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Legal & Regulatory Update 2024

Well, here's to another election year.

Presentation by: Robert W. Markette, Jr. CHC

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- And finally…

Remember

I am just the messenger. Don't shoot the messenger.

Agenda

- Lots of Change to cover.
  - Home health and hospice regulatory changes
  - Supreme Court Activity
  - DOL Activity
  - EEOC enforcement
  - Hospice Proposed Rule
  - Hospice Special Focus Program
  - Survey update (sort of)
  - and more

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New Home Health Survey Guidelines

- On March 15, 2024, CMS issued QSO-24-07-HHA
- This document announced changes to SOM Appendix B – Guidance for Surveyors: Home Health Agencies.
- Lots of changes in this document. Need to read carefully.

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New Home Health Survey Guidelines

For example, new guidance at 484.50:

- Ensuring that patients (and representative, if any) are aware of their rights and how to exercise them is **vital to quality of care** and patient satisfaction. HHAs must inform patients of their rights and protect and promote the exercise of these rights, e.g., by informing the patient how to exercise those rights.
- The manner and degree of noncompliance identified in relation to the standard level tags for §484.50 may result in substantial noncompliance with this CoP, requiring citation at the condition level.

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New Home Health Survey Guidelines

- Many tags are given specific survey Procedures.
- These have directions to surveyors and specific questions for surveyors to ask.
- In patient rights, much of the guidance directs surveyors to ask patients questions. For example, ask patient about notice of rights. (Hope they remember.)

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New Home Health Survey Guidelines

- Other changes are clean up.
  - adding headers
  - clarifying NPP involvement by adding the phrase allowed practitioner.
- Not clear yet how this will impact surveys.

Survey Update

- CMS QCOR is no longer being updated.
- Survey Issues in past year:
  - Governing Body. Need to clearly document appointment/election of governing body (this is usually just the corporate governing body): who is on it; how did they get appointed/elected; Governing body needs to carefully and clearly document its actions, meetings, etc. If same group of individuals is GB for multiple providers, need to keep separate documentation.
  - GB/governance, corporate organization and contract issues drive a significant number of survey issues.
    - Clear documentation, organizational charts, etc.
  - Surveyors have recently raised fraud during survey.

Final FY 2025 Hospice Wage Index and Payment Update

- On August 6, 2024, published the final FY 2025 Hospice Wage Index and Payment Rate Update Rule. It addresses several areas:
  - Annual Rate Increase
  - Changes to Hospice Quality Reporting Program
  - Proposal to adopt most recent OMB Statistical Areas
  - Clarify policy related to the Election Statement, Notice of Election and clarify language regarding hospice certification

Final FY 2025 Hospice Wage Index and Payment Update

- CMS uses the most recent market basket increase based upon IHS Global, Inc.'s forecast, which is 3.4%. (It was projected at 3.0%)
- The market basket increase is adjusted by the mandated "productivity adjustment" of 0.5%. (It was projected at 0.4%)
- This means that the proposed payment increase for FY2025 is **2.9%.** CMS estimates that this will increase hospice spending by $790 Million.
  - This is an increase of $85 Million from the proposed rule.

Final FY 2025 Hospice Wage Index and Payment Update

- Final Rates:

TABLE 9: Final FY 2025 Hospice RHC Payment Rates-

Code	Description	FY 2024 Payment Rates	SIA Budget Neutrality Factor	Wage Index Standardization Factor	FY 2025 Hospice Payment Update	FY 2025 Payment Rates
651	Routine Home Care (days 1-60)	$218.33	1.0014	0.9984	1.029	$224.62
651	Routine Home Care (days 61+)	$172.35	1.0001	0.9975	1.029	$176.92

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Final FY 2025 Hospice Wage Index and Payment Update

- Final Rates:

TABLE 10: Final FY 2025 Hospice CHC, IRC, and GIP Payment Rates-

Code	Description	FY 2024 Payment Rates	Wage Index Standardization Factor	FY 2025 Hospice Payment Update	FY 2025 Payment Rates
652	Continuous Home Care Full Rate = 24 hours of care.	$1,565.46	1.0048	1.029	$1,618.59 ($67.44 per hour)
655	Inpatient Respite Care	$507.71	0.9930	1.029	$518.78
656	General Inpatient Care	$1,145.31	0.9928	1.029	$1,170.04

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Final FY 2025 Hospice Wage Index and Payment Update

- **<u>These rates will be reduced by 4% for hospices that fail to submit HQRP data.</u>**
- CMS received a number of comments that it should keep the hospice cap at its 2024 level or even reduce it.
- CMS noted that it is required to update the cap amount by the hospice payment update percentage. The hospice cap will be updated by 2.9% to $34,465.34. (An increase from the proposed amount of $34,364.85.)

Final FY 2025 Hospice Wage Index and Payment Update

- CMS finalizes the proposal to adopt the most recent OMB statistical area delineations, which revise the existing core-based statistical areas (CBSA) based on data collected during the 2020 Decennial Census.
- Hospices negatively affected by the change to their geographic wage index will only experience a maximum 5% reduction to their 2024 wage index, as there is a 5% cap on any decrease to the wage index from the prior year.
- This permanent cap, finalized in the FY 2023 Hospice Final Rule, prevents a geographic area's wage index from falling below 95% of its wage index calculated in the prior FY.

Final FY 2025 Hospice Wage Index and Payment Update

- CMS is adopting its proposal to clarify the discrepancies between the hospice Medical Director COP (42 CFR § 418.102) and the payment requirements at 42 CFR § 418.22 and 42 CFR § 418.25.
- Issue: CoP limits who can certify terminal illness to Medical Director and physician designee. Statute and payment requirements allow IDG physician to certify.

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Final FY 2025 Hospice Wage Index and Payment Update

- Adding physician member of the IDG to 418.102(b) & (c)
- Based upon comments, removing "physician designated by" and replacing it with "physician designee (as defined in § 418.3)"
- Adding "physician designee (as defined in § 418.3)" to 418.22(c) and 418.25. Not a change in policy. Simply clarifying that the physician designee can act when the Medical Director is not available.

