BAIRD HOLM'S 32nd Annual VIRTUAL HEALTH LAW FORUM

Starts at 8:45 a.m.

Welcome

Michael W. Chase

CARES Act Funds: No Strings Attached?

Starts at 9:00 a.m.

John R. Holdenried
Zachary J. Buxton

Disclaimer

Legal advice is often highly dependent on the facts unique to each situation. As such, the content of this presentation is not legal advice and is provided for general information purposes only. No attorney-client relationship is created by the use of this content. Any opinions that we express herein are our own and do not necessarily represent the opinions of Baird Holm LLP.

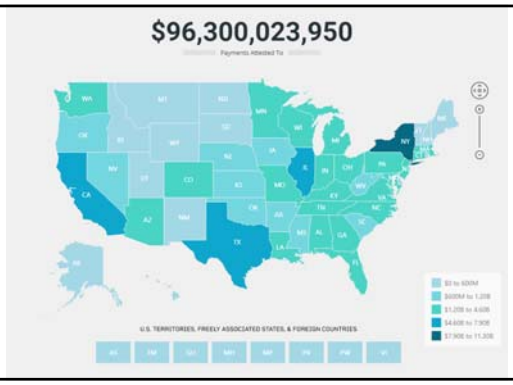
Outline

- Provider Relief Fund Payments
- Paycheck Protection Program
- Medicare Accelerated and Advance Payments

Goals

- Highlight the background on PRF payments and improve familiarity with acceptable and unacceptable uses of funds
- Outline potential risk areas in Paycheck Protection Program
- Identify risks of Medicare Accelerated and Advance Payments and steps for repayment to CMS
- Understand necessary steps for compliance

PROVIDER RELIEF FUND



State	# of Individual PRF Payments	Total PRF Payments by State	Minimum PRF Payment	Average PRF Payment	Maximum PRF Payment
IL	14,287	$ 5,008,471,295.00	$ 1.00	$ 350,561.44	$ 315,963,153.00
WI	4,737	$ 1,410,082,079.00	$ 3.00	$ 297,674.07	$ 63,987,172.00
IA	3,600	$ 1,050,850,595.00	$ 3.00	$ 291,902.94	$ 58,494,560.00
KS	3,664	$ 1,026,713,624.00	$ 3.00	$ 280,216.60	$ 68,157,597.00
NE	2,564	$ 736,549,789.00	$ 4.00	$ 287,265.91	$ 63,127,282.00
SD	1,032	$ 429,189,114.00	$ 2.00	$ 415,880.92	$ 65,197,203.00

Top 10 Recipients of PRF Payments by State						
	Illinois	Wisconsin	Iowa	Kansas	Nebraska	South Dakota
1	$315,963,153	$63,987,172	$58,494,560	$68,157,597	$63,127,282	$65,197,203
2	$159,153,092	$63,027,573	$32,025,837	$36,019,520	$22,292,114	$35,619,556
3	$153,392,712	$46,988,617	$30,111,586	$30,260,621	$18,126,646	$24,957,377
4	$115,670,858	$40,861,039	$26,444,420	$19,928,965	$15,153,601	$24,594,405
5	$106,806,199	$40,123,172	$24,922,926	$16,104,845	$14,702,528	$17,356,926
6	$95,183,813	$37,361,241	$23,841,028	$15,145,648	$13,619,212	$15,663,411
7	$93,874,366	$30,047,911	$19,353,626	$12,626,235	$13,526,603	$12,997,833
8	$86,084,926	$26,730,140	$17,881,581	$12,190,474	$13,301,829	$12,270,756
9	$84,449,924	$26,366,986	$16,663,271	$12,056,282	$13,269,351	$11,821,019
10	$82,985,287	$23,842,186	$14,611,489	$11,761,466	$12,822,687	$9,141,308

PRF Payments; Measures of Central Tendency				Top 50 Recipients as % of State Total
State	Mean	Median	Mode	
Illinois	$ 350,561.40	$ 8,764.00	$ 7.00	54.96%
Wisconsin	$ 297,674.07	$ 5,961.00	$ 13.00	59.27%
Iowa	$ 291,902.90	$ 6,820.00	$ 33.00	49.14%
Kansas	$ 280,216.60	$ 10,252.00	$ 1,849.00	52.00%
Nebraska	$ 287,265.90	$ 7,238.00	$ 390.00	58.52%
South Dakota	$ 415,880.92	$ 5,530.50	$ 609.00	88.75%

Phase 1 March 6, 2020	Phase 2 March 18, 2020	Phase 3 March 27, 2020	Phase 3.5 April 24, 2020
Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020	Families First Coronavirus Response Act	CARES Act	Paycheck Protection Program and Health Care Enhancement Act
~$8 Billion	$192 Billion	$2.7 Trillion	$799 Billion
Immediate health response	Tax credits for families; waived cost sharing for COVID-19 treatment	PRF; PPP; Direct payments to individuals; Medicare Advanced & Accelerated payments	Additional $ for PRF, PPP, and EIDL

Provider Relief Fund, generally

- "Public Health and Social Services Emergency Fund"
- $175 billion appropriated in Phases 3 and 3.5
  - CARES Act: $100 billion; PPP HCE Act: $75 billion
- HHS provides oversight; managed by HRSA
  - Payments distributed through United Healthcare via Optum Bank
  - "HHSPAYMENT"

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Distribution		Amount	Dates	Recipients	Calculation
Phase 1 General Distribution	Tranche 1	$30 Billion	4/10-4/17	~320,000 providers who bill Medicare FFS	Payment Allocation per Provider = 2019 Medicare Fee-For-Service Payments / $453 Billion** x $30 Billion
	Tranche 2	$20 Billion	4/24	~15,000 providers who bill Medicare FFS	Payment Allocation per Provider = ((Most Recent Tax Year Annual Gross Receipts x $50 Billion) / $2.5 Trillion) – Initial General Distribution Payment to Provider
Phase 2 General Distribution		$18 Billion		Application based (Medicaid and CHIP; dental practices, ALFs)	Payment allocation per Provider = 2% of patient care revenue based on FY 2017, 2018, or 2019 tax returns
Phase 3 General Distribution		$20 Billion	10/1	Similar to Phase 1 and 2	Payment allocation per provider = % change in operating revenues from patient care minus operating expenses from patient care; adjusted for payments received, if any, under Phase 1, Phase 2, and Targeted distributions
Uninsured Reimbursement		$1.3 Billion*	10/6	Application based (funding is ongoing)	Medicare rate, subject to additional funding from PRF

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Distribution		Amount	Dates	Recipients	Calculation
Targeted Distributions	Safety Net Hospitals	$14.4 Billion	06/9; 07/10; 08/14	Safety net hospitals, acute care facilities, 80 free-standing children's hospitals	The distribution amount for an eligible safety net hospital is the proportion of the individual facility score (number of facility beds multiplied by DPP for an acute care facility or number of facility beds multiplied by Medicaid only ratio for a children's hospital) to the cumulative facility scores for all safety net hospitals, times the $10 billion safety net distribution.
	Rural Providers	$11 Billion	05/06; 07/10	4,000 rural health care providers; 500 specialty rural hospitals, urban hospitals with certain rural Medicare designations, and hospitals in small metro areas	Payment Allocation per Hospital = Graduated Base Payment* + 1.97% of the Hospital's Operating Expenses
	High-Impact Hospitals	$10 Billion	05/07; 07/17	395 hospitals (round 1); 695 hospitals (round 2)	Payment Allocation per Hospital = Number of COVID-19 Admissions* x $76,975 (Round 1); Additional Payment Allocation per Hospital = $2 Billion x (Hospital Medicare Funding / Sum of Medicare Funding for 395 Hospitals) (Round 2)
	SNFs	$4.9 Billion	5/22	~13,000 SNFs	Payment Allocation per Facility = Fixed Payment of $50,000 + $2,500 per Certified Bed*
	SNFs and Nursing Homes	$2.5 Billion	8/27	~15,000 SNFs and nursing homes	Eligible facilities received a per-facility payment of $10,000 plus a per-bed payment of $1,450. A facility has to have at least 6 certified beds to be deemed as eligible for payment.
	Indian Health Service	$0.5 Billion	5/29	~300 hospitals, clinics, and urban health centers	Payment Allocation per Hospital = $2.81 Million + 3% of Total Operating Expenses (Hospitals); Payment Allocation per Clinic/Program = $187,000 + 5% (Estimated Service Population x Average Cost per User) (Clinics and Programs); Payment Allocation per Program = $181,000 + 6% (Estimated Service Population x Average Cost per User) (Urban Programs)

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Acceptable Uses of PRF Payments

- Sources governing acceptable uses:
  - Statutory language appropriating PRF payments under CARES Act and PPP HCE Act
  - Terms & Conditions
  - Reporting Requirements (10/22/2020)
- To a lesser extent:
  - PRF FAQs published by HHS

CARES Act/PPP HCE Act

"[T]o prevent, prepare for, and respond to coronavirus, domestically or internationally, for necessary expenses to reimburse, through grants or other mechanisms, eligible health care providers for health care related expenses or lost revenues that are attributable to coronavirus."

