAP

- Passed on March 27, 2020.
- Allocated $100 billion in emergency funding to healthcare providers for:
  - Treating patients with COVID-19; and
  - Mitigating financial losses stemming from pandemic
- In general – not a lot of guidance for how these funds would be distributed

CARES ACT RECAP

- Medical Supplies and Drug Shortages – allocated $16 billion to replenish Strategic National Stockpile of pharmaceuticals, PPE, and other medical supplies
- Additional $1 billion allocated for Defense Production Act to bolster domestic supply chains for production of PPE, ventilators, and other medical supplies

CARES ACT RECAP

- Directed Department of Health and Human Services (HHS) to enter into agreements with National Academies of Sciences, Engineering and Medicine to assess and evaluate the dependence of the country on critical drugs/devices manufactured outside US
- Established reporting requirements of current / expected shortages of critical drugs and supplies and required reports to be made publicly available by HHS

CARES ACT RECAP

- Mandated COVID-19 Testing Coverage
  - Group health plans and health insurance issuers are required to reimburse providers for diagnostic testing for suspected COVID-19 patients
  - At negotiated rate (if available) or cash price for service
  - Providers are required to publish cash price for testing on website

CARES ACT RECAP

- Mandated COVID-19 Preventive Services Coverage
- Adjustment of Payment for Hospitals – 20% add-on payment for providing inpatient services to patients diagnosed with COVID-19

PROVIDER RELIEF FUNDS

Phase 1 General Distribution	
Distribution & Eligibility	Formulas to Determine Allocation
Initial $30 billion Automatic based on provider's share of Medicare fee-for-service reimbursements in 2019	Payment Allocation per Provider = (Provider's 2019 Medicare Fee-For-Service Payments / $453 Billion) x $30 Billion
Additional $20 billion Based on CMS cost reports, submitted revenue information, or incurred losses	Payment Allocation per Provider = ((Most Recent Tax Year Annual Gross Receipts x $50 Billion) / $2.5 Trillion) – Initial General Distribution Payment to Provider

PROVIDER RELIEF FUNDS

Phase 2 General Distribution	
Distribution & Eligibility	Formulas to Determine Allocation
$18 billion Providers who participate in state Medicaid/CHIP programs, Medicaid managed care plans, or provide dental care, as well as certain Medicare providers, including those who missed Phase 1 General Distribution payment equal to 2% of their total patient care revenue or had a change in ownership in 2019 or 2020	Payment Allocation per Provider = 2% (Revenues **x** Percent of Revenues from Patient Care)* *Most recent tax filings (CY2017, 2018, or 2019)

PROVIDER RELIEF FUNDS

Phase 3 General Distribution Deadline: November 6, 2020

HHS has made $20 billion in new funding available for Phase 3 General Distribution allocation. Providers that have already received Provider Relief Fund payments will are invited to apply for additional funding that considers financial losses and changes in operating expenses caused by the coronavirus. Previously ineligible providers, such as those who began practicing in 2020 will also be invited to apply, and an expanded group of behavioral health providers will also be eligible for relief payments.

Total Amount	Recipients
$20 billion	Applicant submission-based

PROVIDER RELIEF FUNDS

Targeted Distribution

- High-Impact Distribution (>100 COVID-10 admissions)
- Rural Distribution
- Skilled Nursing Facilities
- Indian Health Services
- Safety Net Hospitals

PROVIDER RELIEF FUNDS

Patient Protections

- Uninsured Patient Care – Provider Reimbursement
- Cost-sharing Waivers by Commercial Carriers
- No “surprise billing” or “balance billing”

PROVIDER RELIEF FUNDS

HHS issued new guidance on September 19 – providers will need to submit:

- Health-care expenses attributable to COVID-19 that another source has not reimbursed (can include general and administrative expenses as well as other operating expenses)
- Payments not fully expended on healthcare-related expenses attributable to COVID-19 using year-over-year comparisons to determine lost revenue – capped at net gain from healthcare related activities in calendar year 2019
  - This is a big change from previous guidance.