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Final FY 2025 Hospice Wage Index and Payment Update

- Hospice Election. CMS is concerned that there is confusion between the Election Statement and the Notice of Election.
- CMS notes that these are two different documents with two different purposes.
- CMS is finalizing its proposal to reorganize the regulations to clarify this difference. Will reorganize and add titles:
  - 418.24(b) – "Election Statement"
  - 418.24(e) – "Notice of Election"

Final FY 2025 Hospice Wage Index and Payment Update

- CMS received several comments regarding MACs relying upon the model NOE and denying claims due to provider's non-compliance with the model NOE form.
- Comments may have been submitted, in part, as a response to CMS encouraging providers to use the model NOE.
- CMS' response: "We reiterate that the model election statement is intended to be an example of a form that hospices may utilize and that hospice agencies are not required to use this exact example.

Final FY 2025 Hospice Wage Index and Payment Update

- RFI regarding "complex palliative treatments."
- This is a follow-up to last years rule in which CMS noted a concern that patients who might be appropriate for hospice, but who received dialysis, blood transfusions, chemotherapy and radiation treatment were told these treatments were not available in Hospice.
- CMS acknowledges comments it received that indicated the hospice Per Diem model did not make it economically feasible to provide these services.
- CMS is seeking information related to this issue.

Final FY 2025 Hospice Wage Index and Payment Update

- CMS received 60 comments on this topic.
- CMS discusses the general and specific recommendations it received.
- CMS does not make any formal proposal.
- CMS states, "We will consider all comments and recommendations received on this rule and will continue to welcome thoughts regarding these issues through our hospice policy mailbox at hospicepolicy@cms.hhs.gov. We also remind readers they can report suspected fraud, waste, or abuse to CMS."
- Notice the reminder about reporting fraud, waste and abuse.

Final FY 2025 Hospice Wage Index and Payment Update

- HQRP changes/updates
- CMS finalizes its proposal to add two new process quality measures based upon HOPE data:
  - Timely Reassessment of Pain Impact and
  - Timely Reassessment of Non-Pain Symptom Impact.
- "these two measures would determine whether a follow-up visit occurs within 48 hours of an initial assessment of moderate or severe symptom impact."
- Take effect in FY2028

Final FY 2025 Hospice Wage Index and Payment Update

- HQRP changes/updates
- CMS finalizes proposal to begin replace current HIS with HOPE. HOPE data collection to begin on or after October 1, 2025.
- Failure to submit HOPE collections timely will be subject to the same 4% penalty.
- Training to begin. HOPE 1.0 Guidance Manual will be made available after publication of FY2025 Final Rule.
- CMS will analyze data collected in 2026 during 2027 to determine whether to publicly report it.
- Public reporting of HOPE data will be no earlier than 2028.

Final FY 2025 Hospice Wage Index and Payment Update

- HQRP changes/updates
- CMS rejected requests to phase in the 90% requirement with HOPE, "because hospices already have a 90 percent reporting threshold for HIS and HOPE builds on the foundations of HIS, we anticipate that hospices will be able to continue meeting the 90 percent reporting threshold after HOPE implementation."
- Also rejected requests to allow telehealth visits for HOPE "based on expert input regarding hospice best practices."

Final FY 2025 Hospice Wage Index and Payment Update

- CMS finalizes proposed changes to the CAHPS process based upon results of experiment conducted with 56 large hospices in 2021.
- Revised survey will remove several measures to make survey shorter and simpler.
- Finalizes administrative changes to survey (each increased responses):
  - CMS is adding a web-mail mode (email invitation to a web survey, with mail follow-up to non-responders). This mode is optional providers may select it in any future quarter they are ready;
  - adding a pre-notification letter; and
  - extending the field period from 42 to 49 days,

Final FY 2025 Hospice Wage Index and Payment Update

- Hospice CAHPS changes will take effect in April 2025.
- Training materials will be available in early fall 2024.
- Administration for April 2025 not set to begin until summer 2025.
- CMS states this allows providers and vendors 10 months to prepare.
- CMS provides a side by side comparison of the old and new tool in the comments.

Proposed FY 2025 Home Health PPS Update

- BEHAVIORAL ADJUSTMENTS

- CMS continues to implement the statutory behavioral adjustments required by Congress.
- CMS determined that a -4.067% permanent adjustment is necessary.
- CMS proposes to implement the full amount.
- This, obviously has a significant impact on payment.

Proposed FY 2025 Home Health PPS Update

- FY 2025 Payment Update

TABLE 34: CY 2025 NATIONAL, STANDARDIZED 30-DAY PERIOD PAYMENT AMOUNT

CY 2024 National Standardized 30-Day Period Payment	Permanent Adjustment Factor	Case-Mix Weights Recalibration Budget Neutrality Factor	Wage Index Budget Neutrality Factor	CY 2025 HH Payment Update Factor	CY 2025 National, Standardized 30-Day Period Payment
$2,038.13	0.95933	1.0035	0.9985	1.025	$2,008.12

- This will result in a $280 Million reduction to home health payments.

Proposed FY 2025 Home Health PPS Update

- CMS proposes to add a new requirement to the CoPs – Acceptance to Service Policy
- CMS notes that "a timely, appropriate admission process serves both prospective patients seeking care and ensures that HHAs accept for treatment only those patients for whom there is a reasonable expectation of being able to meet the patient's care needs."
- Of course, the CoPs already state, "Patients are accepted for treatment on the reasonable expectation that an HHA can meet the patient's medical, nursing, rehabilitative, and social needs." 42 CFR 484.60.

Proposed FY 2025 Home Health PPS Update

- New standard would require HHA to develop an acceptance to service policy.
- Policy must address the "criteria related to the HHA's capacity to provide patient care, including, but not limited to":
  - Anticipated needs of the referred prospective patients
  - Case load and case mix of the HHA
  - Staffing levels of the HHA
  - Skills and competencies of the HHA staff
- Must also make available to the public accurate information regarding the agency's services.