Terms & Conditions*

"The Recipient certifies that the Payment will only be used to prevent, prepare for, and respond to coronavirus, and that the Payment shall reimburse the Recipient only for health care related expenses or lost revenues that are attributable to coronavirus."

CARES Act/PPP HCE Act

- Temporary structures;
- Leasing of properties medical supplies and equipment including protecting equipment and testing supplies;
- Increased workforce and trainings;
- Emergency operations centers;
- Retrofitting facilities; and
- Surge capacity

Reporting Requirements

- General and administrative expenses attributable to coronavirus (mortgage/rent, insurance, personnel, lease payments, etc.);
- Healthcare related expenses attributable to coronavirus (supplies, facilities, IT, other health care related expenses)

FAQs*

- Supplies;
- Equipment;
- Workforce training;
- Developing and staff emergency operations centers;
- Reporting COVID-19 test results;
- Building or constructing temporary structures;
- Acquiring additional resources to expand or preserve care delivery;
- Lost revenues attributable to coronavirus; and
- Vaccine distribution

REMEMBER: "[T]O PREVENT, PREPARE FOR, AND RESPOND TO CORONAVIRUS"

Unacceptable Uses of PRF Payments

- Expenses or losses reimbursed from other sources
  - Paycheck Protection Program
  - Direct patient billing, commercial insurance, Medicare/Medicaid, CHIP, FEMA, PRF COVID-19 claims reimbursement
- Balance billing for presumptive or actual cases of COVID-19
- Slew of statutes at end of Terms & Conditions
- No clear connection to prevent, prepare for, or respond to coronavirus
  - If the coronavirus had never occurred, would you have this expense/lost revenue?
  - Clear permissible and impermissible uses, but what about gray areas?

Reporting Requirements

- Update published November 2, 2020
  - HHS has updated guidance twice since original publication in September 2020
- Portal opens January 15, 2021; reports due by:
  - February 15, 2021 (funds used in CY20)
  - July 31, 2021 (funds used 1/1/21-6/30/21)
- Recipients will report:
  - Step 1 → Expenses attributable to coronavirus not reimbursed by other sources;
  - Step 2 → Lost revenues attributable to coronavirus;
  - Additional non-financial data
- *See* "Use of Funds" in PRF FAQ (page 15)
  - Note: As sub-regulatory guidance, these FAQs are subject to change

Government Oversight

- HHS OIG
  - Multiple initiatives in OIG work plan related to PRF
- Pandemic Response Accountability Committee (PRAC)
  - Oversight across agencies (e.g., potential fraud in PRF payments and PPP)
- DOJ for False Claims Act enforcement
  - Attestation and Terms & Conditions
  - *Qui tam*/whistleblower lawsuits
- Data submitted by providers through HHS

Compliance Steps

- Appoint individual or committee to lead both compliance and reporting efforts
  - Be familiar with acceptable and unacceptable uses
- Monitor frequent changes and updates from HHS
- Maintain appropriate documentation; could be years before audit
- Be prepared to work closely with outside advisers (i.e., accountants, consultants, attorneys)
- Assume that government will closely scrutinize appropriate uses of the PRF payments and position organization to demonstrate compliance
- Accurate accounting practices

Takeaways

- Avoid clearly ***unacceptable*** uses of PRF payments and closely scrutinize "gray" areas
  - For those "gray" areas, be prepared to demonstrate how those uses qualify and be prepared to potentially repay if you cannot justify those amounts
- Know reporting guidelines and reporting deadlines
  - February 15, 2021 (***before*** 12/31/20)
  - July 31, 2021 (1/1/21-6/30/21)
- Continue to monitor for updates; current surge of coronavirus in Midwest ***may*** impact reporting requirements, certain deadlines, etc.
- Be prepared for government oversight; PRAC's strategic plan published online for 2020-2025

PAYCHECK PROTECTION PROGRAM

Paycheck Protection Program

- **Lender:** Participating banks, loans guaranteed by SBA
- **Amount:** Up to 2.5x monthly payroll expense
- **Terms:**
  - 1% interest
  - 2-year term or 5-year term, depending on when loan was originated
  - Forgivable, if proceeds spent properly

Applicable Legislation

- Families First Coronavirus Response Act (FFCRA)
  - Enacted on March 18, 2020
  - Emergency paid sick leave and emergency paid family leave; payroll tax credits
- Coronavirus Aid, Relief, and Economic Security Act
  - Enacted on March 27, 2020
  - Economic stimulus, tax relief & additional employer relief
- PPP Flexibility Act
  - Enacted June 4, 2020
  - Expands PPP and relaxes requirements

Eligible Uses

- Payroll costs
- Interest on mortgage or other debts incurred before 2/15/20
- Rent on lease agreement in force before 2/15/20
- Utilities that began before 2/15/20

Scrutiny

- Many hospitals, medical practices, nursing homes, and ancillary providers applied for and received loans
- Some subsequent backlash about receipt by health care providers and other businesses
- Additional scrutiny prompted by public release of recipient information

Government Oversight

- House Oversight Panel (9-1-2020) alleges multiple problems:
  - Multiple loans to same companies
  - Ineligible to contract
  - Incomplete info

"Double Dippers"

- News articles about hospitals receiving PRF, PPP, and Medicare Advance Payments (e.g. COVID Stimulus Watch)

Certification

- Application must certify to good faith belief in need for funds to support ongoing operations
- Early concern about retrospective review of need
- Recent guidance: if less than $2 million, then deemed to be in good faith
- If greater than $2 million, what's necessary to support good faith?

Loan Necessity Questionnaire

- Released 10-26-2020
- Required for Loans over $2 million
- Questions
  - Receipts, expenses, Q2 of 2020 and 2019
  - Ordered to shut down or alter operations, or voluntary
  - Cash outlays for mandatory alterations and voluntary alterations
  - Borrower's cash, savings, and temporary cash investments prior to the PPP application
  - Prepayment of any outstanding debt prior to the end of its Covered Period
  - Employee received compensation in excess of $250,000
  - Funds from any other CARES Act program

Impact on Cost Report

- Early guidance suggested offset to costs
- Current guidance
  - Will not offset expenses
  - Report PPP as revenue (informational)
  - A direct incentive to keep workers on payroll

Impact on PRF

- PRF payments cannot be used to reimburse expenses reimbursed by PPP loans
- Recordkeeping will be key

Takeaways

- Closely scrutinize "gray" areas
- Continue to monitor for updates
- Be prepared for increased government oversight
- Unclear whether greater scrutiny than PRF payments

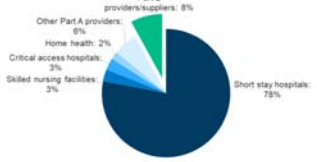
MEDICARE ACCELERATED AND ADVANCE PAYMENTS

	Top 10 Recipients of Medicare Accelerated or Advance Payments by State					
	Illinois	Wisconsin	Iowa	Kansas	Nebraska	South Dakota
1	$ 220,768,655.00	$ 156,543,636.00	$ 92,799,950.00	$ 163,187,000.00	$ 135,000,000.00	$ 57,152,877.66
2	$ 172,327,619.00	$ 143,821,840.00	$ 74,898,600.00	$ 81,916,315.00	$ 88,957,892.00	$ 21,408,434.00
3	$ 164,884,487.12	$ 136,100,000.00	$ 55,046,626.00	$ 73,131,759.00	$ 52,671,839.00	$ 19,831,876.00
4	$ 163,200,000.00	$ 71,028,478.00	$ 51,279,576.00	$ 31,204,780.00	$ 28,963,793.00	$ 12,783,112.00
5	$ 142,394,144.00	$ 64,800,000.00	$ 36,282,934.00	$ 31,000,000.00	$ 24,267,346.00	$ 11,587,946.00
6	$ 123,754,840.00	$ 53,881,345.00	$ 35,206,784.00	$ 29,325,000.00	$ 24,000,000.00	$ 10,446,122.96
7	$ 106,179,182.00	$ 42,764,977.00	$ 30,305,198.00	$ 26,681,235.00	$ 23,783,460.00	$ 9,670,970.00
8	$ 93,240,897.00	$ 40,707,800.00	$ 26,003,692.00	$ 26,141,251.00	$ 22,127,736.00	$ 6,013,363.33
9	$ 80,911,892.00	$ 36,745,835.00	$ 24,711,659.00	$ 22,198,628.00	$ 18,817,307.00	$ 4,170,209.40
10	$ 75,354,124.00	$ 33,325,285.00	$ 24,328,051.00	$ 21,883,886.00	$ 18,000,000.00	$ 2,931,121.82

Medicare Accelerated and Advance Payments; Measures of Central Tendency			
State	Mean	Median	Mode
Illinois	$ 4,175,410.00	$ 234,809.00	$ 150,000.00
Wisconsin	$ 7,210,123.00	$ 344,082.00	$ 350,000.00
Iowa	$ 4,655,642.00	$ 291,189.00	$ 127,000.00
Kansas	$ 4,479,116.00	$ 370,000.00	$ 30,000.00
Nebraska	$ 5,176,035.00	$ 435,733.00	$ 500,000.00
South Dakota	$ 2,617,468.00	$ 193,059.00	n/a

Figure 1

The Vast Majority of Medicare Accelerated and Advance Payments (92%) Went to Part A Providers



Total Medicare Advance Payments: $100 billion

NOTE: Funds to Part A providers that offer both Part A and Part B services include loans for services that were funded through both the Part A trust fund (for Part A services) and the Part B trust fund (for Part B services).
SOURCE: KFF analysis of Centers for Medicare & Medicaid Services data on Accelerated and Advance Payments.

