HEALTHCARE REGULATORY ROUND-UP - Episode #43

So Many Proposed Rules… So Little Time

February 8, 2023

Introductions

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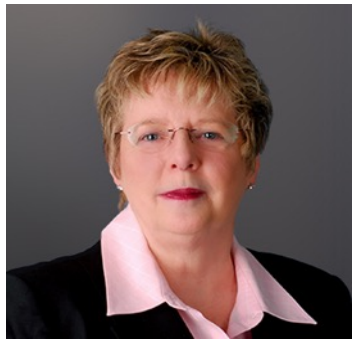

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Agenda

1. No Surprises Act Update
2. MA Policy and Technical Changes for CY2024
3. Prior Authorizations
4. Healthcare Attachment Transactions
5. Non-Compete Clauses
6. Rights of Conscience
7. Confidentiality of Substance Use Disorder Patient Records

1. No Surprises Act Update

Updated FAQs

- FAQ Part 3 – December 2, 2022
  - Indefinite enforcement delay in provision of GFEs from co-providers and co-facilities
  - Need for interoperability standard for transmission of GFE data between providers
    - Potential application for HL7® Fast Healthcare Interoperability Resources (FHIR®) standard
- FAQ Part 4 – December 27, 2022
  - Addresses GFE when provider offers sliding fee discounts

Independent Dispute Resolution Process

Step in the Process	Must Be Completed By
Payer sends provider initial payment or notice of denial of payment along with QPA	**30 business days**, starting on day payer receives all relevant data
Provider initiates 30-business-day open negotiation period	**30 business days**, starting on day of initial payment or notice of denial of payment
Either party initiates independent dispute resolution (IDR) following failed open negotiation (Federal IDR portal)	**4 business days**, starting business day after the open negotiation period ends
Mutual agreement on certified IDR entity selection; each party pays **$350** administrative fee (increase from $50 effective 1/1/23)	**3 business days** after IDR initiation date
Departments select certified IDR entity in case of no conflict-free selection by parties	**6 business days** after IDR initiation date
Parties submit payment offers and supporting information to certified IDR entity (with IDR entity fee – between $350 and $700; higher for batched determinations)	**10 business days** after date of certified IDR entity selection
IDR entity issues written opinion accepting one party's offer	**30 business days** after date of certified IDR entity selection
Payment made to provider (if successful); refund of successful party's IDR entity fee	**30 business days** after payment determination

2. Contract Year 2024 Policy and Technical Changes for Medicare Advantage

87 Fed. Reg. 79,452 (Dec. 27, 2022) (298 pages)

Comments due February 13

MA Policy and Technical Changes for CY2024

- Would modify regulations for reporting and returning Medicare overpayments
- Removes “reasonable diligence” standard and adopts FCA definition of “knowing” and “knowingly”
  - Impact on current 6-month period for investigation

Proposed Rule: Standard for Identification Under 60-day Overpayment Rule

	Current Identification Standard	Proposed Identification Standard
Medicare Parts A/B - 42 C.F.R. § 401.305(a)(2)	A person has identified an overpayment when the person ***has, or should have through the exercise of reasonable diligence, determined that*** the person has received an overpayment and ***quantified the amount of the overpayment***. A person should have determined that the person received an overpayment and quantified the amount of the overpayment if the person ***fails to exercise reasonable diligence*** and the person in fact received an overpayment.	A person has identified an overpayment when the person ***knowingly receives or retains*** an overpayment. ***The term "knowingly" has the meaning set forth in 31 U.S.C. 3729(b)(1)(A).***
Medicare Parts C/D – 42 C.F.R. § 422.326(c) and 42 C.F.R. § 423.360(c)	The MA organization has identified an overpayment when the MA organization ***has determined or should have determined through the exercise of reasonable diligence***, that the MA organization has received an overpayment. The Part D sponsor has identified an overpayment when the Part D sponsor ***has determined or should have determined through the exercise of reasonable diligence***, that the Part D sponsor has received an overpayment.	The MA organization has identified an overpayment when the MA organization ***knowingly receives or retains*** an overpayment. ***The term "knowingly" has the meaning set forth in 31 U.S.C. 3729(b)(1)(A).*** The Part D sponsor has identified an overpayment when the Part D sponsor ***knowingly receives or retains*** an overpayment. ***The term "knowingly" has the meaning set forth in 31 U.S.C. 3729(b)(1)(A).***

1) Source: King & Spalding Health Headlines: January 3, 2023

MA Policy and Technical Changes for CY2024

- Other provisions –
  - Goal is to focus on policies restricting or delaying access to patient care
  - Would require MA plans to adhere to traditional Medicare coverage policies for medical necessity determinations
  - Prior authorizations would be valid for prescribed treatment period
    - Including transition for newly enrolled beneficiaries on established treatment plans prior to enrollment