Proposed FY 2025 Home Health PPS Update

- HHQRP Changes
- Proposing to add four new items and modify one OASIS item.
- Collection of four new items would begin in 2027.
- Four new items related to Social Determinants of Health:
  - Living situation
  - Food – 2 items
  - Utilities
- Propose to modify OASIS Transportation question.
- Provide additional clarification on all-payer OASIS collection.

Proposed FY 2025 Home Health PPS Update

- CMS also proposing an additional expansion/clarification of Provisional Period of Enhanced Oversight.
- Adds reactivating providers to list of providers subject to PPEO.
- CMS notes that a reactivating provider is "effectively returning to the program as a new provider or supplier after having departed."
- CMS considers this situation to be no "different from that where the provider or supplier is enrolling in Medicare for the first time."

Hospice 36 Month Rule

- Home health final rule brought a new change for hospice.
- The prohibition on a direct change in majority ownership within 36 months of (i) certification or (ii) a preceding direct change in majority ownership now applies to hospices.
- Took effect January 1, 2024.
- Reflects CMS' growing concerns about fraud and abuse in the hospice industry.
- Need to consider the 36 month rule in hospice transactions now.

Hospice Special Focus Program

- Hospice Special Focus Program ("SFP") went into effect on January 1, 2024.
- Includes informal dispute resolution ("IDR") process as part of the SFP.
- IDR provides an informal means to challenge condition level survey findings. IT IS NOT A FORMAL APPEAL.
- Notified of right to IDR with 2567. Hospice has 10 days to request IDR.
- IDR does not delay enforcement process.
- CMS does not believe there have been any concerns about HHA IDR process.

Hospice Special Focus Program

- CMS proposes to identify 10% of hospices from which SFP participants will be selected.
- CMS identified "several indicators" that can be used to identify poorly performing hospices: Condition Level Surveys; substantiated complaints; and Data from the Hospice Quality Reporting Program.
- CMS algorithm uses – Surveys from prior 3 years, complaint surveys over three years, HCI, and 2 times the hospices CAHPS index.
- CAHPS score is double counted and, therefore, has a much larger impact on your "eligibility" for SFP.
- User guide available: https://www.cms.gov/files/document/special-focus-program-users-guide-algorithm-and-public-reporting.pdf

Hospice Special Focus Program

- CMS will use the data and its algorithm to give each hospice a score. These scores will be used to rank hospice in order.
- A higher score is worse. In the Final Rule example, a score of 8.2 was the highest score for all hospices.
- CMS will then select hospices for the SFP from the bottom 10%.
- CAHPS score is double weighted, which means it has more impact on the agencies score.

Hospice Special Focus Program

- SFP providers will be selected end of 2024.
- CMS will notify selected providers by letter.
- CMS will publish list of SFP hospices.
- SFP hospices are surveyed every 6 months.
- Deemed hospice that is selected for SFP will have its deemed status removed while in the SFP.
- Hospices in SFP are also subject to survey penalties outlined at 42 CFR 418.1220.
- Penalties may be of increasing severity, should hospice be cited for additional condition level deficiencies.

Hospice Special Focus Program

- To Graduate from SFP, Hospice must have two SFP surveys within 18 months with no condition-level deficiencies, **and**
  - no pending complaint survey triaged at an immediate jeopardy or condition level, or
  - that has returned to substantial compliance with all requirements may complete the SFP.
- Failure to meet these criteria will result in termination.
- If any survey while in the SFP results in an IJ, CMS may terminate.

Labor and Employment Updates

- As expected, the DOL and NLRB have continued a trend of being much more pro-employee.
- The pace and scope of the change is somewhat surprising.
- Administration aggressively moving to change established precedents and rules.
- DOL continues to “view homecare as a low wage high violation industry.”

DOL Activity

- The U.S. Department of Labor continues to be very active.
- For FY2023, healthcare (identified as a Low Wage, High Violation Sector) was the second most targeted industry:
  - 2,492 actions
  - $31,799,787 in back wages recovered.
  - 24,330 employees received back wages
  - $2,057,090 in CMPs imposed on providers.
- Total recovered back wages in all areas = $156,152,548.
- Healthcare was 20.4% of all recoveries.

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DOL Activity

- July 25, 2024, DOL recovered $135,000 from a MN homecare employer. Employer failed to pay overtime.
- July 11, 2024, DOL files a contempt action against owner of Indiana homecare company for violating a 2022 Consent Judgment.
- May 14, 2024, consent judgment with Caring Hearts Health Care Services, LLC, a Pennsylvania home health agency. Agency to pay $1 Million in back wages and damages. Agency failed to pay overtime.

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DOL Activity

- May 11, 2024, agreed judgment with Indianapolis Home Health Agency. Agency paid $151,444 in back wages and damages.
- May 1, 2024, DOL recovers $422,484 in back wages and damages for 219 employees of 5 agencies. Agencies failed to pay overtime and misclassified employees.
- April 11, 2024, DOL recovers $37,000 for 35 employees of home health company in South Carolina. Agency misclassified employees as independent contractors.

DOL Activity

- There are many more like these. The DOL continues to focus on homecare (home health, hospice and private duty). We are viewed as a low wage high violation sector.

Worker Classification

- On January 10, 2024, DOL published its final rule on Worker Classification.
- "Employee or Independent Contractor Classification Under the Fair Labor Standards Act".
- DOL calls it the Independent Contractor Rule.
- Replaces the rule promulgated by DOL under Trump Administration.

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Worker Classification

- Final Rule Adopts following factors to assess "Economic Reality"
  - Opportunity for profit or loss depending upon managerial skill.
  - Investments by the worker and the employer
  - Degree of permanence of the working relationship
  - Nature and degree of control
  - Extent to which the work is an integral part of the employer's business
  - Skill and Initiative
  - Additional factors.

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Worker Classification

- Factors outlined in rule are similar to rule it replaces and to federal case law.
- DOL specifically claims need for this new rule because the 2021 rule, "did not fully comport with the FLSA's text and purpose as interpreted by courts and *departed from decades of case law applying the economic reality test*."

