Michigan Center for Rural Health

Health Law Updates

April 28, 2023 Brian F. Bauer, Esq.

Agenda

- Rural Emergency Hospital, "*To Be Or Not To Be*"
- Whence (and what) be CINs and ACOs?
- OCR and Web Tracking Technologies
- Rights of Conscience
- Changes to Overpayment Refund Rule
- Risk Adjustment Data Validation (RADV) Audits

REHs: TO BE OR NOT TO BE

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- Eligible hospitals
  - CAHs or Rural PPS Hospitals with 50 or fewer beds
  - In existence as of 12/27/20 (not available for closed or new hospitals)
- Services
  - No inpatient services
  - Average patient length of stay under 24 hours
  - Emergency (CAH equivalent standards) and observation services
  - Other medical and health services on outpatient basis as specified by HHS

REHs: TO BE OR NOT TO BE

- Requirements: An REH must:
  - Have a transfer agreement in place with a Level I or II trauma center; and
  - Maintain a staffed emergency department, including staffing 24 hours a day, seven days a week by a physician, nurse practitioner, clinical nurse specialist, or physician assistant; and
  - Meet CAH-equivalent Conditions of Participation (CoPs) for emergency services; and
  - Meet applicable state licensing requirements;

REHs: TO BE OR NOT TO BE

- Pro/Con:
  - Monthly facility payment (based on average CAH benefit in 2019 over PPS)
    - CMS calculates CAH benefit > PPS in 2019 = $4,404,308,465
    - Number of CAHs in 2019 = 1,368
    - 12 months/year = **$268,294/ month or $3,219,528/year for calendar year 2023**
    - 2024 and beyond updated by market basket
  - CMS Proposed Rules do not address 340B for REHs
    - HRSA, not CMS, area of authority
    - Likely to require statutory amendments to 340B law

REHs: TO BE OR NOT TO BE

- Pro/Con:
  - CAH to REH Comparison:
    - MFP = $3.2 million/year for closing inpatient
    - Inpatient operating margin: Add loss, subtract profit
    - Add expenses eliminated from closing inpatient services
    - Subtract:
      - 340B benefit
      - Swing bed cost reimbursement to SNF PPS
      - 15% MPFS on Method II billing
      - Outpatient cost to 105% HOPPS

Whence (and what) be CINs and ACOs?

Whence (and what) be CINs and ACOs?

- Affordable Care Act
  - Medicare Shared Savings Program (MSSP)
  - CMMI
- CINs: 3.0
  - Restructured Health System CINs
  - Venture Capital CINs
  - Insurance Company CINs

Whence (and what) be CINs and ACOs?

- 3.0 CINs:
  - REACH or MSSP, prefer REACH
  - Medicare Advantage
  - Commercial
  - Employer Sponsored Plans (self insured)
  - Medicaid (not so much, except PCA CINs)
- 3.0 CINs:
  - Which programs and the nature of participation will generally be driven by ownership
    - Health Systems
    - Insurance Companies
    - Venture capital

Whence (and what) be CINs and ACOs?

- 3.0 CINs:
  - DATA
    - Data about your performance is now publicly available
  - LIVES
    - Well managed lives = $$$$$
    - By analyzing data and selecting only high performers CINs have no worries about downside risk
    - This puts Health System CINs at a disadvantage
  - Cost of exclusion
    - MIPS

Whence (and what) be CINs and ACOs?

- 3.0 CINs:
  - Employer Sponsored (self insured) Plans
    - Holy Grail?
      - Health Systems
      - Insurance Companies
    - Structure
      - Network, or
      - ACO
  - Medicare Advantage Plans
    - Required Quality Improvement Programs

Whence (and what) be CINs and ACOs?

- Super CINs: Myth or Next Evolutionary Step (CINs 4.0)?
  - Types:
    - CIN with wholly owned subsidiary CINs
    - CIN of CINs
    - Large CIN that crosses state lines

OCR and Web Tracking Technologies

OCR and Web Tracking Technologies

- Nearly all (98.6%) hospital websites leverage third-party tracking code that routinely transfers patient data to large technology companies, social media giants, advertising firms, and data brokers
  - Likely in violation of federal privacy laws (Health Affairs/SC Media)
- 69% of hospital homepages transferred data to third-party domains, of which the parent company could not be identified (Health Affairs/SC Media)
- OCR Bulletin re HIPAA Obligations of Hospitals (and other providers) re:
  - cookies
  - web beacons and
  - pixels

OCR and Web Tracking Technologies

- Generally, tracking technologies send information directly to the third parties
- OCR provides guidance re
  - when the data is PHI
  - processes to prevent transfer of PHI
- Bulletin Points:
  - Information disclosed to tracking technology vendors is likely PHI when it includes any individually identifiable information because such information connects the individual to the regulated entity
    - if the information collected from an individual and transmitted through the use of tracking technologies includes any information that identifies the individual (email or IP address), even indirectly, the presence of the tracking technology itself may be enough to create an inference that the information is related to the health of an individual

OCR and Web Tracking Technologies

- Bulletin Points:
  - The specific page that an individual interacts with on the provider's website impacts whether or not the information is PHI. Tracking tools on authenticated pages of a website are more likely to collect PHI
    - any tracking technologies implemented on a website for which the provider requires a user to log in before accessing certain content (i.e., portal or telehealth) must be managed in accordance with the HIPAA
    - Provider directories
    - web pages that address specific symptoms or conditions