PROVIDER RELIEF FUNDS

Reporting Requirements

- January 15, 2021: Reporting System Opens
- February 15, 2021: First Reporting Deadline on Use of Funds
- July 31, 2021: Final Reporting Deadline
  - For providers who did not fully expend funds prior to December 31, 2020

PAYCHECK PROTECTION PROGRAM

- Loan Forgiveness – if funds were used for eligible payroll costs, business mortgage interest or rent
- Can apply for forgiveness at any time up to the maturity date of the loan
- If borrowers do not apply for forgiveness within 10 months after the last day of the covered period, then PPP loan payments are no longer deferred and payments will become due

TELEHEALTH EXPANSION

- CARES Act appropriated $200M in new funding to the Federal Communications Commission (FCC) to boost tele-health efforts
- Rural Health Clinics now authorized to act as distant site (site that furnishes telehealth service to patient)

TELEHEALTH EXPANSION

- In March, the Office for Civil Rights (OCR) announced enforcement discretion on HIPAA enforcement for telemedicine furnished through every day technology (Skype, Facetime, etc.) during public health emergency
- When possible, providers should still make every effort to utilize HIPAA compliant technology platforms and enter into Business Associate Agreements with vendors

TELEHEALTH EXPANSION

- Location limitations for Medicare patients waived – can now receive telehealth services in all areas of country (including at patient's home)
- Telehealth visits now covered at same rate as in-person visit
- Flexibility for providers to waive cost-sharing for telehealth visits paid by federal healthcare programs in limited circumstances

TELEHEALTH EXPANSION

- Established Relationship Requirement
  - Medicare will not enforce during public health emergency
  - Arkansas has relaxed this statutory requirement by Executive Order
  - May establish relationship via telephone (previously needed audio and visual connection)
  - Note: these are *temporary*!

TELEHEALTH EXPANSION

- Virtual check-in services – already covered
- E-visits – communication via patient portal
- Arkansas Medicaid has followed suit for covering virtual visits
- Last week, CMS announced permanent expansion for certain services offered to rural beneficiaries (60+ new services)

TELEHEALTH CONSIDERATIONS

- Do you currently have a Telemedicine Policy?
- Do you have a Consent to Participate in Telemedicine?
- Assess whether a Telemedicine Agreement is necessary.

FFCRA

FAMILIES FIRST CORONAVIRUS RESPONSE ACT

FFCRA

- Includes two provisions regarding paid leave:
  - Emergency Family and Medical Leave Expansion Act
  - Emergency Paid Sick Leave Act
- Both provisions went into effect April 1, 2020 and expire on December 31, 2020
- We may see an expansion.

Emergency Family and Medical Leave Expansion Act

- Covers employers with 500 or fewer employees, and employees who have been employed by the employer for at least 30 calendar days
- Provides paid leave only where “employee is unable to work (or telework) due to a need for leave to care for the son or daughter under 18 years of age of such employee if the school or place of care has been closed, or if the child care provider is unavailable due to a public health emergency.”

Emergency Family and Medical Leave Expansion Act

- Provides up to 12 weeks of leave, the first 10 days of which are unpaid
- Employee may elect to use PTO during the first 10 days
- After the first 10 days, remaining period must be paid at 2/3 of employee's regular rate
  - Capped at $200 per day per employee, not to exceed a total of $10,000

“Unable to Work”

What constitutes being “unable to work (or telework)”?

- Employees “telework” when employers permit them to perform work while they are at home or at a location other than their normal workplace.
- Employees are unable to work when their “employer has work for [them] and one of the coronavirus-qualifying reasons set forth in the FFCRA prevents [them] from being able to perform that work, either under normal circumstances at [their] normal worksite or by means of telework.”

“Unable to Work” cont.

- Employers and employees may agree for employees to work (or telework) their regular number of hours outside their normally scheduled hours in order for the employee to be able to work.
- In such cases, FFCRA leave is not available unless a coronavirus-qualifying reason prevents the employee from working that modified schedule

“Unable to Work” cont.

- Therefore, if an employer permits telework but an employee is unable to complete the required tasks or hours because of one of the qualifying reasons for paid sick leave, then the employee is entitled to paid sick leave.
- The same is true regarding emergency FMLA leave as discussed below
- Thus, paid sick leave and emergency FMLA leave are not available, to the extent an employee is able to telework while caring for their child or for themselves.

“Healthcare Providers” Exempted

- Employers of “healthcare providers” and emergency responders may exclude such employees from the expanded FMLA provisions
- Originally, this was *very broad*
- Has been significantly narrowed

"Healthcare Providers" Exempted

- Does the individual…..
  - Provide direct patient care?
  - Directly assist providers who provide patient care?
  - Integral to patient care services?
    - Example: lab technicians who process diagnostic test services

Emergency Paid Sick Leave Act

- This provision provides full time employees eighty hours of paid sick time at their regular rate of pay and part time employees the equivalent of two weeks' worth of hours at their regular rate of pay for six purposes:

Emergency Paid Sick Leave Act

1. Employee is subject to a Federal, State, or local quarantine or isolation order related to COVID-19
2. Employee has been advised by a health care provider to self-quarantine due to concerns related to COVID-19
3. Employee is experiencing symptoms of COVID-19 and seeking a medical diagnosis

Emergency Paid Sick Leave Act

Employees who take emergency sick leave for reasons (1), (2), or (3), must be compensated at their regular rate, with a cap of $511 per day, and $5,110 in the aggregate

Emergency Paid Sick Leave Act

4. The employee is caring for an individual who is subject to an order to isolate by Federal, State, or local authorities or on recommendation of a health care provider.

