HEALTHCARE REGULATORY ROUND-UP - Episode #46

Reading the Tea Leaves: What's Next In Healthcare Regulation

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Introductions

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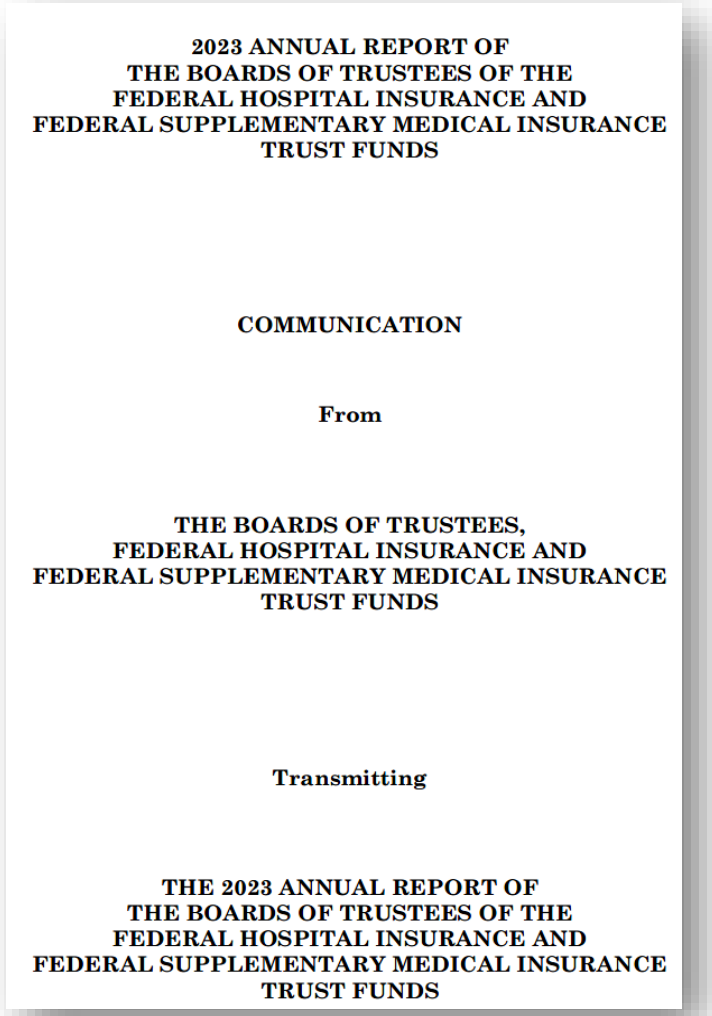
Yet Another Top Ten List

1. 2023 Medicare Trustees Report
2. President's FY 2024 Proposed Budget
3. 2023 MedPAC Reports
4. FY 2024 Medicare Proposed Rules
5. Medicare Advantage
6. Interpretive Guidelines for Revised Hospital QAPI CoPs
7. ACA-Mandated First Dollar Coverage for Preventive Services
8. State and Local Initiatives
9. Price Transparency
10. HIPAA

1. 2023 Medicare Trustees Report



2023 ANNUAL REPORT OF
THE BOARDS OF TRUSTEES OF THE
FEDERAL HOSPITAL INSURANCE AND
FEDERAL SUPPLEMENTARY MEDICAL INSURANCE
TRUST FUNDS