KFF

Medicare AAPs

- Section 3719 of the CARES Act expanded existing program
  - Inpatient hospitals, critical access hospitals, cancer hospitals, children's hospitals
- Application through Medicare Administrative Contractor
- $100 billion distributed
  - $78.4 billion to short stay hospitals
  - $2.6 billion to CAHs
- CMS suspended program April 26, 2020 (and again on October 8, 2020)

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Medicare AAPs

- Congress extended repayment obligations in Continuing Appropriations Act, 2021 and Other Extensions Act
- Repayment of Medicare Accelerated and Advance Payments
  - Repayment does not begin until one year from the date of disbursement
  - Thereafter, Medicare payments due to provider offset by 25% for next 11 months
  - Thereafter, Medicare payments due to provider offset by 50% for next 6 months
  - After 29 months, any outstanding balance shall be paid in full
  - Interest accrues at 4% if balance is unpaid after 30 months

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FAQS from CMS

- Recoupment will automatically begin 12 months after disbursement
  - Likely spring 2021
- Cannot extend recoupment beyond 29-month window
- Providers are allowed to repay in one lump sum; Confirm the process for repayment with your MAC
  - Can pay lump sum at any time, even after recoupment begins
- Can request an Extended Repayment Schedule
  - Need to meet criteria for "hardship" or "extreme hardship" (which is a high hurdle)

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Takeaways

- Monitor when original Medicare AAP was received; tickler for 12-months out
- Evaluate if recoupment or lump sum payment makes sense for your organization
- Do not plan on Congress forgiving Medicare AAPs as ~$100 billion and coronavirus have both strained the Medicare trust fund

Questions?

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Transformations in Telemedicine During 2020's Public Health Emergency
Starts at 9:45 a.m.

Kimberly A. Lammers
Michael W. Chase

Agenda

- Current state of telehealth
- Federal and state policy changes
- Legal issues
  - The Good News
  - The Bad News
- Takeaways and other important considerations

Telemedicine … Then

Telemedicine … Then

- Sluggish adoption of telemedicine technology
- Providers (and consumers) struggled with awareness and adoption
- Often times inconvenient
- Limited in both location and reimbursement
- Lots of red tape
- Easier to practice the same

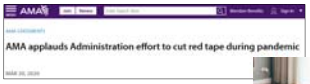
Telemedicine … Now

Telemedicine … Now

Economy May Be Down, but Digital Health Investments Boom

Is Telehealth the New Normal?

Telehealth's evolution continues as COVID-19 restrictions loosen



The COVID Seesaw: Telehealth Visits Way Up, In-person Visits Down

How Did We Get Here So Quickly?

- CMS issued waivers and interim final rules to expand access to telehealth services
- Many state Medicaid plans and private payors followed suit

"Dr. Jones! What have I told you about messing around with the 3D bioprinter!?"

Issue #1: Fraud & Abuse

- Regulators' growing focus on telehealth
- What leads to (potentially) fraudulent activity?
  - Manipulating the system
  - Substantiating level of service billed
  - Over-treating patients
  - Billing for multiple visits (when only 1 is necessary)
  - Medical necessity
  - Documentation to support referrals/orders for diagnostic tests

The Good News

- Enforcement examples help providers enhance ongoing compliance efforts
- OIG Work Plan includes telehealth
- Most organizations have a good start – dust off your compliance plans
  - Integrate telehealth waste, fraud, and abuse into your existing compliance efforts

The Bad News

- DOJ recently released largest-ever health care fraud enforcement action

https://oig.hhs.gov/newsroom/media-materials/2020takedown/

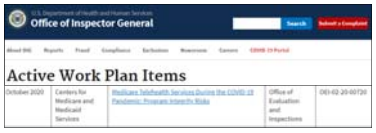
Telehealth Takedown

- Alleged scheme involved paying doctors and NPs to order unnecessary DME, genetic and diagnostic testing, or medications without any patient interaction or only a brief phone conversation
- CMS revoked billing privileges for 256 individuals

https://www.justice.gov/opa/pr/national-health-care-fraud-and-opioid-takedown-results-charges-against-345-defendants
https://oig.hhs.gov/media/documents/2020HealthCareTakedown_FactSheet.pdf
https://oig.hhs.gov/media/documents/telemed-scheme-print.pdf

The Bad News

- It's on the OIG's Radar (and should be on yours)



- Expect enforcement trend to continue

Recommendations

- Don't forget about documentation/recordkeeping
- Update compliance plans to address telehealth issues
  - Keep up-to-date with OIG Work Plan, enforcement examples, and guidance
  - Including compensation and billing arrangements

Issue #2: Reimbursement

- Prior to public health emergency, CMS had restrictive limits
  - Concern about potential fraud and abuse
  - Caution due to fear of explosion in growth (and cost to Medicare)

Telehealth Expansion

- Telehealth services in patient homes and other settings
- For new patients in addition to established patients
- Some telephone only services permitted
- Virtual check-in visits and e-visits
- Ability to waive copay/cost-sharing requirements for certain services

The Good News

- Creates opportunities to furnish telehealth services in new ways (and get paid for them!)
  - Replace volumes of in-person visits lost during pandemic
  - Attract new patients worried about pandemic and/or seeking convenience
- Expands access to specialists and high demand services

The Bad News

- Rapid change has occurred
- Guidance is not consistent among payors
  - Even guidance issued by CMS has evolved over the months for some issues
- Not one-size-fits-all solution

The Bad News

- Increased competition
  - May create negative effect over the long term in provider/patient relationship and continuity of care
- Cost of platforms/tools
- Uncertainty regarding which changes will be permanent

Recommendations

- Evaluate coding and billing practices to be consistent with government and commercial payor requirements
  - Audit (when you can go) to spot check compliance with changed codes & guidelines
- Keep track of dates of waivers and policy changes
  - May be difficult to recreate if/when audits occur

Recommendations

- Monitor status of waivers and expansion in coverage for changes
- Capitalize on momentum for telehealth services to add convenience and attract patients (even after pandemic)
- Consider areas where access is limited and whether telehealth services could be viable option to bring providers to patients

Issue #3: Licensure

- Telehealth has been limited by geographic rules
- Telemedicine providers are usually required to be licensed in each state in which he/she practices (the state where the ***patient*** is located)
- Some states have special permits/licenses for telemedicine providers
- DEA controlled substance dispensing rules/e-prescribing rules

Licensure Issues

- In response to COVID-19, many states have loosened the requirements

Licensure Issues

STATE of NEBRASKA
OFFICE OF THE GOVERNOR
LINCOLN

EXECUTIVE ORDER No. 20-10

CORONAVIRUS – ADDITIONAL HEALTHCARE WORKFORCE CAPACITY

Pursuant to this declaration, I hereby order and direct the following:

1. The provisions of Neb. Rev. Stat. § 38-121 regarding credentialing, and its implementing regulations, are hereby temporarily suspended in order to permit individuals who are properly and lawfully licensed to engage in advanced practice nursing, emergency medical services, medicine and surgery, mental health practice, nursing, osteopathy, perfusion, pharmacy, psychology, respiratory care, and surgical assisting in a U.S. state or territory to work in Nebraska during the state of emergency so long as they are in good standing and free from disciplinary action in the states where they are licensed; and

http://dhhs.ne.gov/Pages/COVID-19-Nebraska-Guidance-Documents.aspx

Licensure Issues

COVID-19 – EMERGENCY PROCLAMATION

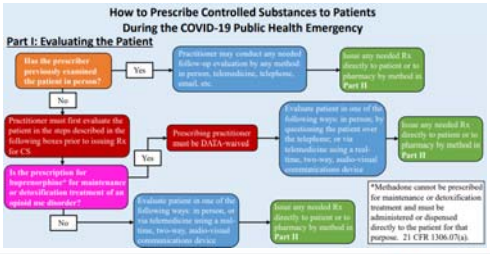
(Effective November 10, 2020)

Governor Kim Reynolds issued an Emergency Proclamation due to COVID-19 extending the following temporary provisions from **Tuesday, November 10, 2020, until Thursday, December 10, 2020, at 11:59 p.m.**

1. **No Iowa Medical License Required:** A physician may practice medicine/telemedicine in Iowa without an Iowa medical license on a temporary basis to aid in the emergency, if a physician holds at least one active medical license in another United State jurisdiction, and all medical licenses held by a physician in other United States jurisdictions are in good standing, without restrictions or conditions.

https://medicalboard.iowa.gov/

Licensure Issues



The Good News

- More flexibility for providers and improved access to telehealth services

The Bad News

- Organizations still must ensure verifications of clinicians
- Each state has its own set of regulations (no national telemedicine program)
- Lack of license portability
- After COVID-19, be prepared to comply with pre-pandemic laws and regulations

Recommendations

- Monitor state licensure requirements, including exceptions/waivers (each state has its own "sunset" provisions)
- Evaluate state consent laws/requirements and online prescribing rules

Issue #4: Medical Staff

- Credentialing and privileging process must be followed for hospital services, even if practitioners are remote
- In other settings, must still vet practitioner qualifications and monitor quality of services

Credentialing by Proxy/Delegated Credentialing

- Creates streamlined credentialing process
  - Rely on certain portions of process being done by others
- Good solution for telehealth services with multiple covering practitioners
  - Tele-ICU, tele-stroke, tele-ED, etc.