5. The employee is caring for a son or daughter of such employee if the school or place of care of the son or daughter has been closed, or the child care provider of such son or daughter is unavailable due to COVID-19 precautions.

6. The employee is experiencing any other substantially similar condition specified by the Secretary of Health and Human Services in consultation with the Secretary of Treasury and the Secretary of Labor.

Emergency Paid Sick Leave Act

- Employees who take emergency sick leave for reasons (4), (5), or (6) above, must be compensated at two-thirds their regular rate, with a cap of $200 per day and $2,000 in the aggregate.

“Healthcare Providers” Exempted

As above in the Emergency Family and Medical Leave Expansion Act, employers of health care providers and emergency responders may exempt those employees from the paid leave provisions.

"Healthcare Providers" Exempted

- Does the individual…..
  - Provide direct patient care?
  - Directly assist providers who provide patient care?
  - Integral to patient care services?
    - Example: lab technicians who process diagnostic test services

Emergency Paid Sick Leave Act

- Employees may take emergency paid sick leave for any of the reasons described above **regardless of their tenure** with the company.
- Employers must allow employees to take the emergency paid sick leave under this provision before taking any other paid leave the employer may provide.
- Further, employers are prohibited from amending their paid leave policies to avoid paying leave in addition to emergency paid sick leave.

Emergency Paid Sick Leave Act

- Employers who pay employees for paid leave under either provision will be eligible for tax credits for 100 percent of qualified paid leave wages against their Social Security payroll taxes.
- The caps on tax credits mirror the caps for employees on paid leave. Under the Emergency Family and Medical Leave Expansion Act the tax credit cap will be $200 per day per employee.
- Leave under the Emergency Paid Sick Leave Act will be capped at $511 per date for employees who personally sick or quarantined (reasons (1), (2), and (3)), or $200 per day for employees taking leave to care for others (reasons (4), (5), and (6)).

Record Retention

- The DOL guidance advises that if employers intend on claiming a tax credit under the FFCRA for paid sick leave or emergency FMLA leave, employers should retain “appropriate documentation” in their records.
- Employers should follow IRS applicable forms and instructions for procedures required to claim a tax credit (which, as of the date of this posting, do not appear to yet be available), including any “needed substantiation to be retained to support the credit.”

Record Retention

If an employee takes emergency FMLA leave to care for their child whose school or place of care is closed, or child care provider is unavailable due to coronavirus precautions, employers may require that employee to provide additional documentation in support of such leave, “to the extent permitted under the certification rules for conventional FMLA leave requests.”

Example – notice posted on school website or email from child care provider

FFCRA Analysis

1. Is the employee a healthcare worker?
2. Expanded FMLA applies if the answer to the following is "yes":
   1. Is the employee caring for his or her child?
   2. Has the child's school or daycare been closed?

FFCRA Analysis

- Is the employee a healthcare worker?
- The Emergency Paid Sick Leave Act applies in the following circumstances:
  - Employee subject to quarantine order (or caring for individual who is)
  - Employee advised by healthcare provider to self-quarantine (or caring for individual who is)
  - Employee experiencing symptoms/seeking diagnosis
  - Employee caring for child whose school / daycare is closed

FFCRA Analysis

- Make these determinations on a case by case basis
- Different results
  - Job Duties
  - Reasons for Leave

21ST CENTURY CURES ACT

21st Century Cures Act

- Signed into law on December 13, 2016
- Strong bipartisan support
- Authorized $6.3 billion in funding – mostly for the National Institutes of Health
  - Small Business Health Reimbursement Arrangement
  - Research and Drug Development
  - Behavioral Health
  - Healthcare Access and Quality Improvement
  - Electronic Health Records Information Blocking

21st Century Cures Act

General provisions of the Cures Act

- Allocate funds for opioid misuse prevention efforts and biomedical research
- Accelerate drug and medical device approval processes
- Bolster mental health treatment reform

Focus on health data

- Encourage patients' **electronic access** to their health information
- Promote **interoperability** and use IT to improve quality of care
- Inhibit **information blocking**

EXECUTIVE ORDER 13813

EXECUTIVE ORDERS

Presidential Executive Order Promoting Healthcare Choice and Competition Across the United States

HEALTHCARE | Issued on: October 12, 2017

★ ★ ★

Government rules and guidelines should "improve access to and the quality of information that Americans need to make informed healthcare decisions, including data about healthcare prices and outcomes, while minimizing reporting burdens on affected plans, providers, or payers."