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Worker Classification

- When evaluating the economic realities, federal courts have, for decades, generally looked at these factors:
  1. the nature and degree of the alleged employer's control;
  2. the worker's opportunity for profit or loss;
  3. the worker's investment in equipment or materials;
  4. whether the service rendered requires a special skill;
  5. the degree of permanency and duration of the relationship;
  6. the extent to which the service is an integral part of the alleged employer's business.
- *Sec'y of Labor, U.S. Dep't of Labor v. Lauritzen*, 835 F.2d 1529, 1534–35 (7th Cir. 1987)
- Notice the similarity to the new DOL Rule.

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Worker Classification

- The 2021 Rule identified two factors as "core factors" to simplify the analysis.
- New rule uses a "totality of the circumstances test" involving all of the factors. No one factor is considered "more important."
- Many concerns that this new rule will result in more workers being identified as employees instead of independent contractors.

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Worker Classification

- DOL's comments, which articulate their rationale in terms of maintaining compliance with federal court case law, seem to limit the breadth of the rule.
- However, by eliminating the core factors and returning to the totality of the circumstances, the DOL does have more room to interpret.
- DOL can simply place more weight on whichever factors they think support the conclusion that the individual is an employee in any given case.

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Worker Classification

- IMPORTANT: Current administration views most workers as employees, not independent contractors. Need to understand this when thinking about employee classification.
- DOL will likely apply these factors from the starting assumption that the worker is an employee.
- Burden is, as always, on employer to prove the worker is an independent contractor.

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Worker Classification

- 2021 IC regulation and new regulations have key differences. In most homecare situations, DOL comes to same conclusion – homecare worker is an employee.
- Agencies need to consider how these factors and the totality of the circumstances apply to their operations.
- FACTS OF RELATIONSHIP CONTROL.

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Worker Classification

- When classifying workers as independent contractors, need to be very careful.
- When you think you have identified workers who are independent contractors, it is highly recommended that you seek legal advice.
- Get a written opinion – allows you to at least raise a good faith defense, because you relied upon advice of counsel.

DOL Final Salary Rule

- On April 23, 2024, DOL announced the final rule to update the white-collar exemptions.
- Final rule will raise the minimum salary threshold for the white collar exemptions:
  - July 1, 2024 – June 30, 2025: $844/week
  - July 1, 2025 – June 30, 2027: $1128/week
  - July 1, 2027 and after – amount calculated according to rule.
- Rule requires salary level to be updated every three years to set salary level to the 35th percentile of weekly earnings of full-time non-hourly workers in the lowest-wage Census Region.

DOL Final Salary Rule

- Any employee you have designated as exempt due to one of the white-collar exemptions will need to meet the minimum salary, once the rule takes effect.
- Proposed three-year salary increase would automatically raise the minimum salary to the salary level of the 35th percentile of weekly earnings for the lowest wage Census Region.
- For ongoing future increases: DOL will publish a notice in the Federal Register 150 days before the new minimum salary takes effect.

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DOL Final Salary Rule

- DOL received 33,000 comments to its proposed rule.
- In 2016, DOL attempted to more than double the minimum salary. Court determined "the Department exceeds its delegated authority and ignores Congress's intent by raising the minimum salary level such that it supplants the duties test." Court found the major increase in salary made salary the "de facto" exemption test.

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DOL Final Salary Rule

- A lawsuit was filed on May 22, 2024 seeking to prevent the rule from taking effect.
- Last time DOL tried to significantly increase the salary threshold, court ruled against DOL.
- DOL had attempted to address arguments in last litigation in comments to this rule.
- This DOL rule does not increase the salary threshold as much as the previous rule.

DOL Final Salary Rule

- On June 28, 2024, Federal District Court for the Eastern District of Texas issued an injunction against the Salary Rule.
- Injunction only applies to state of Texas as an employer.
- No one else is impacted by injunction.
- However…

DOL Final Salary Rule

- Court appears to be prepared to rule that the Salary Rule is illegal.
- Court noted that the FLSA defines the Executive, Administrative and Professional exemptions by duties.
- Original purpose of salary test was limited
- When reviewing the text court stated, “Glaringly absent from [the statutory] definitions is any mention of salary.”
- Court noted that from the beginning, courts were skeptical of the DOL utilizing salary as part of the EAP exemptions.
- Focus must be on duties.

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DOL Final Salary Rule

- Court concluded that the proposed rule effectively eliminates duties as a consideration.
- DOL estimated that on July 1, 2024, 1,000,000 workers would suddenly cease to be exempt despite their job duties not changing. Then, on January 1, 2025, another 3,000,000 workers would cease to be exempt despite their job duties not changing.
- DOL conceded that a salary requirement that supplants the duties test was beyond its authority.

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DOL Final Salary Rule

- Court appears prepared to resolve this matter by summary judgment hearing shortly.
- Court has already found that Texas has a likelihood of success on the merits.
- Court will likely rule in Texas' favor.
- Expect DOL to appeal.
- Issue may be impacted by election.

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DOL Final Salary Rule

- Injunction only applies to Texas.
- This means the new salary requirements took effect for all other employers.
- Not clear if DOL is enforcing rule given Texas court's ruling.
- Two other cases challenging the rule failed to obtain injunctions.
- Need to treat rule as in effect. May consider moving salary employees to "non-exempt status" and reevaluating later.

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FTC Noncompete Rule

- On April 23, 2024, the FTC voted (3-2) to finalize the Non-Compete Rule it proposed in January 2023.
- FTC concluded that non-competition agreements:
  - Limit a worker's ability to move to other positions or start a new business.
  - Negatively impact competition in labor markets.
  - Reduce wages for workers.
  - Negatively impact competition in product and service markets.
- FTC received 26,000 comments.

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FTC Noncompete Rule

- Makes it an unfair method of competition to, with respect to a WORKER:
  - To enter into or attempt to enter into a non-compete clause;
  - To enforce or attempt to enforce a non-compete clause; or
  - To represent that the worker is subject to a non-compete clause.
- Exception for "senior executives".
  - Final rule allows non-competes with senior executives that are currently in place to remain.
  - No new non-competes.

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FTC Noncompete Rule

- IMPORTANT: Rule applies to agreements with WORKERs.
- Worker means: "a natural person who works or who previously worked, whether *paid or unpaid*, without regard to the worker's title or the worker's status under any other State or Federal laws, including, but not limited to, whether the worker is an employee, independent contractor, extern, intern, volunteer, apprentice, or a sole proprietor who provides a service to a person.
- Worker means more than employee.