The Good News

- Eases burden on medical staff, office staff and credentialing committees
  - Can still use regular process for practitioners providing both in-person & telehealth services
- Promotes quicker implementation and improved access to services

The Bad News

- Bylaws must address process for credentialing telehealth practitioners
  - Not the same as disaster privileging or temporary privileging
- Must comply with CoP requirements
  - Contract is required

Recommendations

- Review bylaws to determine whether delegated credentialing/telehealth credentialing language is included
- Verify process being followed matches process outlined in bylaws

Issue #5: HIPAA

- Pre-pandemic privacy and security requirements were a perceived barrier to wider adoption of telehealth
- Needed to increase telehealth services quickly
- What is a "HIPAA compliant" platform?
- Cyber risk remains at an all-time high in health care

Don't Forget HIPAA

HHS.gov
Health Information Privacy

Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency

We are empowering medical providers to serve patients wherever they are during this national public health emergency. We are especially concerned about reaching those most at risk, including older persons and persons with disabilities. – Roger Severino, OCR Director.

https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html

Don't Forget HIPAA

Under this Notice, covered health care providers may use popular applications that allow for video chats, including Apple FaceTime, Facebook Messenger video chat, Google Hangouts video, Zoom, or Skype, to provide telehealth without risk that OCR might seek to impose a penalty for noncompliance with the HIPAA Rules related to the good faith provision of telehealth during the COVID-19 nationwide public health emergency. Providers are encouraged to notify patients that these third-party applications potentially introduce privacy risks, and providers should enable all available encryption and privacy modes when using such applications.

Under this Notice, however, Facebook Live, Twitch, TikTok, and similar video communication applications are public facing, and should not be used in the provision of telehealth by covered health care providers.

The Good News

- (During the pandemic, at least), providers can use platforms that may not be "HIPAA compliant"
- Increases access to care (and, probably, some consumers' satisfaction)
- Platforms are widely available (and being used a LOT during the pandemic)

The Bad News

- Cyber attacks continue in health care
  - March 2020: dark web searches for telehealth companies climbed 144%
- A lot more data is exposed versus a one-on-one/in-person setting
- How does telehealth technology communicate with EHR technology?
  - Does it need to be embedded?

Recommendations

- Evaluate security safeguards; update Security Risk Analysis
- Careful vendor evaluation and selection
- Think about how to integrate telehealth with existing technology platforms

Takeaways

- Telehealth is here to stay
  - No longer a short-term resource
- Compliance will continue to be a challenge
- Organizations need a long-term implementation strategy

Questions?

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Michael W. Chase
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Resources

- CMS
  - https://www.cms.gov/files/document/general-telemedicine-toolkit.pdf
  - https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet
  - https://edit.cms.gov/files/document/medicare-telehealth-frequently-asked-questions-faqs-31720.pdf
  - https://www.cms.gov/files/document/03052020-medicare-covid-19-fact-sheet.pdf

Resources

- Iowa
  - https://medicalboard.iowa.gov/
  - https://dhs.iowa.gov/ime/providers/faqs/covid19/telehealth
- Nebraska
  - http://dhhs.ne.gov/Pages/COVID-19-Nebraska-Guidance-Documents.aspx

Resources

- DEA
  - https://www.deadiversion.usdoj.gov/coronavirus.html
  - https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-023)(DEA075)Decision_Tree_(Final)_33120_2007.pdf

Resources

- AMA
  - https://www.ama-assn.org/system/files/2020-04/telemedicine-state-orders-directives-chart.pdf
- Federation of State Medical Boards
  - https://www.fsmb.org/siteassets/advocacy/pdf/states-waiving-licensure-requirements-for-telehealth-in-response-to-covid-19.pdf

Resources

- HIPAA
  - https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html
  - https://www.hhs.gov/sites/default/files/february-2020-hipaa-and-novel-coronavirus.pdf

Questions?

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The Election is Over—Now what?

Starts at 10:30 a.m.

John R. Holdenried
Tessa M. Lancaster

President Biden's Focus in Democratic Platform:

- Decreasing drug pricing
- Taking on the pharmaceutical industry
- Health care security through a public option
- Expanding long term care & services
- Affordable prescription drugs
- Attacking corporate concentration
- Rolling back Trump administration policy

Impact of Divided Congress

- Healthcare initiatives are likely to initially focus on regulatory initiatives
- Expect general review or pause of all pending regulations (and those finalized in lame duck)
- Unlikely to see bold legislative healthcare proposals but potential for compromise

Wild Cards

- Supreme Court decision on constitutionality of ACA
- COVID
- Biden healthcare experience
- The Courts (and all those Trump appointed judges)

General Areas

- HIPAA
- General fraud & abuse enforcement
- Value based arrangements & quality
- Anti-trust enforcement
- Rural healthcare
- Medicaid expansion

HIPAA

- HIPAA has never been a partisan issue
- Expect general review of all pending regulations (including information blocking)
- Greater focus on privacy enforcement

Fraud & Abuse Enforcement

- Trend of increased enforcement
- Recent Enforcement
- Current trends in criminal enforcement
- Data mining increasingly used by HHS OIG

Value Based Arrangements and Quality

- Value-based arrangements and payment for quality were a central focus of ACA
- Despite Republican opposition to ACA, CMS has pursued many VB and quality initiatives
- Expect a Biden administration to continue this

Anti-Trust

- Review M&A activity during Trump presidency
- General trends
  - Consolidation
  - Limited to no behavioral remedies
  - Increasing prominence of State Regulators
- Vertical integration guidelines
- COVID impacts
- Vice President elect Harris' Record

Rural Healthcare

- 340B likely to be protected from further cuts
- Should benefit from expanded access initiatives

Medicaid Expansion: Nebraska & Iowa

- Biden administration position
- Nebraska Medicaid expansion
  - Work requirement
- Iowa Medicaid expansion
  - Work requirement

Questions?

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The State of Health Information Privacy

Starts at 11:00 a.m.

Vickie B. Ahlers
Abigail T. Mohs

Accomplishments and Priorities

- Developments around the Individual Right to Access
- Information Blocking Rule
- Part 2: Statutory and Regulatory Changes
- Health Information Security
- Proposed Privacy Rule

Timeline of the Individual Right to Access

- 2000 HIPAA Privacy Rule
  - Establishes the Right
  - Creates a patient fee limitation
- 2009 HITECH Act
  - Permits individuals to direct electronic records to third parties under the Right to Access
  - Capped fee for ePHI for personal use requests; permitted costs associated with labor to extract ePHI
- 2013 Omnibus Rule
  - Extends third party directive to any record
  - Excludes from the patient rate the labor for retrieval of ePHI
- 2016 OCR Right to Access Guidance
  - Extends the patient rate to third party directives

Ciox Health, LLC v. Azar

- Background of the Case
  - Ciox (now MRO) is a business associate that processes medical records for hundreds of large health care providers across the country
  - Lawsuit stemmed from Ciox charging fees to third parties in excess of what could be charged to the individual

Ciox Decision

- Court sides with Ciox on two main issues
  - Omnibus Rule's expansion of the HITECH Act's third party directive was arbitrary and capricious
  - Fee limitation set forth in the 2016 guidance violated Administrative Procedures Act; is a "final agency action subject to review"

What Does This Ruling Mean For You?

- Third party directive
  - Only applies to ePHI
  - Good news: confusion rules around third party directive don't apply to paper records (for now)
  - Bad news: Bifurcated approach to third party directives
- Patient fee
  - Limited to personal use requests
  - Confusion continues around what labor costs can be charged to patients
  - But watch out … impending Proposed Rule could extend the fee limitation to third party directives

Right to Access Settlements

9 Settlements in 13 months; 7 of which came AFTER CIOX

- OCR Settles First Case in HIPAA Right of Access Initiative – September 9, 2019
- OCR Settles Ninth Investigation in HIPAA Right of Access Initiative – October 9, 2020

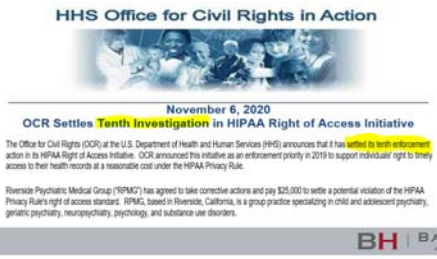
OCR collected $566,500 total from hospitals, physician practices and other covered entities. Collections ranged from $3,500 to $160,000 and included Corrective Action Plans

A couple of the violations had received technical assistance from OCR prior to the final resolution agreement


Resolution Agreements

Resolution Agreements and Civil Money Penalties

Do You Think They are Counting?