3. Advancing Interoperability and Improving Prior Authorization Processes

87 Fed. Reg. 76,238 (Dec. 13, 2022) (134 pages)

Comments due March 13

Processes Related to Prior Authorization

- Applies to MAOs, state Medicaid and CHIP fee-for-service and managed care programs, Medicaid managed care plans, and Qualified Health Plan issuers on federally facilitated exchanges
- Establish timeframes for standard and expedited prior authorization requests
  - Expedited: no later than 72 hours of request
  - Standard: no later than 7 **calendar** days of request
- Payers required to include specific reason for denying prior authorization
- Includes provider incentives for electronic requests using certified EHR technology

4. Adoption of Standards for Health Care Attachments Transactions and Electronic Signatures

87 Fed. Reg. 78,438 (Dec. 21, 2022) (31 pages)

Comments due March 21

Healthcare Attachment Transactions

- Promotes more consistent, effective and reliable communications between providers and health plans
- Addresses solicited and unsolicited documents
- Updated X12 version (5010 to 6020) for referral certification and authorization transaction standard

Healthcare Attachment Transactions

- Applies to both healthcare claims and prior authorizations
- Applies to all health plans, clearinghouses, and providers
- Includes expanded definition of electronic signature
  - Defines electronic signatures as “electric sound, symbol, or process attached to or logically associated with attachment information and executed by a person with the intent to sign the attachment information”

5. Non-Complete Clause Rule

88 Fed. Reg. 3,482 (Jan. 19, 2023) (65 pages)

Comments due March 20

What Is a Non-Compete?

- Contractual term between employer and worker that typically blocks worker from working for a competing employer, or starting a competing business, within certain geographic area and period of tie after the worker's employment ends
  - Employer seeks non-competes to protect investment made in worker
    - E.g., practice employs doctor and pays salary while doctor builds practice, then doctor terminates employment and starts competing practice
- Distinguish from non-disclosure and non-solicitation agreements
  - Consulting firm hires consultant who builds relationships with firm’s clients, then consultant goes to work for competitor and tries to lure clients to new firm

Anti-Competitive

- “[R]esearch has shown the use of non-compete clauses by employers has negatively affected competition in labor markets, resulting in reduced wages for workers across the labor force—including workers not bound by non-compete clauses. This research has also shown that, by suppressing labor mobility, non-compete clauses have negatively affected competition in product and service markets in several ways.
- “[T]he existing legal frameworks governing non-compete clauses—formed decades ago, without the benefit of this evidence—allow serious anticompetitive harm to labor, product, and service markets to go unchecked.”

Proposed Rule

- Employer engages in “unfair method of competition” in violation of Section 5 of the FTC Act by –
  - entering into, or attempting to enter into, a non-compete clause with a worker
  - maintaining with a worker a non-compete clause
  - representing to a worker that the worker is subject to a non-compete clause where the employer has no good faith basis to believe that the worker is subject to an enforceable non-compete clause
- “Worker” includes employees, independent contractors, externs, interns, volunteers, apprentices, and sole proprietors providing a service to a client or a customer
- Effective date = 60 days following publication of Final Rule; compliance date = 120 days thereafter

Exception

- Non-compete included as part of sale of business entity or all/substantially all of business' operating assets, but only if person is "substantial" owner of, or "substantial" member or "substantial" partner in, business entity at time of non-compete
- "Substantial owner" = 25% or more ownership interest in the business
  - Those with ownership interest of less than 25% cannot be subject to non-compete associated with sale of business

Rescission

- Employer must rescind existing non-compete clauses (current AND former workers) no later than compliance date
  - actively inform workers their non-compete agreements no longer in effect and may not be enforced against them
  - provide notice in individualized communication
    - on paper or in a digitized format, e.g., email or text message
    - within 45 days of rescinding non-compete
- **Safe Harbor**: employer who provides notice to a worker as specified above complies with the rescission requirement

Model Language for Notice

A new rule enforced by the Federal Trade Commission makes it unlawful for us to maintain a non-compete clause in your employment contract. As of ***[Date 180 days after date of publication of final rule]***, the non-compete clause in your contract is no longer in effect. This means that once you stop working for ***[Employer name]:***

- You may seek or accept a job with any company or any person – even if they compete with ***[Employer name];***
- You may run your own business – even if it competes with ***[Employer name]***;
- You may compete with ***[Employer name]*** at any time following your employment with ***[Employer name].***

The FTC's new rule does not affect any other terms of your employment contract. For more information about the rule, visit ***[link to final rule landing page***].

Not-for-Profit Organizations

- The FTC Act limits FTC's jurisdiction to business entities organized to conduct business "for [their] own profit or that of its members."
- Not-for-profit organizations generally considered exempt from FTC Act
- Application to not-for-profit organization's for-profit affiliate or joint venture?

Request for Comment

- Should senior executives be exempt, or subject to rebuttable presumption instead of prohibition?
- Should low- and high-wage workers be treated differently?
- Should prohibition extend to non-competes between franchisees and franchisors?
- What tools other than non-competes might employer use to protect valuable investments and how sufficient are those alternatives?