COMMUNICATION

From

THE BOARDS OF TRUSTEES,
FEDERAL HOSPITAL INSURANCE AND
FEDERAL SUPPLEMENTARY MEDICAL INSURANCE
TRUST FUNDS

Transmitting

THE 2023 ANNUAL REPORT OF
THE BOARDS OF TRUSTEES OF THE
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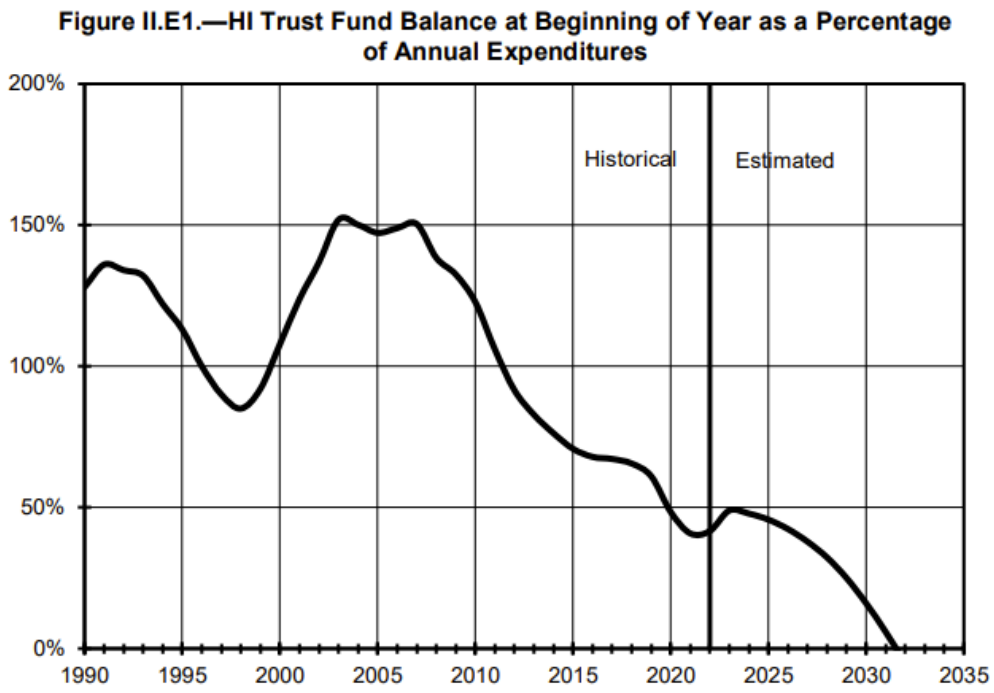
TRUST FUNDS

- In 2022, Medicare covered 65 million with total expenditures of $905.1B ($14K per beneficiary)
- Hospital Insurance (HI) Trust Fund
  - Part A – funded by payroll taxes ($397B in income and $343B in expenditures in 2022)
- Supplemental Medical Insurance (SMI) Trust Fund
  - Parts B & D – funded by general revenue ($330B in 2022) + beneficiary premiums ($131B in 2022)
- Part C (Medicare Advantage) – payments to MA plans funded by HI ($170B in 2022) and SMI Trust Funds ($234B in 2022) (44.5% of all expenditures)
- Administrative expense = $11B in 2022 (1.2%)

2023 Medicare Trustees Report



- Beginning in 2031, projected amount in HI Trust Fund will be less than projected cost of Part A services (only cover 89% of incurred program costs)
- SMI Trust Fund remains solvent, but only because general revenue contributions and premiums will increase automatically to cover higher costs
- "The financial projections in this report indicate a need for substantial changes to address Medicare's financial challenges. The sooner solutions are enacted, the more flexible and gradual they can be. The early introduction of reforms increases the time available for affected individuals and organizations—including health care providers, beneficiaries, and taxpayers—to adjust their expectations and behavior."

Options

1. Raise taxes
2. Shift more costs to beneficiaries
   - Reduce/restrict coverage
   - Increase % of Part B funded by premiums
   - Increase beneficiary co-insurance obligation
3. Cut provider reimbursement
   - Recent efforts: drug price negotiations, inpatient to outpatient services
   - Already facing additional 4% sequestration starting in 2025
4. Reduce demand for services
   - Reduce number of eligible beneficiaries
   - Manage beneficiaries' health
5. Reduce payments to MA plans
6. Reduce administrative costs
   - But only 1.2% of total spend
7. Eliminate fraud, waste, and abuse
   - $4B in 2021 and 2022 – less than 0.5% of total spend