HHS Office for Civil Rights in Action

November 6, 2020

OCR Settles Tenth Investigation in HIPAA Right of Access Initiative

The Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services (HHS) announces that it has settled its tenth enforcement action in its HIPAA Right of Access Initiative. OCR announced this initiative as an enforcement priority in 2019 to support individuals' right to timely access to their health records at a reasonable cost under the HIPAA Privacy Rule.

Riverside Psychiatric Medical Group ("RPMG") has agreed to take corrective actions and pay $25,000 to settle a potential violation of the HIPAA Privacy Rule's right of access standard. RPMG, based in Riverside, California, is a group practice specializing in child and adolescent psychiatry, geriatric psychiatry, neuropsychiatry, psychology, and substance use disorders.

Right to Access Settlements-OCR is Sending a Message

Sending a Message about the Importance of Access to Health Records

OCR's enforcement actions are designed to send a message to the health care industry about the importance and necessity of compliance with the HIPAA Rules. OCR considers a variety of factors in determining the amount of a settlement including the nature and extent of the potential HIPAA violation; the nature and extent of the harm resulting from the potential HIPAA violation; the entity's history with respect to compliance with the HIPAA Rules; the financial condition of the entity, including its size and the impact of the COVID-19 public health emergency; and other matters as justice may require.

"Patients can't take charge of their health care decisions, without timely access to their own medical information," said OCR Director Roger Severino. "Today's announcement is about empowering patients and holding health care providers accountable for failing to take their HIPAA obligations seriously enough," Severino added.

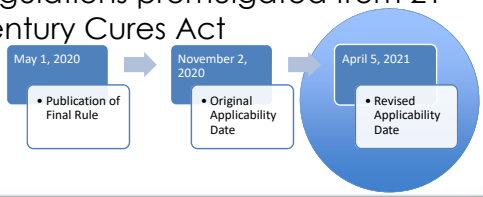
Natural Segue

Speaking of access to records…

HIPAA is no longer the only federal enforcement mechanism to ensure patients have access to their health information

Information Blocking Background

- Regulations promulgated from 21st Century Cures Act



Information Blocking Prohibition

- Information Blocking is a practice by an "actor" that is **likely to interfere** with **access, exchange, or use** of electronic health information ("**EHI**")

- INTERFERENCE
- INTENT
- NO EXCEPTION

Exceptions

ONC infographic found at https://www.healthit.gov/topic/information-blocking

Information Blocking Practices?

- Setting a standard 3 day delay on posting test results
- Restricting portal access of a parent/guardian when a minor patient turns 12
- Requiring multi-factor authentication for portal access
- Providing a USB containing requested records that aren't in current EHR
- Limiting the sharing of records to only providers with the same EHR vendor

Part 2 Statutory Updates

- Included in the CARES Act (March 27)
- Updated/added several statutory provisions
  - Aligned terms with HIPAA
  - Disclosures with Consent
  - Breach Notification
  - Penalties
- Promulgated amendments to regulations not to be effective sooner than March 27, 2021

Part 2 Regulatory Updates

- Regulatory Sprint to Coordinated Care-related final rule (July 15, 2020)
- The proposed rule was published in 2019, before the CARES Act, but intended to act as an interim, transitional standard
  - "takes important first steps toward the greater flexibility for information sharing envisioned by Congress in its passage of [...] the CARES Act."
- Changes/clarifications around several provisions:
  - When a non-Part 2 provider holds Part 2 records
  - Permitting broader consents; disclosures for payment/operations

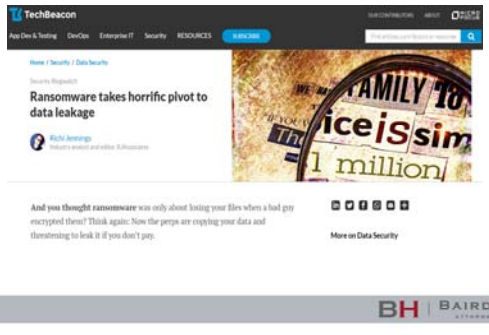
Part 2 Compliance

- Continues to be a moving target (this year's regulatory action was the third final rule since 2017)
- Alignment with HIPAA is finally "realized," but does that mean record maintenance is even muddier?
- How will the new statutory enforcement be implemented?

Security

Criminals are Opportunistic

- Enterprise-scale ransomware operations (BGH or "big game hunting")
- Ransomware-as-a-Service (RaaS)
  - Developers sell access to distributors through a partnership program
  - Financial model that splits profits
- Enterprise/Affiliate model
  - Initial attack installs multiple malware families
  - Partner with other cyber criminals and sell access to certain components of the criminal activity
- Examples
  - TrickBot – malware-as-a-service (MaaS)
  - Access to networks of devices infected by TrickBot are sold or rented to other cybercriminals



‘Horrific Pivot’: Data Extortion

- Significant percentage of ransomware incidents now involve data exfiltration
- Alternative method of monetization
- Enter system, gather data on your operations, exfiltrate data – then encrypt the data
- And only then do you get the ransom demand

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CrowdStrike: 2020 Global Threat Report

USD	BTC	Malware
$12.5M	~1,600	Ryuk
$10.0M	565	DoppelPaymer
$10.0M	1,326	REvil
$9.0M	1,250	Ryuk
$6.1M	850	Maze
$6.0M	763	REvil
$5.3M	680	Ryuk
$2.9M	375	DoppelPaymer
$2.5M	250	REvil
$2.5M	250	DoppelPaymer
$2.3M	300	Maze
$1.9M	280	DoppelPaymer
$1.6M	216	BitPaymer
$1.0M	126	Maze

Table 1.
Largest Ransom Demands Reported in 2019

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2020 Amounts Increasing

IBM Says Ransomware Hackers Netted At Lease $81M In 2020

Law360 (September 28, 2020), 9:17 PM EDT) – Hackers using a popular strain of ransomware known as Sodinokibi have received at least $81 million in payouts in 2020 alone, IBM's cybersecurity team said Monday as it described a flood of attacks targeting manufacturers, governments and academic institutions.

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Sources of Attack

- **Phishing continues to be number one source**
  - TrickBot example – use phishing email spam campaign to distribute malicious attachments that execute on Windows machine if opened
- Remote Access Points
  - Exploitation of Remote Desktop Protocols (RDP) – increased use during COVID-19
- Exploit a known or identified vulnerability
  - e.g., unpatched software

Proposed Changes to the Privacy Rule

- November 10, 2020 – News that the Proposed Rule was approved by OMB
- Any update?

Questions?

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The Latest Word
Starts at 12:00 p.m.

Zachary J. Buxton
Scott S. Moore
Krista M. Eckhoff
Morgan L. Kreiser
Barbra E. Person
Tessa M. Lancaster
Eli A. Rosenberg
Andrew D. Kloeckner

Hospital Price Transparency Regulations

Zachary J. Buxton

Drug Manufacturers

- Eli Lilly, Merck*, AstraZeneca, Sanofi*, Novartis*
- Letters requesting 340B covered entities upload contract pharmacy claims data to third-party website
  - Second Sight Solutions' 340B ESP platform
- Merck letter:
  - "Absent significant cooperation from covered entities, Merck may take further action to address 340B Program integrity, which may include seeking 340B Program claims information **in a manner that may be less collaborative, and substantially more burdensome for covered entities**."

Industry Response

- No legal obligation under 340B statute to provide contract pharmacy data to drug manufacturers
- 340B CEs already monitor duplicate discounts
- HIPAA concerns
- Contract pharmacies = this is our data
- Significant impact on 340B covered entities who rely on margins in 340B program to provide other services to community
- Terrible timing as hospitals and other covered entities respond to coronavirus

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340B Update: Drug Manufacturers Restrict Shipments to Contract Pharmacies

Zachary J. Buxton

High-Level Overview

- Effective date January 1, 2021
- Hospitals must make public:
  - A machine-readable file containing list of all ***standard charges*** for all items and services
  - A consumer-friendly list of ***standard charges*** for a limited set of shoppable services or a price estimator tool
- Standard charges defined as:
  - Gross charges
  - Payer-specific negotiated charges
  - De-identified minimum negotiated charge
  - De-identified maximum negotiated charge
  - Discounted cash price
- ***AHA et al. v. Alex M. Azar***
  - Oral arguments October 2020; reporting described D.C. Circuit Court of Appeals as "skeptical" of AHA's position

Pressure on HHS & Drug Manufacturers

- AHA letters to Secretary Azar (July and October 2020)
- Letter from 1,000+ 340B hospitals to Secretary Azar
- House letter (9-14-20)
- Senate letter (9-17-20)
- HHS General Counsel letter to SVP & GC of Eli Lilly (9-21-20)

Useful Resources

- "Posting Negotiated Rates & More: Overview of CMS's New Price Transparency Rule for Hospitals" (Baird Holm Webinar Series; October 12, 2020)
- Helpful CMS resources:
  - Website
    - https://www.cms.gov/hospital-price-transparency/hospitals#key-provisions
  - Hospital Price Transparency Frequently Asked Questions
    - https://www.cms.gov/files/document/hospital-price-transparency-frequently-asked-questions.pdf
  - 8-Steps to a Machine Readable File of All Items and Services
    - https://www.cms.gov/files/document/steps-machine-readable-file.pdf
  - 10-Steps to Making Public Standard Charges for Shoppable Services
    - https://www.cms.gov/files/document/steps-making-public-standard-charges-shoppable-services.pdf
  - Hospital Price Transparency Requirements Quick Reference Checklists
    - https://www.cms.gov/files/document/hospital-price-transparency-final-rule-quick-reference-checklists.pdf
- And a couple more things:
  - Transparency in Coverage (85 FR 72158; 11/12/2020)
  - Price Transparency for COVID-19 Diagnostic Tests (45 CFR Part 182; CARES Act; Regulations effective 11/2/2020)