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FTC Noncompete Rule

- The final rule *allows existing non-competes* with senior executives to remain in force. Because the harm of these non-competes is principally that they tend to negatively affect competitive conditions (rather than exploiting or coercing the executives themselves), and due to practical concerns with extinguishing existing non-competes for such executives, the final rule prohibits employers only from entering into or enforcing new non-competes with senior executives.
- **No new noncompetes with senior executives**.

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FTC Noncompete Rule

Senior executive means a worker who:

(1) Was in a policy-making position; and

(2) Received from a person for the employment:

(i) Total annual compensation of at least $151,164 in the preceding year; or

(ii) Total compensation of at least $151,164 when annualized if the worker was employed during only part of the preceding year; or

(iii) Total compensation of at least $151,164 when annualized in the preceding year prior to the worker's departure if the worker departed from employment prior to the preceding year and the worker is subject to a non-compete clause.

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FTC Noncompete Rule

- The Rule defines a non-competition agreement as:
- (1) A term or condition of employment that prohibits a worker from, penalizes a worker for, or functions to prevent a worker from:
  - (i) seeking or accepting work in the United States with a different person where such work would begin after the conclusion of the employment that includes the term or condition; or
  - (ii) operating a business in the United States after the conclusion of the employment that includes the term or condition.
- (2) For the purposes of this [rule], term or condition of employment includes, but is not limited to, a contractual term or workplace policy, whether written or oral.

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FTC Noncompete Rule

Commentary leaves some opening to protect employer without violating FTC rule:

- "the term "prohibits," the definition applies to terms and conditions that expressly prohibit a worker from seeking or accepting other work or starting a business after their employment ends."
- Not just agreements that expressly prohibit.
- FTC lists a number of examples of agreements that "penalize":
  - severance agreement that only pays if employee agrees not to work elsewhere.
  - terms that require worker to pay a penalty for seeking work elsewhere (liquidated damages clauses)

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FTC Noncompete Rule

- "The common thread that makes each of these types of agreements non-compete clauses, whether they "prohibit" or "penalize" a worker, is that on their face, they are *triggered where a worker seeks to work for another person or start a business after they leave their job*—i.e., they prohibit or penalize post-employment work for another employer or business."

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FTC Noncompete Rule

- FTC notes, “the definition of non-compete clause also applies to terms and conditions that restrain such a large scope of activity that they function to prevent a worker from seeking or accepting other work or starting a new business after their employment ends.”
- Applies to agreements with “terms and conditions that restrain such a large scope of activity that they function to prevent a worker from seeking or accepting other work or starting a new business after their employment ends”

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FTC Noncompete Rule

- FTC will look at terms and conditions of employment beyond those described as non-competition agreements.
- FTC: “[I]f an employer adopts a term or condition that is so broad or onerous that it has the same functional effect as a term or condition prohibiting or penalizing a worker from seeking or accepting other work or starting a business after their employment ends, such a term is a non-compete clause under the final rule.”
- This is the “functional test.”

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FTC Noncompete Rule

- Functional test prohibits defacto non-competition agreements. Examples include:
  - Non-disclosure agreements that are written so broadly as to effectively preclude the employee from working elsewhere.
  - A requirement to repay training costs which is not reasonable related to the employer's actual training costs.

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FTC Noncompete Rule-Rescission

- FTC removed the "rescission requirement" for existing non-competes, but, with one exception, non-competes will cease to be enforceable on September 4.
- Employers "must provide clear and conspicuous notice to the worker **by the effective date** that the worker's non-compete clause will not be, and cannot legally be, enforced against the worker."
- As of September 4, whether rescinded or not, you cannot enforce a non-compete.

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FTC Noncompete Rule-Rescission

- Final regulation includes a model notice.
- May utilize the notice, but may need to modify for clarity.
- For example, may want to address that non-disclosure, non-solicitation and confidentiality terms are still in effect.

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FTC Noncompete Rule

- Prohibition on Non-Competition Agreements does not apply:
  - to a noncompete clause that is entered into by a person pursuant to a bona fide sale of a business entity, of the person's ownership interest in a business entity, or of all or substantially all of a business entity's operating assets.

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What does it mean?

- Final Rule takes effect on September 4.
- Rule faces a number of challenges.
- One of the FTC Commissioners voted against rule stating:
  - FTC lacks authority to promulgate
  - Rule violates the "major questions doctrine"
  - Rule is arbitrary and capricious
- Three lawsuits have already been filed challenging the rule.
- FTC does not have authority over not-for-profit entities. Could create an unusual situation in healthcare.

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Court Challenges

- Two courts have already issued rulings.
- TX court issued an injunction on July 3. Injunction only applies to parties.
- Court found that FTC lacked the authority to promulgate substantive rules. In fact, "for the first forty-eight years of its existence, the Commission explicitly disclaimed substantive rulemaking authority."
- Cour concludes that the non-compete rule exceeds the FTC's authority.
- BUT….

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Court Challenges

- A federal district court in PA found the FTC DOES have the authority.
- Reached the opposite conclusion of the Texas District Court.
- This issue will likely make it to the U.S. Supreme Court.
- Not clear if DOJ will enforce the rule come September 4.

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Where does that leave us?

- FTC comments indicate that the proposed rule would not apply to non-disclosure agreements (that are not defacto non-competes), non-solicitation agreements (that are not defacto non-competes), anti-piracy agreements (that are not defacto non-competes), and other arrangements that "do not prevent a worker from seeking or accepting work with a person or operating a business after the conclusion of the worker's employment with the employer" but only "affect the way a worker competes with their former employer."

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Where does that leave us?

- Even if rule takes effect, employers may be able to continue some restrictions:
  - Cease use of traditional non-competes.
  - Focus on non-solicitation, anti-piracy, and non-disclosure agreements.
  - Ensure agreements are narrowly tailored. (Avoid "de facto" non-competes.)
- You can protect your business using alternative restrictive covenants.