Issues for Healthcare Providers

- Patient choice considerations with physician non-competes?
- Fair market valuation of compensation arrangement that included consideration of non-compete?
- Impact on future compensation arrangements (physician less valuable given ability to establish/join competing practice
- Limitations of sale-of-business exception – businesses with physician investors who each hold less than 25% interest

6. Safeguarding the Rights of Conscience as Protected By Federal Statute

88 Fed. Reg. 820 (Jan. 5, 2023) (11 pages)

Comments due March 6

Conscience Rights and Protections

- Several provisions of Federal law prohibit discrimination against health care providers who refuse to participate in services they find religiously or morally objectionable
  - None of these provisions require promulgation of implementing regulations
- Rulemaking
  - 2008 Final Rule - *Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law*
  - 2011 Final Rule - *Regulation for the Enforcement of Federal Health Care Provider Conscience Protection Laws*
  - 2019 Final Rule - *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority*
  - 2023 Proposed Rule - *Safeguarding the Rights of Conscience as Protected by Federal Statutes*

Proposed Rule

- Seeks to strike “careful balance” between patient’s right to timely care and health care professional’s right to religious or conscious objections
- Proposes to rescind most of the 2019 Final Rule, leaving the 2011 Final Rule’s framework in place
- Proposes to retain modified versions of 3 aspects of 2019 Rule
  1. Expand category of “federal health care provider conscience protection statutes” to include conscience protections embedded in wide range of HHS programs (e.g., Medicare and Medicaid statutes)
  2. Retain enforcement provisions related to complaint handling and investigations, such as:
     1. Expansion of 2011 Final Rule’s description of complaint handling and investigation; and
     2. OCR investigatory procedures
        - How OCR will proceed if an investigation reveals a violation of a federal health care provider conscience protection statute
        - Providing that OCR will seek voluntary resolution of violations and will inform relevant parties if it has found no violation.
  3. Voluntary notice provisions
        - Entities subject to federal health care provider statutes should inform the public about their rights and entity’s obligations under Federal conscience and nondiscrimination laws.
        - Posting of notice considered “best practice”

7. Confidentiality of Substance Use Disorder Patient Records

87 Fed. Reg. 74,287 (Dec. 2, 2022) (72 pages)

Comments were due January 21, 2023

42 C.F.R. Part 2 vs. HIPAA

- Part 2 governs confidentiality of records generated by individual or entity that (a) provides alcohol or drug abuse diagnosis, treatment, or referral for treatment; and (b) receives federal assistance (Part 2 Programs)
- Part 2 differs from HIPAA rules, creating compliance challenges
  - Part 2 protections attach to records created by Part 2 Programs (not just Part 2 Programs) while HIPAA obligates covered entities to use and disclose PHI in specific manner
- Part 2 Programs face challenges in accessing complete information when treating patients
- Section 3221 of the CARES Act directed HHS to bring Part 2 into greater alignment with HIPAA

Key Changes

- Permits use and disclosure of Part 2 records based on single patient consent given once for all future uses and disclosures for treatment, payment, and health care operations
- Permits redisclosure of Part 2 records in any manner permitted by the HIPAA Privacy Rule, with certain exceptions
- Creates new patient rights under Part 2 obtain accounting of disclosures and to request restrictions on certain disclosures
- Expands prohibitions on use and disclosure of Part 2 records in civil, criminal, administrative, and legislative proceedings
- Applies HIPAA civil and criminal penalties to Part 2 violations
- Applies HIPAA breach notification rules to breaches of Part 2 records by SUD treatment providers
- Modifies Part 2 confidentiality notice requirements to align with HIPAA Notice of Privacy Practices

Notice of Privacy Practices

- Updates HIPAA Privacy Rule Notice of Privacy Practices requirements to address uses and disclosures of Part 2 records and individual rights with respect to those records
  - Only required if covered entity receives Part 2 records
- Incorporates additional changes to Notice of Privacy Practices previously proposed in January 2021
  - Revise standard header (including designated contact person with phone number and email)
  - Revise section on right of access to describe how individual can exercise this right to obtain copy of their records at limited cost or, in some cases, free of charge, and right to direct provider to transmit electronic copy of PHI in an EHR to third party
  - No more written acknowledgements!!!
- Fate of other provisions in January 2021 proposed rule?

Enforcement

- Affords providers 24 months from publication of final rule to bring operations in compliance with new rules
  - Tolls compliance date for Part 2 programs until effective date of final rule on HIPAA accounting of disclosures standard required by HITECH Act
    - No proposed rule has been published following December 2018 Request For Information

One More NSA Update

- Texas Medical Ass'n v. U.S. Dep't of Health and Human Services (Feb. 6, 2023)
  - Court grants TMA's motion for summary judgment that NSA regulations limiting information IDR entity may consider in determining appropriate payment amount
  - Court vacates those portions of regulations requiring "QPA first, all the rest next"
  - IDR entities apply statutory factors as they deem appropriate
  - What happens to prior IDR determinations?

Our Next Healthcare Regulatory Round-Up:

“Getting Ready for May 11 and the End of the PHE”

March 1, 2023