Employment Law Update

Scott S. Moore

Employment Law Update

- Race and Sex Stereotyping
- Fluctuating Workweek Salaries/Incentives
- Biometrics and AI
- Union Organizing
- FFCRA Leave
- COVID Liability Act Protection

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COVID Litigation

Krista M. Eckhoff

COVID Litigation

- Lawsuits against healthcare entities
  - PPE for nurses
  - Employment retaliation
- Malpractice/liability lawsuits
  - Sending patient home
  - Failing to isolate patient

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Other COVID Litigation

- Contracts
  - Failure to deliver PPE (Nebraska case)
  - Force majeure
- Paycheck Protection Program lawsuits
- Business insurance coverage

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Employee Benefits Update
SECURE Act
(Setting Every Community Up for Retirement Enhancement Act of 2019)

Morgan L. Kreiser

SECURE Act – Key Changes

- Required Minimum Distributions (RMDs) pushed from age 70½ to 72
- Post-death RMDs limited for defined contribution plans
- Expanded eligibility for long-term, part-time employees under 401(k) plans
- Expanded in-service withdrawals under defined benefit plans and governmental 457(b) plans
- Annual lifetime income disclosures required for defined contribution plans

96-Hour Rule

Barbara E. Person

CAHs' 96-Hour LOS Limit

- CMS has published a Section 1135 Waiver of the CAH Medicare Condition of Participation at 42 CFR §485.620, requiring that the CAH's average length of stay be limited to 96 hours.
- No such waiver has been published for the corresponding CAH Condition of Payment at 42 CFR §424.15 As a condition of payment for inpatient CAH services, a physician must certify that the patient is expected to be discharged or transferred within 96 hours of admission. This certification is to be completed at least 1 day before the claim for payment is submitted.

CAHs' 96-Hour LOS Limit

- Remdesivir is currently the medication recommended for COVID-19 patients with severe disease. The standard treatment course is 5 days. For a COVID patient admitted for a course of Remdesivir, the length of stay would be about 120 hours, and the physician could not make the required certification in good faith.
- CMS invites inquiries related to the Section 1135 Waivers. The question has been submitted to the appropriate CMS email address.

Telephone Consumer Protection Act Update and Anthem Ruling

Tessa M. Lancaster

Anthem Ruling

- Background on TCPA
- Anthem Exemptions Requested
- FCC Response
- Why this matters?

Ransomware Payment

Eli A. Rosenberg

OFAC Guidance – Ransomware Payments

- OFAC
  - Division of US Treasury
  - Enforces economic and trade sanctions
  - Specially Designated Nationals List
  - Embargoed Countries
- Who does OFAC apply to?
  - All U.S. persons, wherever they are located. All U.S. incorporated entities and their foreign branches.
- What happens if you violate OFAC regulations?
  - Criminal and civil penalties apply
  - Up to 20 years in prison per violation
  - Seizure / forfeiture of goods involved

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OFAC – Ransomware Guidance

- Issued on October 1, 2020
- Directed at banks and any other companies involved in addressing cyberattacks: Insurance firms, digital forensics, incidence response companies
- Broadly states that facilitating ransomware payments on behalf of a victim to anyone on the SDN list or to an embargoed country violates OFAC regulations
- OFAC expects security programs to account for the risk that a ransomware attack may require engaging in transactions with an OFAC sanctions nexus

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Take-Aways

- Take-aways: if a ransomware attack may involve OFAC regulations –
  - Everyone involved in a payment to the attacker (hospital, bank, insurance carrier etc.) faces a risk of violating the law
  - Likely, a victim's financial institution would refuse to conduct a transaction on behalf of a victim to pay the attacker (e.g., there's no way to "pay the ransom")
  - Attack may no longer be covered by insurance policy

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Public Meetings and COVID

Andrew D. Kloeckner

Public Meetings and COVID

- Virtual public meetings
  - Nebraska
    - General proclamation suspending certain in person open meeting requirements expired June 30th and was not renewed
    - New proclamation permitting virtual attendance by board members if quarantine or isolation are ordered – through December 31st
  - Iowa
    - Suspends certain in person open meetings requirements
- Must continue to comply with all other non-waived elements of open meetings laws
- Question of gubernatorial authority?
- Best practice – Ratify all actions taken while meeting virtually at first in person meeting

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Hot Topics for Medical Staffs: No One's Getting Any Younger & Avoiding Conflicts Over Conflict of Interest

Starts at 12:45 p.m.

Barbara E. Person
Kimberly A. Lammers

LB 755 – Amendment of Neb. PA Licensure Statutes

- 2017 – New licensure statutes for APRNs
  - Recognized as independent medical providers
- Aug. 14, 2020 – G. Ricketts signed LB 755
- Nov. 14, 2020 – Effective date
- Some existing regulations will become ineffective because they are not in line with LB 755

Major Accomplishments of LB 755

- Clean up working relationship with supervising physician
- More consistent with the various types of PA engagement:
  - Employment by physician
  - Employment by group practice
  - Employment by multi-specialty practice
  - Employment by hospital/co-employed with supervising physician

Supervisory Relationship

- Still dependent practitioners
  - Physician still "delegates" and "supervises"
  - Definition of "supervision" remains the same
  - "Ready availability of [MD] for consultation and "collaboration" (replaces "direction")
  - Deleted telephonic availability as "ready availability"
  - Deleted authority for regulations re new licensees being in physical presence of supervising physician
  - Insertion of PA being in a setting geographically remote from supervising physician
- PA must have one supervising physician for each employer
- Multi-specialty groups: one supervising physician for each specialty in which PA practices

Collaboration Agreement

- New name; no longer "supervisory agreement"
- No list of required contents in agreement
  - No requirement of listing medical functions delegated
  - No longer any requirement to authorize determination of death or signing of death certificates
  - Authority to prescribe drugs and devices no longer calls attention to physician authority to withhold this delegation
- Supervising physician must maintain a copy of the agreement at the PA's practice locations
  - If more than one supervising physician, each has duty

Hospital Credentialing

- Require collaboration agreement with PA's application
- Statutes no longer require that supervising physician be on medical staff as a condition of PA's hospital practice authority
  - But most hospitals will require this anyway
  - For CAHs seeking PA coverage of ED in a pinch, this might come in handy
  - But PA still needs a supervisor while providing ED coverage

Scope of Licensure Expanded

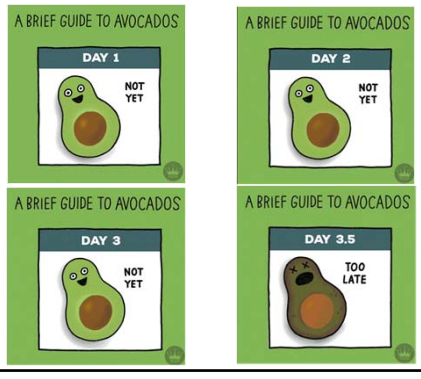
- PAs may plan and initiate a therapeutic regimen, including ordering and prescribing nonpharmacological interventions, including but not limited to DME, nutrition, blood and blood products and diagnostic support services such as home health care, hospice, PT and OT
- NDHHS advises that APRNs are pleased that PAs can now share this authority
  - This must have been a limit on third party reimbursement
  - Licensure and physician delegation otherwise would have supported it
- Podiatrists may now supervise PAs
  - Presumably podiatric services only

Strict Liability for Supervising Physicians

- Holdover from initial introduction of PAs into Nebraska licensure
  - Seemed designed to address risk of greedy physicians hiring lots of PAs and supervising them poorly; risk to patient safety
- Should have been deleted from licensure statutes
- Respondeat Superior – legal theory holding employer liable for negligence of employee
  - This would be sufficient to protect patients
  - More in line with the trend toward hospital employment of PAs

Difference Between PAs and APRNs

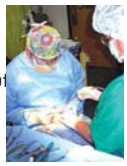
- Dependence vs. Independence
- This can make a difference in Medicare CoPs for restraints
- However, for the most part, CAH CoPs treat them the same
  - Many CAHs will continue to handle them the same
  - Others will take advantage of the distinctions, particularly CAHs that have a dire shortage of physicians to provide supervision



Scenario

- Dr. Strawbridge is a 77-year-old general surgeon
  - Has been in practice for 44 years
  - Has been at your hospital for the last 18 years
  - Has had same privileges since initial credentialing
  - Sees patients in office and at outreach locations
  - Still performs significant number of surgeries and colonoscopies

Scenario



- He is due for reappointment
  - Some surgical complications, but nothing that is not known complication (nicked bowel, wound dehiscence, etc.)
  - No malpractice allegations/claims
  - Patient satisfaction survey results remain favorable
  - Some reports from OR staff of slowed turnover of cases

Questions

1. What special issues, if any, does Dr. Strawbridge present?
2. How well will credentialing processes identify those issues?
3. Can you have a policy based on age?
4. What if someone should retire but won't?