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NLRB Update

- The NLRB was very busy in 2023.
- Announced several major decisions that fundamentally changed the landscape for employers.
- This continues the trend under the Biden administration of an extremely pro-employee slant at the NLRB.

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Cemex Decision

- The NLRB's CEMEX decision effectively overhauled the NLRB's framework for how employee's form unions. Overturned 50 years of precedent.
- New Rule: When union demands to be recognized and claims majority support, employer must either (i)recognize union or (ii)file a petition with NLRB for an election.
  - If employer does neither – NLRB will order recognition
  - If employer petitions for election and commits even 1 violation – NLRB will order recognition.

NLRB Quickie Election Rules

- On December 26, 2023, NLRB's new "Quickie Election Rules" took effect.
- Significantly compresses time for union elections.
- Limits employers time to prepare and to campaign.
- Remember, by the time you get to this point, the union has been "campaigning" for some time.

NLRB GC Opinion

- NLRB's General Counsel has also issued a memorandum expressing the GC's opinion that non-competes violate the National Labor Relations Act, unless they are "narrowly tailored to address special circumstances justifying the infringement on employee rights."
- Several cases now pending before NLRB regarding this theory.

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NLRB GC Opinion

- Some recent NLRB GC opinions have upheld non-solicitation and narrowly drafted non-disclosure agreements.
- One recent opinion applied new Stericycle decision to an NDA and found it was not an unfair labor practice. NDA focused on trade secrets and clearly proprietary material.

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DOL FTC MOU

- On August 20, 2023, the U.S. Department of Labor and the Federal Trade Commission entered into a Memorandum of Understanding.
- "The Agencies share an interest in protecting and promoting competition in labor markets and promoting the welfare of American workers."
- "The Agencies share an interest in protecting workers who have been harmed or may be at risk of being harmed as a result of unfair methods of competition and unfair or deceptive acts or practices."
- MOU provides a number of examples including non-competition agreements and "the impact of algorithmic decision making on workers."

DOL FTC MOU

- According to the FTC's press release, "The agreement is part of a broader FTC initiative to use the agency's full authority, including enforcement actions and Commission rulemaking, to protect workers."
- FTC and DOL will now be sharing information, coordinating investigations, cross training and taking other steps.
- This is another facet of the Biden Administration's "Whole of government" approach. All agencies are to "cooperate fully in the exercise of their oversight authority."
- Will likely lead to further enforcement efforts as agencies cooperate and share details.

EEOC Enforcement Update

- For FY 2023, the EEOC:
  - Secured more than $665 Million for victims of discrimination
  - Received 81,055 new discrimination charges. **Increased 10% from FY2022.**
  - Received more than 500,000 calls and 85,000 e-mails from the public.
  - Successfully resolved 46.7% of conciliations.
  - Filed 143 lawsuits. **A 50% INCREASE FROM FY2022.**
  - Resolved 98 lawsuits and received favorable outcomes in 91% of cases.
  - Conducted 7,471 mediations that resulted in $201.2 million in benefits for charging parties
- Enforcement by the EEOC has increased under this administration.

EEOC Enforcement Update

- EEOC published proposed revised enforcement guidance on October 2, 2023.
- Incorporates recent case law, such as *Bostock*, which noted that Title VII applies to discrimination based upon sexual orientation and gender identity.
- Also addresses harassment based upon a woman's reproductive decisions which has been the subject of recent case law.
- Comment period ended in November, 2023, but no final manual yet.

Muldrow v. St. Louis

- This is a Title VII case decided by the U.S Supreme Court this term.
- Plaintiff was transferred to a new position. This was a lateral move to a "less prestigious" position. This transfer did not cause any change to her pay, benefits, rank, working conditions or career prospects.
- Issue before the court: whether Title VII requires an allegedly discriminatory employment action to "produce a significant employment disadvantage" or is any disadvantage sufficient.
- This is important, if the allegedly discriminatory action does not need to create a significant disadvantage, then many more employees will have claims.

Muldrow v. St. Louis

- Court noted that "there is nothing in the provision to distinguish, as the courts below did, between transfers causing significant disadvantages and transfers causing not-so-significant ones."
- The Court concluded that a plaintiff under Title VII "need show only some injury respecting her employment terms or conditions. The transfer must have left her worse off, but need not have left her significantly so."
- Plaintiff in this case seems to have had more than a minimal impact.

EEOC v. Charter Communications

- EEOC brought a lawsuit against Charter Communications for a failure to accommodate.
- Employee had cataracts which made driving at night difficult. Employee sought a schedule change from his current schedule, which ended at 9:00 p.m.
- Charter granted the request on a temporary basis, but when it expired, they did not renew it.
- Charter concluded that the ADA did not require them to accommodate the employee's commute. Trial court agreed.

EEOC v. Charter Communications

- Seventh Circuit ruled in favor of the employee/EEOC.
- "The broad question here is whether an employee with a disability can be entitled to a work-schedule accommodation to allow him to commute more safely. Equal Employment Opportunity Comm'n v. Charter Commc'ns, LLC, 75 F.4th 729, 731 (7th Cir. 2023)
- Court agreed with Charter that getting to work was the employee's responsibility. Court went on to state, "[w]e determine that if an employee's disability **substantially interferes with his ability to travel to and from work**, the employee **may be entitled to a reasonable accommodation if commuting to work is a prerequisite to an essential job function**, including attendance in the workplace, and if the accommodation is reasonable under all the circumstances."

EEOC v. Charter Communications

- Court noted that the parties all assumed the employee's presence at the workplace was an essential job function.
- Court did not consider or address when attendance at work might be an essential job function.
- Court noted employee sought an alternative work schedule, which is an accommodation specifically mentioned in text and legislative history of the ADA.
- Court noted accommodations that are primarily for the employee's benefit are not necessary.

Corporate Transparency Act

- Corporate Transparency Act, 31 USC 5336, imposed new corporate reporting requirements.
- Primarily intended as an anti-money laundering law. Require businesses to report information to prevent use of "shell companies" in money laundering.
- CTA and related regulations took effect on January 1, 2024.
- Report to FINCEN – Financial Crimes Enforcement Network
- Penalties: $591 per day up to $10,000 and up to 2 years in prison.