CMS FINAL RULE

Interoperability and Patient Access Final Rule

- Finalized 4 new policies for Payers and 3 for Providers
- Payer policies apply to CMS Payers:
  - Medicare Advantage Plans
  - Medicaid
  - CHIP
  - Qualified Health Plan (QHP) in Federally Facilitated Exchange (FFE)
- Payer policies will also apply to providers who have their own health plan that includes Medicare Advantage

Application Programming Interfaces

- An API is a set of commands, functions, protocols, or tools published by a software developer
- That enables other developers to create programs (“Apps”) that interact with the software
- Without needing to know its internal workings
- And that maintain consumer data privacy standards

CMS FINAL RULE

Interoperability and Patient Access Final Rule

- CMS says the “touch points” of this rule are:
  - Enabling patients to access health information electronically without special effort through APIs
  - Ensuring that providers have access to information on patients regardless of whether they previously received care; preventing providers from inappropriately restricting the flow of information to other providers and payers; and reducing burden on providers
  - Ensuring that payers make enrollee electronic health information available through an API
  - Making it easy for patients and providers to identify providers within a plan’s network

Summary of New Policies

Affected Party	Policies	Compliance Dates
CMS Payers - Medicaid - CHIP - Medicare Advantage Plans - QHPs through the ACA Exchange	1. Patient Access through APIs	January 1, 2021 Update: CMS will not enforce until July 1, 2021
	2. API access to published provider directory data	January 1, 2021 Update: CMS will not enforce until July 1, 2021
Providers	3. Admission, Discharge, and Transfer Event Notifications	May 1, 2021
	4. CMS to report providers that may be information blocking	Fall 2020
	5. CMS to report providers that don't list or update digital contact information	Fall 2020

Avoiding Public Reporting

	Impact to providers	Next steps
Prevention of information blocking	• Applies to providers that attest to information blocking statements as part of **Promoting Interoperability (PI) program** requirements • Providers who attest "no" to statements will be publically listed	• Continue to attest that Certified EHR Technology (CEHRT) is implemented and used according to three prevention of information blocking statements
Digital contact information	• Encourages providers to include their digital contact information in **National Plan & Provider Enumeration System (NPPES)** • NPPES could offer another source of information for direct addresses • Providers who do not list their digital contact information will be publically listed	• Consider adding your own providers' digital contact information to NPPES • Encourage trading partners to add digital contact information to NPPES, and update your EHR's directory accordingly

Summary of Provider Impact

- Review statements in the Promoting Interoperability Program of Merit-based Incentive Payment System (MIPS) reporting
  - Make sure these statements reflect that you do not engage in information blocking.
  - CMS will publicly report providers who engage in information blocking through the database of Physician Compare and on the CMS website.
- Update digital contact information in National Plan and Provider Enumeration System (NPPES)
  - CMS will begin reporting names and NPIs of providers who do not have updated / digital contact information
- Prepare to make Admissions, Transfer, and Discharge Notifications beginning May 2021

ONC FINAL RULE

The ONC Interoperability and Information Blocking Final Regulation

- Issued by the Office of the National Coordinator for Health Information Technology
- Defines eight (8) exceptions to “information blocking” as defined in the 21st Century Cures Act
- Also provides updates to the 2015 Edition Certification Criteria, including Adoption of the United States Core Data for Interoperability (USCDI) as a Standard
- These rules and exceptions also apply to providers!

Summary of Changes for Providers

Policy	Compliance Date
Information Blocking	May 2021
EHR certification criteria updated	Adoption of USCDI – Vendor Compliance: Year 2022
	Clinical Quality Measures (CQMs) Report – June 30, 2020
	Electronic Health Information (EHI) Export – Vendor Compliance: Year 2023
	Application Programming Interfaces (API) – Vendor Compliance Year 2022

ONC FINAL RULE

- This rule is complicated – and the majority of it is targeted toward health IT developers.
- Establishes Conditions of Certification requirements for the ONC Health IT Certification Program.
- Developers will utilize this program / certification who wish to provide applications for patients to access EHR
- This is a long-term implementation

INFORMATION BLOCKING

- In general, information blocking is:
  - A practice engaged in by a
    - Health IT developer of certified health IT
    - Health information network;
    - Health information exchange; or
    - Healthcare provider
  - That is likely to interfere with access, exchange, or use of electronic health information (EHI).
    - Except as required by law or specified by the Secretary of Health and Human Services (HHS) as a reasonable and necessary activity

Examples of Information Blocking

- A health care provider has the capability to provide same-day access to EHI in a form and format requested by a patient or patient's health care provider, but takes several days to respond.
- A health care provider charges unnecessary and unsubstantiated fees for access to EHI.