Aging Practitioner Policy

- Yale – New Haven *Hospital: Late Career Practitioner Policy*
  - Applied to all practitioners 70 years of age and older
  - Required neuropsychological screening & ophthalmologic exam

Aging Practitioner Policy

- Yale – New Haven *Hospital: Late Career Practitioner Policy*
  - Cognitive function evaluation = 16 tests
  - Results reviewed by subcommittee which then made recommendations to Credentials Committee

Testing Results

- Applied to 145 individuals ages 70 to 84
  - 89 passed
  - 38 "Qualified Passed"
  - 18 demonstrated cognitive deficits likely to compromise ability to practice
    - **None** were independently identified with performance problems
    - All opted to discontinue practice or move to structured setting

Lawsuit

- EEOC v. Yale – New Haven Hospital
  - Alleged policy violated ADEA and ADA by discriminating against practitioners based on age
- Case brought by a practitioner who passed testing

Lawsuit

- Case still pending – Yale-New Haven Hospital in for the "long haul"
- Additional employment law issue related to academic medical center structure
  - Physicians were employed by Medical Center, not Hospital
  - Implications for independent practitioners

Aging Practitioner Policy Issues

- Negligent credentialing
- Direct duty to protect patients
- Conditions of Participation/ accreditation requirements
- Research and support for policy
- Shortcomings in traditional OPPE/peer review
- Discrimination (ADEA & ADA)
- Employed or independent
- Practitioner rights & dignity
- Based on generalization

Aging Practitioners

- Risk to patients
  - Age as risk factor
  - Years from graduation as risk factor
  - Statistics support declining performance as generalization
- Risk of litigation
- Risk of NPDB Reporting

Physician Conflicts of Interest

- Many hospitals have adopted policies applicable to **all** employees, prohibiting the acceptance of gifts, food, etc.
- Academic Medical Centers, in particular, have addressed conflicts of interest in clinical research, technology development, research grants, etc.
- Is there anything to worry about in the intersection of these two trends?

How Do Conflicts Arise in Most Medical Practices?

American College of Physicians: "Physicians meet industry representatives at the office and at professional meetings, collaborate in community-based research, and develop or invest in health-related industries. In all of these spheres, partnered activities often offer important opportunities to advance medical knowledge and patient care, but they also create an opportunity for the introduction of bias."

Physician Payment Models and Conflict of Interest

- Physician payment models involve COI
  - Fee for service encourages overutilization
  - Higher reimbursement for procedures increases orders for procedures and causes splintering of providers toward ownership of revenue-producing services (ASCs, imaging centers, etc.)
  - Capitation encourages underutilization

Medicare Compliance Laws Address Conflicts of Interest

- Anti-Kickback Statute
- Self-Referral/Stark Law
- Requirements to Disclose Physician Ownership

Industry Promotional Activities

- Pharmaceutical companies, medical device firms and biotech companies
- Interaction with physicians:
  - Gifts, food
  - Drug samples
  - Use physicians as marketing agents
    - Merck: discussion groups led by physicians yield 2x benefit in additional prescriptions compared to groups led by sales reps
    - Physicians are paid set fee for each presentation
  - Reimbursement of costs for CME or professional meetings
  - Consulting on marketing research for lucrative fees
  - Enrolling patients in drug trials

Move of Clinical Research to Community Medical Practices

- Community physicians might have more influence over patients than in academic medical centers where resident and faculty turnover is high
- Clinical trial might be faster and lower cost in community medical practices
- Community physicians' patient pools might be more typical and study results might be more easily generalized
- More opportunity to educate the community physicians who are otherwise too busy
- "Seeding" trials are more interested in changing prescription patterns than gathering clinical research data; these studies are administered through marketing departments rather than R&D

COI Concerns For Hospitals and Physician Employers

- Industry influence leads to
  - Requests for drugs to be added to formulary
  - Placing expensive medical devices in inventory
  - Maintaining multiple brands of certain devices in inventory to satisfy multiple physician preferences
  - Lower use of generic and OTC drugs
  - Increased drug costs
  - Reduced treatment and reliance on nonpharmaceutical therapies

Some States and Agencies Address Conflicts of Interest

- Massachusetts law limits Industry payments to physicians and requires disclosure of Industry fees paid for studies sponsored by marketing departments
- Wisconsin Medical Society: Physicians should not accept gifts from companies whose products they prescribe to their patients (nonbinding)
- PhRMA Code on Interactions with Healthcare Professionals
- AdvaMed has published a similar code

PhRMA Code: Legit Industry Contract Traits

- Written contract describes consulting services and basis for payment for them
- A legit need for the service is identified in advance of requesting the services and contracting for them
- Criteria for selecting consultants is directly related to the purpose and those Industry reps selecting consultants have expertise to evaluate the possible consultants' qualifications
- Number of consultants retained is not greater than those reasonably needed
- Industry retains records and uses data/services provided by consultants
- Venue and circumstances of any meeting are conducive to consulting services, which are primary focus of the meeting (not resorts)

Possible Medical Staff/Employer Code of Conduct Language

- Physicians should not:
  - Accept items of material value from Industry (pharma, device or biotech companies) except as payment at FMV for a legit service
  - Make educational presentations or publish articles controlled by Industry or containing substantial portions written by someone who is not identified as an author
  - Enter into consulting arrangement unless based on written contract for expert services to be paid at FMV
  - Meet with Industry reps except by documented appointment and at physician's express invitation; Physician may obtain needed education on internet
  - Accept drug samples, except on behalf of patients without financial means to buy meds
  - Enter a patient in a trial without disclosing Industry payment to physician for each enrollee

Questions?

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2020 by the Numbers: Physician Compensation Compliance Updates

Starts at 1:15 p.m.

Andy Kloeckner
Abby Mohs

Agenda

- 3 "Themes" of the Stark/AKS Proposed Rules
- 2 Changes to Physician wRVUs
- 1 Pandemic

Three Themes of the Stark Proposed Rule

- Yes, we're still waiting on the Final Rule
- Three "Themes"
  - Interpretations and clarifications
  - Revisions to current exceptions
  - New exceptions

What We Know; What We Don't Know

- Final Rule was expected late summer 2020
  - Sent to the OMB (final stage before it's published) in July
  - Delay published – August 2021
- Fate of the Rule is unknown
  - Will Trump administration push to have it finalized before the end of the term?
  - Will the new administration finalize and/or disrupt implementation?

Interpretations and Clarifications

- Revised Definitions
  - Fair Market Value
  - Commercial Reasonableness
  - Volume/Value
  - Designated Health Services
- Mistaken Payments
- Isolated Transactions

Revised Exceptions

- Unrelated to DHS
- Payments by a Physician
- Temporary Non-Compliance
- EHR – Sunset removed

New Exceptions

- Limited Remuneration to a Physician
- Cyber Technology Exception
- Value-Based Exceptions:
  - Full Financial Risk
  - Meaningful Downside Financial Risk to Physician
  - Value-Based Arrangements

Two Important wRVU Changes

- 2021 Medicare Physician Fee Schedule ("MPFS") Proposed Rule published August 2020
- Notable changes to the wRVU payments
  - E&M codes increase in wRVU value
  - Medicare conversion factor—impacting all codes and all specialties—decreases for budget neutrality purposes

E&M Code wRVU Changes

HCPCS Code	Current Minimum Minutes per Visit	Current wRVU for Code	2021 Minutes per Visit	2021 wRVU for Code	Percentage Increase in wRVU Value
99201[1]	17	0.48	N/A	N/A	N/A
99202	22	0.93	22	0.93	0%
99203	29	1.42	40	1.60	13%
99204	45	2.43	60	2.60	7%
99205	67	3.17	85	3.50	10%
99211	7	0.18	7	0.18	0%
99212	16	0.48	18	0.70	46%
99213	23	0.97	30	1.30	34%
99214	40	1.50	49	1.92	28%
99215	55	2.11	70	2.80	33%
99XXX[2]	N/A	N/A	15	0.61	N/A
GPC1X[3]	N/A	N/A	11	0.33	N/A

[1] This code to be eliminated in 2021.
[2] This is an add-on code for every 15 minutes of extended patient office visit time.
[3] This code is an add-on code to recognize complexity for qualified chronic patient conditions.