Corporate Transparency Act

- Applies to a "corporation, limited liability company, or other similar entity that is--
  - (i) created by the filing of a document with a secretary of state or a similar office under the law of a State or Indian Tribe; or
  - (ii) formed under the law of a foreign country and registered to do business in the United States by the filing of a document with a secretary of state or a similar office under the laws of a State or Indian Tribe;
- Unless an exception applies.

Corporate Transparency Act

- Exceptions:
  - Certain 501(c) organizations
  - Entities that: (i) employ more than 20 full-time employees (avg. more than 30 hours a week); (ii) filed tax returns showing more than $5,000,000 in gross receipts or sales; **and** (iii) has an operating presence at a physical office within the United States
  - Entities that are no longer operational (as defined).

Corporate Transparency Act

- Reporting Requirements for Company (Initial Report)
  - The full legal name of the reporting company;
  - Any trade name or "doing business as" name of the reporting company;
  - A complete current address consisting of the street address of such principal place of business; and
  - The State, Tribal, or foreign jurisdiction of formation of the reporting company;
  - The Internal Revenue Service (IRS) Taxpayer Identification Number (TIN)

  31 C.F.R. § 1010.380(b)(1)(i)

Corporate Transparency Act

- Entity must also report for Beneficial Owner or Company Applicant:
  - The full legal name of the individual;
  - The date of birth of the individual;
  - A complete current address consisting of:
    - for company applicants who form or register the street address of such business; or
    - In any other case, the individual's residential street address;
  - A unique identifying number and the issuing jurisdiction from:
    - Individual's non-expired US Passport;
    - Individual's non-expired identification document issued by a State, local government, or Indian tribe;
    - Individual's non-expired driver's license; or
    - A non-expired foreign passport if individual does not possess a documents described in paragraph (b)(1)(ii)(D)(1), (b)(1)(ii)(D)(2), or (b)(1)(ii)(D)(3) of this section; and
  - An image of the document.

Corporate Transparency Act

- Beneficial Owner: with respect to an entity, an individual who, directly or indirectly, through any contract, arrangement, understanding, relationship, or otherwise--
  - exercises substantial control over the entity; or
  - owns or controls not less than 25 percent of the ownership interests of the entity
- Exceptions:
  - Minor child (must disclose information of parent or guardian)
  - Individual acting as a nominee, intermediary, custodian, or agent
  - Employee of company
  - Creditor
  - Individual whose only interest is through a right of inheritance

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Corporate Transparency Act

- Company Applicant. A Company Applicant is:
  - Domestic entity: the individual who directly files the document that creates the domestic reporting company;
  - Foreign reporting company: the individual who directly files the document that first registers the foreign reporting company; and
  - For foreign or domestic entities: the individual who is primarily responsible for directing or controlling such filing if more than one individual is involved in the filing of the document.
- Note: for entities formed prior to January 1, 2024, the entity does not need to report the Company Applicant.

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Corporate Transparency Act

- There is no annual filing requirement.
- Once initial filing is made, only need to file update if there is a change or inaccuracy.
- Examples:
  - Company begins using a new DBA
  - Change in beneficial owners – sale of more than 25%, death of beneficial owner, etc.
  - Change in beneficial owner's – name, address, unique identifying number.

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Corporate Transparency Act

- Companies that are subject to the CTA and were in existence on January 1, 2024 must file by January 1, 2025.
- Newly formed companies must meet the filing requirements within 90 days of receiving actual or public notice that their creation or registration is effective.

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Fraud and Abuse Update

- On February 22, 2024, DOJ announced that in FY2023 it had recovered $2.68 Billion under the False Claims Act.
- $1.8 Billion was recovered from the health care industry.
- Major Takeaways:
  - CIGNA agreed to pay $172 Million
  - DOJ continued to litigate claims ***against*** Medicare Managed Care entities.
  - Anti-kickback statute violations were a major source of FCA claims. Examples: Above fair market value fees, remuneration disguised as "medical directorships" (this has a home health case), EMR company receiving kickbacks to recommend a laboratory, discounts and tickets to clients who recommended EMR.

Fraud and Abuse Update

- DOJ also pursuing "pandemic fraud" under the FCA.
  - Many of these cases involve PPP loans that were improperly obtained.
  - May foretell actions related to the Employee Retention Credit
- DOJ also specifically notes its continued efforts to hold individuals accountable. DOJ notes multiple cases where individuals paid the FCA settlement.
- In FY2023, relators received $349 Million in payouts.
  - But in a case decided last June, 3 Supreme Court justices questioned whether Qui Tam lawsuits are constitutional.

Fraud and Abuse Update

- U.S. Supreme Court *Supervalu* decision.
  - Last June, Supreme Court issued a decision in a case involving pharmacies allegedly billing Medicare fraudulently.
  - Pharmacies were providing discounts to customers through a price matching program. (Trying to compete with Walmart.)
  - When they billed Medicare, Medicaid, etc., they did not report the discounted prices as their "usual and customary" charges.
  - Defendants appeared to be aware of the potential problem. E-mails from executives referred to the discount program as a "stealth approach"; recognized that stated that "if you [match a] price offer, that becomes your usual and customary [price] for that day;" and "cautioned that employees should not "put any of this in writing to stores because our official policy is we do not match."

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Fraud and Abuse Update

- U.S. Supreme Court *Supervalu* decision.
  - Defendants argued that, despite all of those statements, they had not knowingly submitted false claims, because regardless of what they actually believed, if their actions "were consistent with any objectively reasonable interpretation of the relevant law that had not been ruled out by definitive legal authority or guidance", then the defendants subjective thoughts about the issue did not matter.
  - In other words, the defendants argued that they may have thought they were doing something wrong, but unless their conduct was "objectively unreasonable" they could not be held liable for knowingly submitting a false claim no matter what they thought.