2. President's FY 2024 Proposed Budget

- Total FY 2024 request for HHS = $1.7T
- Extend solvency of HI Trust Fund
  - Increase Net Investment Income Tax (NIIT) rate on incomes above $400,000 from 3.8% to 5% ($344B)
  - Require all pass-through business income of high-income households to be subject to either NIIT or equivalent Self-Employment Contributions Act tax ($306B)
  - Expand prescription drug price negotiation ($200B)
- Make permanent increased premium tax credits extended though 2025 by the Inflation Reduction Act ($183B)
- Provide Medicare-like coverage for individuals in states without Medicaid expansion ($200B)
- Require all states to provide continuous Medicaid coverage for 12 months postpartum ($2.4B)

President's FY 2024 Proposed Budget

- Expand access to behavioral health services
  - Expand Medicare to provide first-dollar coverage for 3 behavioral health visits per year
  - Allow CMS to identify and designate additional behavioral health professionals to enroll in and be paid by Medicare
  - Eliminate 190-day lifetime limit on psychiatric hospital services under Medicare
  - Apply 2008 Mental Health Parity and Addiction Equity Act to Medicare program
  - Require commercial insurance plans provide first-dollar coverage for at least 3 behavioral health visits and 3 primary care visits per year
  - Strengthen enforcement of mental health parity standards by requiring insurers to use medical necessity criteria consistent with those developed by nonprofit medical specialty association
  - Authorize agencies to regulate behavioral health network adequacy requirements
- Extend $35 cap on insulin to all Americans
- Extend the NSA to ground ambulance

3. 2023 MedPAC Reports

- March Report to Congress focuses on recommended payment updates
  - Inpatient PPS
    - Current law plus 1%
    - Move DSH and uncompensated care payments/create Medicare Safety-Net Index (MSNI)
      - Add $2B to pool
      - Distribute as add-on payments under IPPS and OPPs
      - Exclude from MA benchmarks
        - Pay directly to providers

3. 2023 MedPAC Reports

- Physician Update
  - Update base rate by 50% of the projected increase in Medicare Economic Index
  - Non-budget neutral add-on payment (without cost sharing) for services provided to low-income Medicare beneficiaries
    - 15% primary care
    - 5% all others

3. 2023 MedPAC Reports

- Other Providers
  - Inpatient Rehab: reduce base rate by 3%
  - Skilled Nursing: reduce base rate by 3%
  - Home Health: reduce base rate by 7%
    - Implementation of PDGM was to be done in budget-neutral manner
      - Already two overages identified by CMS that must be addressed by 2026
        - One time reduction needed to recoup for 2020-2021 overages ($2 B)
        - As in 2023, reduce spending by 3.925% in future years to address spending above target

3. 2023 MedPAC Reports

- June Report to Congress – topics under discussion
  - Reforming Medicare's wage index systems
  - Aligning fee-for-service payment rates across ambulatory settings
  - Addressing the high prices of drugs covered under Part B
  - Report on design for post-acute care PPS
  - Addressing need for Medicare safety net payments for SNFs and home health agencies
  - Telehealth
  - Behavioral health (following Congressional request)

4. FY 2024 Medicare PPS Proposed Rules

- **Inpatient Rehabilitation Facilities (IRF)**
  - Issued April 3; comments due June 2
  - Update payment rates by 3.7%
    - Increase labor-related share from 77.4% to 78.5%
    - For FY 2023 - proposed 2.8% increase, finalized 3.9% increase
  - Allows IRF units to open anytime during cost report period
  - Updates to IRF Quality Reporting Program
    - FY2025 – adopt discharge function score and COVID-19 staff vaccine measures
      - Remove functional assessment/care plan, functional outcome/change in self-care, and functional outcome/change in mobility measures
    - FY2026 – adopt COVID-19 patient vaccine measure