OCR and Web Tracking Technologies

- Bulletin Points:
  - Filtering mechanisms or de-identification procedures employed by a tracking technology vendor upon receipt of information is insufficient for HIPAA compliance
    - just the capture of the data is the transfer of PHI
  - Providers must enter into BAAs with tracking technology vendors who meet the definition of a business associate
  - Disclosures of PHI through tracking technologies without a BAA require a HIPAA-compliant authorization
  - Providers must include the use of tracking technologies in their risk analysis and risk management processes
  - Where impermissible disclosures of PHI to tracking technology vendors have occurred, providers must provide breach notification to appropriate parties

OCR and Web Tracking Technologies

- Practical Takeaways:
  - Conduct a prompt and thorough investigation
  - Be careful to not interpret the term PHI too narrowly in this context
  - Carefully consider and document any HIPAA breach risk assessment that is performed
  - Implement reasonable and appropriate safeguards for the use of tracking technologies

Rights of Conscience

Rights of Conscience

- Proposed Rule
  - implementing various statutes that provide protections for health care providers and facilities who may have conscientious objections to certain forms of health care
    - repeal Trump era language because it is too vague
      - *"any duty to participate in any way in medical care, including referring patients to other providers for care, when the care relates to any program or activity…"*
    - Inclusion of additional statutes related to rights of conscience not referenced by the pre-Trump rule
    - OCR will be the agency that receives complaints and oversees investigations in accordance with a process set forth in the regulation
    - OCR *encourages* the posting of notices of conscience rights on an entity's website as well as in the place where other employment related notices are posted

Changes to Overpayment Refund Rule

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- Current Rule:
  - “reasonable diligence” standard
  - allows up to six months from the time they received credible information of a potential overpayment to investigate that potential overpayment
  - after this six-month investigation period the 60 days to report starts to run
  - in practice, this allowed provider a total of eight months to report and refund any overpayment and still be considered to have acted with “reasonable diligence”

Changes to Overpayment Refund Rule

- Proposed Rule:
  - “reasonable diligence” standard eliminated
  - False Claims Act (“FCA”) definition of “knowingly” would be adopted into the overpayment rule (in place of “reasonable diligence”)
  - Provider will be deemed to have identified an overpayment if:
    - they had actual knowledge or
    - acted in reckless disregard or deliberate ignorance of such overpayment
  - This change will eliminate the 6 month investigation period
  - Only have 60 days from the time they knew or should have known

Risk Adjustment Data Validation (RADV) Audits

Risk Adjustment Data Validation (RADV) Audits

- CMS finalized its Risk Adjustment Data Validation ("RADV") audit methodology
  - estimated recovery of $4.7 billion in overpayments from MAOs (for years 2011-2017
- RADV audits review documentation in the medical record to ensure the medical records support the diagnoses reported by the MAO for risk adjustments
  - if there is a lack of documentation in the medical record to support the diagnoses reported for the risk adjustment, CMS may collect any risk adjustment payment amount, or overpayment
- Audits to target certain HCC categories
- Application to CINs and Providers (pass-through protection)

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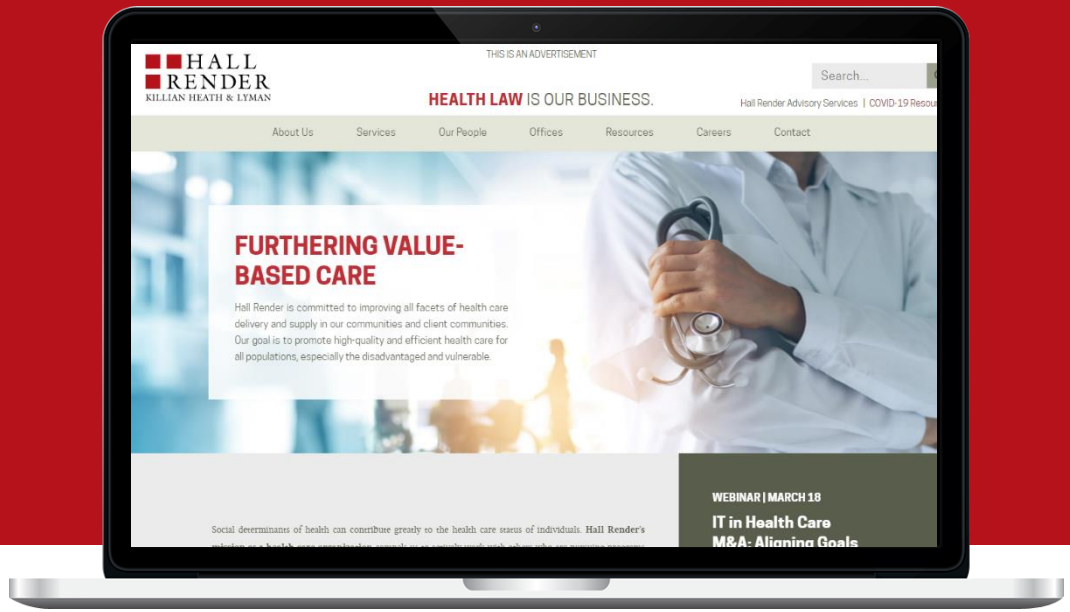

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