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Fraud and Abuse Update

- U.S. Supreme Court *Supervalu* decision.
  - The Supreme Court disagreed with that argument (and the lower court's decision.)
  - Court ruled that the important consideration is "what the defendant thought at the time they submitted the claim, not what the defendant may have thought after submitting the claim."
  - Appears that the e-mails and other internal correspondence made it clear that pharmacies were aware of a substantial likelihood they were not billing the usual and customary amount.
  - Court appears to leave open the door to a defense of mistake, but that would involve a mistaken understanding by the actual defendant, not some third party.

Fraud and Abuse Update

- U.S. Supreme Cour *Supervalu* decision.
  - This case is important, because a number of FCA defendants had raised the "objectively unreasonable" defense in FCA cases.
  - It allowed defendants to stop the case by focusing not on the defendant's conduct, but on whether a reasonable third-party might conclude the conduct was acceptable.
- IMPORTANT: If you think what you are doing may be illegal, you will not be able to avoid liability under the FCA later by arguing someone else might not have thought it was illegal.

Fraud and Abuse Update

- OIG opinion letters
- AO-23-07. Allowed a program where bonafide employee physicians would receive 30% of the profits of employer from procedures performed at either of two ASCs owned by the employer. OIG said this fit within the bonafide employee safe harbor. Opinion states that if physicians were Independent Contractors, the analysis would change.
- AO 23-15. Allowed a consultant's proposal to provide gift cards to physician clients who referred other practices to consultant. OIG noted that there was remuneration, but there were no referrals of federally reimbursable business.

HIPAA Enforcement

- Since April 2003, OCR has received 358,975HIPAA Complaints. Resolved 99% of the claims.
  - 30,839 resolved by requiring corrective action
  - 145 cases resolved with imposition of Civil Money Penalties. Total Dollar Amount: $142,663,772.00.
  - 15,211 cases found no violation has occurred.
  - 63,096 cases OCR intervened early, provided technical assistance and avoided an investigation.
  - 246,929 OCR determined the complaint did not present an eligible case for enforcement.
- Since April 2003, OCR has referred 2,197 cases to DOJ.*

* Source: OCR Enforcement Highlights April 2024

HIPAA Enforcement

- On February 14, 2024, HHS Office of Civil Rights issued two reports to Congress for CY 2022. These reports cited 2022 Enforcement Data.
- In 2022:
  - OCR received 30,435 complaints (this was down from 2021)
  - OCR initiated 676 compliance reviews
  - OCR received 63,966 reports of breaches involving fewer than 500 individuals
  - OCR received 626 reports of breaches involving more than 500 individuals.

HIPAA Enforcement

- OCR noted that the report of breaches by source as follows:
  - Hacking/IT incident – 74%
  - Unauthorized access/disclosure – 19%
  - Theft – 4%
  - Loss – 2%
  - Improper disposal < 1%
- Notice that most breaches are due to hacking/IT incidents, by a very wide margin.

HIPAA Enforcement

- Common HIPAA Deficiencies
  - Impermissible uses and disclosures of protected health information (this has been the top issue going back to 2018);
  - Lack of safeguards of protected health information;
  - Lack of patient access to their protected health information;
  - Lack of administrative safeguards of electronic protected health informati on; and
  - Use or disclosure of more than the minimum necessary protected health information.

HIPAA Compliance Risks

- OCR Enforcement has been steadily increasing over the years.
- This is driven, in part, by OCR's sense of provider complacency and, in part, by an ongoing increase in threats.
- OCR's audits and investigations have led OCR to be concerned about providers' compliance efforts.
- But the increasing volume, sophistication and variety of cyberthreats may be a bigger concern.
- Information from the American healthcare system has significant value to cybercriminals.
- Attacks becoming more common.

Change Healthcare

- February 21, 2024, Change Healthcare was subjected to a ransomware attack by the "Blackcat" group. The "most significant and consequential incident of its kind against the U.S. health care system in history." This attack:
  - Impacted Optum. Optum is used by 67,000 pharmacies and 119 Million patients. 1 in 3 healthcare transactions are touched by its systems;
  - Disrupted Change/Optum for approximately 2 weeks;
  - PHI of millions of patients and source code to Change's applications, was stolen;
  - Change CEO testified to Congress that Change healthcare paid a $22 Million ransom.
  - 5 class action lawsuits already filed.
  - Estimated cost to Change - $1 Billion.

Ascension

- May 8, 2024, Ascension Health system reported a disruption in its systems due to a cybersecurity event. Ascension later confirmed that the event was a ransomware attack.
  - Ascension's EHR was down for 36 days.
  - Impacted Ascension's operations in 12 states.
  - It appears that some patient data was stolen.

One Blood

- July 31, 2024, One Blood, a non-profit that supplies blood and blood products to hospitals throughout the southeast, announced it had been the victim of a Ransomware attack.
- Significantly reduced One Blood's capacity to provide blood to hospitals.
- Hundreds of hospitals impacted. Forced to go to shortage protocols. Elective surgeries postponed.

Cyber Attacks

- Cyberattacks are rising in health care.
- According to FBI, 249 cyber attacks occurred against health care providers and public health in 2023.
- Criminal actors focus on health care providers, due to the value of PHI on the dark web.

Why Does it Matter?

- Common threat vectors:
  - Phishing – 16% of data breaches
  - Stolen or compromised credentials – 15% of data breaches.
  - Cloud misconfiguration – 11% of data breaches
  - Social engineering – 8% (this is your employees making mistakes)
  - Physical security compromise – 8%.
  - Lost or stolen devices – 6%
  - Malicious insider (disgruntled employee) – 6%
- Notice that many breaches result from the mistakes your employees make. Two different reports stated more than 80% of breaches due to employee mistakes.

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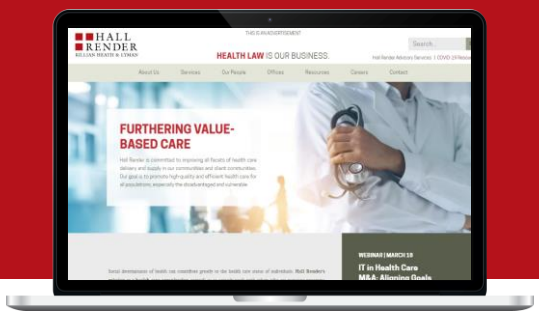

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