4. FY 2024 Medicare PPS Proposed Rules

- **Inpatient Psychiatric Facilities (IPF)**
  - Issued April 4; comments due June 5
  - Update payments by 3.7%
    - Increase labor component of wage index from 72.9% to 74.1%
    - For FY 2023 - proposed 2.7% increase, finalized 3.8% increase
  - Allows IPF units to open anytime during cost report period with notification
  - Updates to IPF Quality Reporting Program – 3 new measures focused on health equity
    - Facility Commitment to Health Equity (FY 2026 payment determination)
    - Screening for Social Drivers of Health (voluntary reporting of CY 2024 data/required FY 2027 payment determination)
    - Screen Positive Rate for SDOH (voluntary reporting of CY 2024 data/required FY 2027 payment determination)

4. FY 2024 Medicare PPS Proposed Rules

- **Skilled Nursing Facilities (SNF)**
  - Issued April 4; comments due June 5
  - Overall payments increased by 3.7%
    - Includes 2.3% parity adjustment due to PDPM transition
    - For FY 2023 - proposed 0.7% decrease, finalized 2.7% increase
  - New and modified measures for SNF Quality Reporting Program
  - Updates to SNF Value Based Purchasing Program measures

4. FY 2024 Medicare PPS Proposed Rules

- **Inpatient Hospital PPS**
  - Issued April 10; comments due June 7
  - Update payments by 2.8%
    - For FY 2023 - proposed 3.2% increase, finalized 4.3% increase
  - Expected decrease in DSH and uncompensated care payments of $115 million
  - Continues low-wage hospital policy; assessment to continue
  - Revision of Inpatient Quality Reporting measures
  - Paying for value
    - No changes to hospital readmissions reduction program
    - Validation process for HAC program
    - Revisions to VBP program

5. Medicare Advantage – 2024 Rate Announcement

- 3.32% payment increase for MA plans ($13.8 billion)
  - CMS had proposed 1.1% payment increase in January
- 3-year phase-in of 2024 risk adjustment model
  - While 2020 model maps 13.3% of all ICD-10s to one of 86 payment condition categories (HCCs), 2024 model maps only 10.5% of ICD-10 codes to 115 payment HCCs
  - CMS re-built HCCs from ground up, reviewing each ICD-10 to determine most appropriate groupings based on clinical considerations and ability to predict Medicare costs
  - CMS had proposed full implementation for 2024, but now will phase in 1/3 in 2024 and 2/3 in 2025
- Impact of Risk Adjustment Data Validation (RADV) Final Rule
  - Extrapolation to begin with PY 2018 RADV audits
  - Only when medical records "comply with all CMS data and documentation requirements, . . . described in current agency policy documents, including the Medicare Managed Care Manual," do they properly support a reported diagnosis for MA documentation purposes

5. Medicare Advantage – April 2023 Final Rule

- Numerous provisions to increase oversight and align MA with FFS Medicare
  - Adherence to “two-midnight” rule
  - Limit ability to apply site restrictions
  - Appropriate clinician making prior authorization decisions
    - Prior authorization valid for course of approved treatment or 90-day transition period if switching plans
  - Prohibition on use of internal or proprietary criteria in coverage decisions
  - Behavioral health network adequacy requirements to be strengthened
  - Address misleading marketing practices

6. Interpretive Guidelines for Revised Hospital QAPI CoP

- March 9, 2023, CMS Center for Clinical Standards and Quality/Quality, Safety & Oversight Group memorandum with IGs for revised 42 CFR 482.21
  - Revisions effective November 2019, but most specific QAPI requirements waived during PHE
- Key provisions
  - Engagement and oversight by hospital's governing body
  - Evidence of resources provided to support QAPI functions
  - Medical error/adverse event reporting system
  - Annual performance improvement projects
  - Demonstration of sustained measurable improvements in selected quality indicators
- Still waiting for IGs for CAH QAPI CoP