Image courtesy of American Association for Physicians Leaders

Proposed Conversion Factor Change

2020	2021
$36.09	$32.26
(10.6%)	

Impact to Collections and Compensation

- Varies by practice type
  - Primary Care/Certain Specialties
  - Surgical/Procedural Specialties
  - Hospital-Based Physicians
- Varies by Compensation Model
  - Salary
  - Base Salary + Production Incentives
  - Production (wRVU)-based

FMV…Again

- Impact on FMV?
  - Leaving compensation formulas "as-is" will likely result in some physicians getting paid more for doing the same (or less) work
  - Will survey data for FMV analysis be reliable?
    - Data lag

Commercial Reasonableness…Again

- Impact on Commercial Reasonableness?
  - Hospitals and physician practices are likely to get paid less due to Conversion Factor decreases while paying physicians the same or more for the same services
  - Larger "practice losses"
  - Business justifications

wRVU Changes: Take Aways

- Review compensation provisions
- Analyze likely impact on both physician compensation and practice collections
- New or revised compensation models and/or amounts may be necessary
- Communication to physicians
- Documentation of commercial reasonableness

One Pandemic

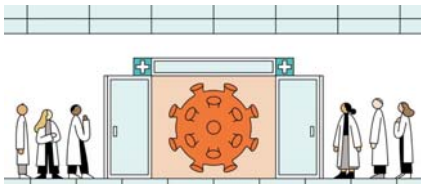

Image courtesy of the Commonwealth Fund

COVID-Related Stark Waivers The Background

- Two types of 1135 Waivers
  - Blanket
    - CMS determines that all similarly situated providers need regulatory modification
    - Applies to all providers in the emergency area
    - Extensions required, otherwise expire after 60 days
    - No longer requires notification to CMS
  - Case-by-case
    - Providers must request specific wavier(s) from CMS based on facts and circumstances
    - Defined process

Stark Waivers: What they Waive

- Does not permit fraudulent or abusive arrangements
  - "Absent any determination of fraud and abuse"
- Does not waive the law itself or the underlying regulations
  - Arrangements entered into during the waiver period are not "excepted"
  - When waiver terminates or expires, if the arrangement is ongoing and doesn't satisfy a Stark exception it may be problematic
- Waiver only applies to "sanctions"

Hypothetical

- Midwest Health System, Inc. prepared for COVID-19 in the spring, but didn't experience any major issues, so its COVID task force began to cancel meetings and leadership paid less attention to the flood of information about the pandemic.
- During the "third spike" the community has seen a significant increase in positive cases.
- Midwest Health System is dusting off the information from the spring and recalls it entered into various physician arrangements under the 1135 waivers.

PPE…PPE…Toilet Paper

- A physician practice in one of Health System's smaller communities experienced extreme difficulty in securing its own supplies during the spring. The practice called the local hospital for help.
- The Health System agreed to give the practice access to its GPO to purchase necessary supplies for the physician practice, like PPE and, ahem, toilet paper.
- The local hospital provided the practice with the supplies at no charge.
- Supply orders continued in this manner all summer and into the fall.
- The Health System didn't realize that the local hospital's supply orders continued to include supplies for the practice.
- It's been working out so well! However, the local hospital contacted the Health System about extending this purchasing practice to another local physician…

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Thoughts?

- Remuneration must be solely related to "COVID-19 purposes"
  - PPE – diagnosis or medically necessary treatment of COVID (confirmed or suspected)
  - Other supplies - addressing medical practice or business interruption due to COVID-19 in order to maintain availability of medical care and related services
- Has a "COVID-19 Purpose" existed the entire time?
  - Was toilet paper always hard to get?
- Did the parties "paper" the arrangement and satisfy other elements of an applicable exception?
  - Waiver only addresses the FMV standard…not the other elements of an exception

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Space in Flux

- In another community, the Health System leases clinic space to a variety of surgeons.
- To address the potential need for additional hospital space and because of the cancellation of elective procedures, the Health System entered into short-term amendments which lowered the physicians' rental rates.
- The term of the amendments tied to the duration of the PHE.
- Health System never had to cancel surgeries or use the clinics.
- However, due the governor's new orders, Health System will likely have to cancel surgeries due to the third spike.

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Thoughts?

- What is the COVID-19 Purpose?
  - Shifting diagnosis and care of patients to appropriate alternative settings
  - Addressing medical practice or business interruption due to the COVID-19 outbreak in order to maintain the availability of medical care
- Does Health System require any additional or different waivers?
  - Third wave shows that potential need for space still exists (COVID Purpose continues)
- Are these amendments still valid?
  - PHE still exists
  - An express end date is wise

Short Staffed

- Health System's largest hospital in the state's largest city is worried about staffing because of COVID-19 outbreaks among its workforce.
- A physician group staffs the ED, but large hospital believes it needs to arrange for additional physicians to ensure current staffing levels.
- An emergency medicine group in a nearby town has extra capacity and can provide additional coverage, but has asked large hospital to pay for lost revenue the group physician will experience from having to quarantine after returning home.
- Hospital is desperate and willing to pay if permitted by the waivers…

Thoughts?

- Remuneration must be solely related to "COVID-19 purposes"
  - Ensuring availability of health care providers to address patient and community needs due to COVID-19 outbreak
  - Securing services of physicians / practitioners to furnish medically necessary services
    - Includes medically necessary services not related to COVID-19
    - But need should be related to impact of COVID-19
- Potentially above FMV payment

Waiver Best Practices

- Must comply with all elements of a Stark exception, with the exception of those elements specifically carved out by a waiver
  - Most often the FMV standard
  - All other standards (written agreement, set in advance, signature) apply

Waiver Best Practices

- The "because" is key
  - Build a file and document appropriate support for the arrangement
    - Why/how does the arrangement satisfy one or more "COVID-19 purposes"?
    - Which blanket waiver covers?

Waiver Best Practices

- Tracking
  - Keep an inventory of the arrangements relying on a waiver
- Analyze and revisit periodically
  - Does the COVID-19 purpose continue to exist?
  - Affirmatively end arrangements if COVID-19 purpose no longer exists

Waiver Best Practices

- End of Waiver Period
  - Uncertain when the waivers will end
    - Will likely receive warning, but unclear the length of time such warning will provide
  - Does the arrangement satisfy an exception?
  - Identify changes that need to be made
  - Start preparing now and educate operations as to what will change when over
  - Determine the practical steps necessary to terminate or revert arrangements at the end of the waiver period

Questions?

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Thank you!

Thank you for attending the 32nd Annual Baird Holm Health Law Forum. Look for an email form us with a link to the event survey and continuing education information.

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COMMONLY USED ACRONYMS

AAMC	*Association of American Medical Colleges*
ACA	*Affordable Care Act*
ACO	*Accountable Care Organization*
AG	*Attorney General*
AHA	*American Hospital Association*
AHIA	*Association of Healthcare Internal Auditors*
AHIP	*America's Health Insurance Plans*
AHLA	*American Health Lawyers Association*
AI	*Artificial Intelligence*
AKS	*Anti-Kickback Statute*
ALJ	*Administrative Law Judge*
AMA	*American Medical Association*
APM	*Alternative Payment Models*
ASC	*Amublatory Surgical Center*
BAT	*Blood Alcohol Tests*
CAH	*Critical Access Hospital*
CAP	*Corrective Action Plan*
CBO	*Congressional Budget Office*
CDAC	*Consolidated Data Analysis Center*
CIA	*Corporate Integrity Agreement*
CLIA	*Clinical Laboratory Improvement Amendments*
CMS	*Centers for Medicare & Medicaid Services*
COI	*Conflict of Interest*
COP	*Conditions of Participation*
D & O INSURANCE	*Directors and Officers Liability Insurance*
DHHS	*Department of Health and Human Services*
DHS	*Designated Health Services*
DME	*Durable Medical Equipment*
DOJ	*Department of Justice*
ECA	*Extraordinary Collection Action*
ED	*Emergency Department*
EEO-1 REPORT	*Employer Information Report EEO-1*
EHR	*Electronic Health Record*
EMC	*Emergency Medical Condition*
EMTALA	*Emergency Medical Treatment and Active Labor Act*
FAP	*Financial Assistance Policy*
FCA	*False Claims Act*
FDA	*Food and Drug Administration*

CONTINUED >>

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COMMONLY USED ACRONYMS

FFS	*Fee-for-Service*
FLSA	*Fair Labor Standards Act*
FMV	*Fair Market Value*
FPPE	*Focused Professional Practice Evaluation*
HCCA	*Health Care Compliance Association*
HCQIA	*Health Care Quality Improvement Act*
HIPAA	*Health Insurance Portability and Accountability Act*
HRA	*Health Reimbursement Arrangement*
IAC	*Iowa Administrative Code*
ICF	*Immediate Care Facility*
IDR	*Independent-Dispute Resolution*
IRS	*Internal Revenue Service*
MACRA	*Medicare Access and CHIP Reauthorization Act*
MEC	*Medical Executive Committee*
MFCU	*Medicaid Fraud Control Unit*
MIPS	*Merit-Based Incentive Payment System*
MSSP	*Medicare Shared Savings Program*
NAC	*Nebraska Administrative Code*
NFP	*Not-For-Profit*
NLRB	*National Labor Relations Board*
NPDB	*National Practitioner Data Bank*
NPP	*Notice of Privacy Practices*
NPRM	*Notice of Proposed Rulemaking*
OIG	*Office of Inspector General*
OSHA	*Occupational Safety & Health Administration*
PART 2	*42 CFR Part 2; Confidentiality of Substance Use Disorder Patient Records*
PHI	*Protected Health Information*
PII	*Personally Identifiable Information*
PQRS	*Physician Quality Reporting System*
RFI	*Request for Information*
RUG	*Resource Utilization Groups*
SNF	*Skilled Nursing Facility*
STARK	*Physician Self-referral Law*
TCPA	*Telephone Consumer Protection Act*
TPO	*Treatment, Payment, and Healthcare Operations*
UCA	*Uniform Credentialing Act*
USC	*United States Code*
VBP	*Value Based Purchasing*