EXCEPTIONS

PREVENTING HARM EXCEPTION
PRIVACY EXCEPTION
SECURITY EXCEPTION
EXCEPTIONS THAT INVOLVE not fulfilling requests to access, exchange, or use EHI
INFEASIBILITY EXCEPTION
HEALTH IT PERFORMACE EXCEPTION
8
EXCEPTIONS TO THE INFORMATION BLOCKING PROVISION
LICENSING EXCEPTION
COSTS EXCEPTION
CONTENT AND MANNER EXCEPTION
EXCEPTIONS THAT INVOLVE procedures for fulfilling requests to access, exchange, or use EHI

Complying with Information Blocking Rule

- Review and revise HIPAA privacy and security policies, and other policies relevant to access and information sharing, to ensure compliance with information blocking rules.
  - Make sure to include procedures for patient requests for EHI
  - Review procedures regarding fees for patient records.
  - Provide timely responses to requests for data access.
  - Check that you're covered under the ONC information blocking exceptions if there are cases where you withhold or delay access.
  - Retain documentation supporting your approach.
    - You need to be prepared to defend against allegations of information blocking.
    - Document requests for information
    - If this information was furnished, how long did it take?
    - If this information was not furnished, what exception applied?

Summary of Provider Impacts

Rules	Policy	Compliance Dates
ONC Final Rule	Information Blocking	May, 2021
CMS Final Rule	CMS publicly reporting providers engaging in information blocking	Fall 2020
	CMS publicly reporting providers who fail to update their digital contact information in the NPPES	Fall 2020
	Admission, Discharge, and Transfer Event Notifications	May 1, 2021

RELATED ISSUES

Price Transparency Final Rule

Two Requirements:

- Publishing the five standard charges for all items and services in comprehensive machine-readable digital file; and
  - Gross charges, payer-specific negotiated charges, discounted cash prices, de-identified minimum negotiated charges, de-identified maximum negotiated charges
- Publishing a list of standard charges for at least 300 non-urgent, “shoppable services” in a patient-friendly format.
- Effective January 1, 2021

MANDATORY VACCINE POLICIES

- Generally, mandatory vaccine policies are legal
- High risk employers mandate the flu vaccine

MANDATORY VACCINE POLICIES

- *Jacobson v. Massachusetts,* 197 U.S. 11 (1905) – Supreme Court says states can, within their police powers, mandate Smallpox for everyone, without exception.
- *Zucht v. King,* 260 U.S. 174 (1922) – Supreme Court says states can prohibit unvaccinated students from attending school.

MANDATORY VACCINE POLICIES

- Mandates generally exist for:
  - Children (entering school for first time / secondary school / college)
  - Healthcare Workers
  - Hospital/Nursing Home Patients
  - Military Personnel
  - Immigrants
  - Persons Traveling to Foreign Countries

MANDATORY VACCINE POLICIES

- Legal Framework
  - Americans With Disabilities Act of 1990 (ADA)
  - Title VII of the Civil Rights Act of 1964

ADA

Relevant to Pandemic in Three Ways:

1. Regulates employers' disability-related inquiries and medical examinations for applicants and employees
2. Prohibits covered employers from excluding individuals with disabilities from the workplace for health/safety reasons unless they pose "direct threat"
3. Requires reasonable accommodations for individuals with disabilities (absent undue hardship)

ADA

Employers will have legal duty under ADA to allow certain exceptions to a mandatory vaccine policy

- EEOC considered this issue in 2009 in response to H1N1 pandemic – an employee with underlying medical conditions may request an accommodation based on their health.
  - For example, if they are high risk and the side effects are unknown.

ADA

If employees request an exemption from a mandatory vaccine policy, employers will need to consider:

- Whether the requested accommodation is a reasonable one; and
- Whether it imposes an undue burden on operations and the health and safety of coworkers.

Title VII

- EEOC concluded in 2009 guidance that Title VII protects employees with sincerely held religious beliefs from being forced to undergo vaccination if vaccination legitimately offends an employee's religious beliefs.
- Employers must balance employees' right to be free from religious discrimination against the burden that accommodation would create in the work place.

OTHER CONIDERATIONS

- Liability
- Public Opinion – 35% of Americans say they will not get the vaccine
- Risk Balancing – employers who cannot effectively socially distance and/or work with high-risk populations
- Alternatives

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