https://www.cms.gov/files/document/qso-23-09-hospital.pdf

7. First Dollar Coverage for Preventive Services

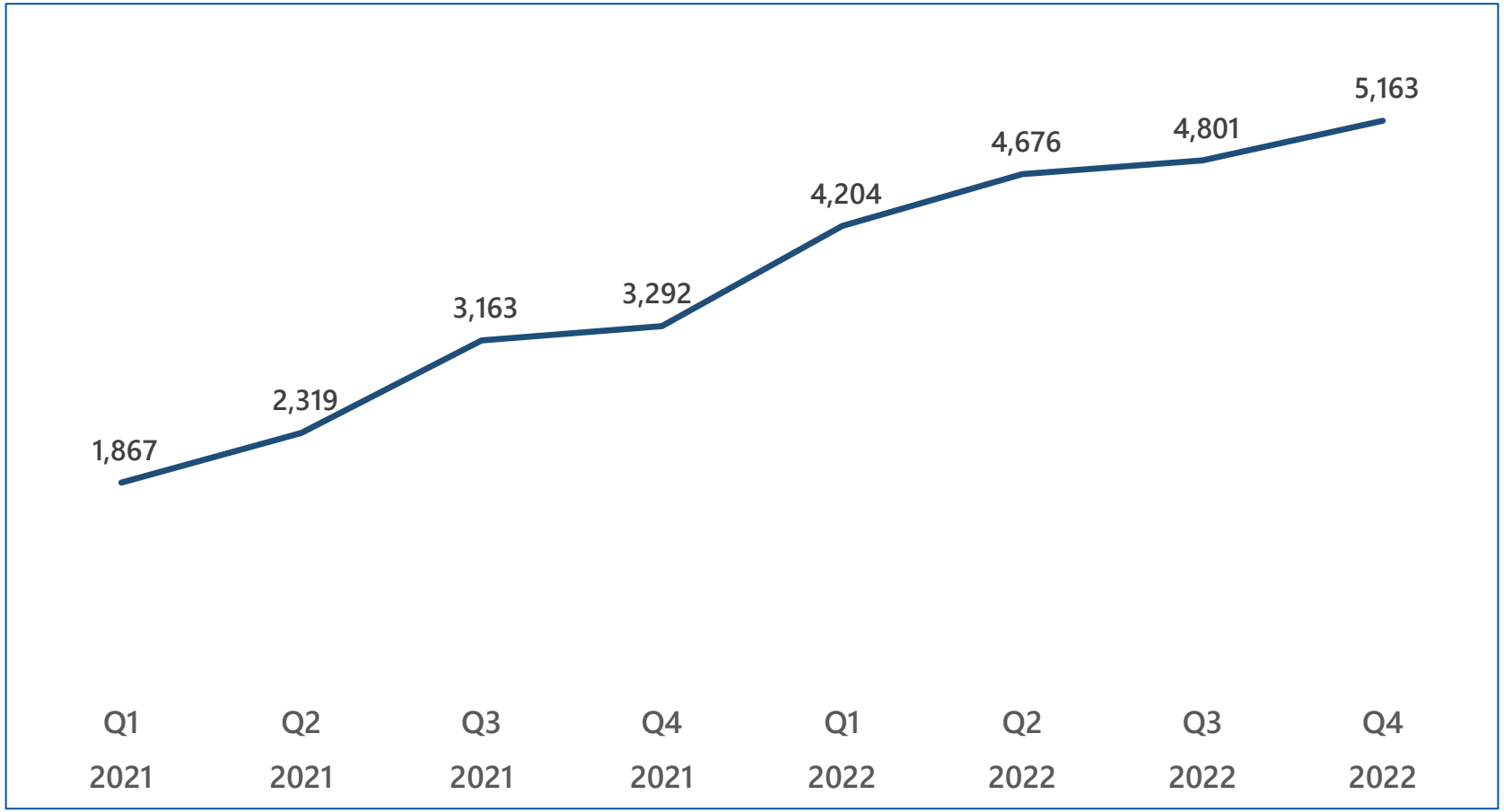
- ACA requires commercial health plans to provide first dollar coverage for services recommended by the U.S. Preventive Services Task Force (USPSTF)
  - Approximately 100 million people receive ACA-required preventive services with no patient cost-sharing annually
- *Braidwood Management vs. Becerra* (N.D. Texas March 30, 2023)
  - Cannot mandate coverage for USPSTF recommendations made after ACA's enactment (improper delegation of legislative authority)
  - Federal government is appealing decision
- Response by commercial health plans? Federal/State legislation?

8. State and Local Initiatives

- Cost controls
  - Reference-based pricing (state employee health plans)
  - Cost growth benchmarks
  - Premium rate reviews
- State public option plans
- Regulation of anti-competitive behavior
  - Prohibition on non-compete clauses
  - Prohibition on most favored nation clauses in payer contracts
- Community benefit
- Hospital executive compensation
  - SEIU-UHW union proposed ballot measure to limit compensation for healthcare executives at Los Angeles facilities to no more than U.S. President's total compensation (currently $450,000 annually)

9. Price Transparency - Compliance

Number of Hospitals that have Posted a Machine-Readable File (2021 – 2022)



Data Source: Turquoise Health Co.

9. Price Transparency – Federal Enforcement

- In March, CMS send ~500 warning letters to hospitals for transparency non-compliance
- Recent CMS consumer listening session on display of information
- Need to drive standardized reporting of hospital data
- Template with standardized set of data for machine-readable files (November 2022: optional)
- Ways to streamline enforcement efforts
  - Expedite timeframes for full compliance following corrective action plan
  - Aggressive additional steps to identify and prioritize action against hospitals that have failed to entirely post files

9. Price Transparency - State Enforcement

- **Texas**
  - **Health & Human Services Commission guidance issued 09/22/22 relating to enforcement of Texas' hospital price transparency law**
  - Commission will monitor hospitals' compliance with transparency rules and impose penalties on those that fail to implement corrective action plans
    - **$10/day for hospitals with gross revenue < $10 M**
    - **$100/day if gross revenue between $10M - $100M**
    - **$1,000/day if gross revenue more than $100M**

- **Colorado**
  - **Legislation effective 08/10/22 (02/15/23 for CAHs)**
  - Hospital cannot use debt collectors, file negative credit reports against patients, or obtain state court judgments for outstanding debts if hospital not compliant with all federal price transparency laws
  - Patient can sue hospital if hospital pursues collection action against patient and patient believes hospital not in material compliance with price transparency laws on date of service
    - **Penalty equal to amount of total debt + attorneys' fees and costs; remove information impacting patient's credit report**

Source: https://www.hhs.texas.gov/sites/default/files/documents/gl-21-2008.pdf; https://leg.Colorado.gov/bills/hb22-1285

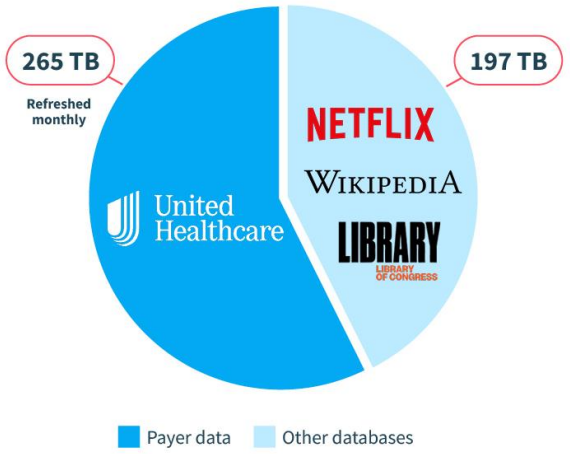
9. Price Transparency: Payer Data

Payer rates data dwarfs some of the largest databases

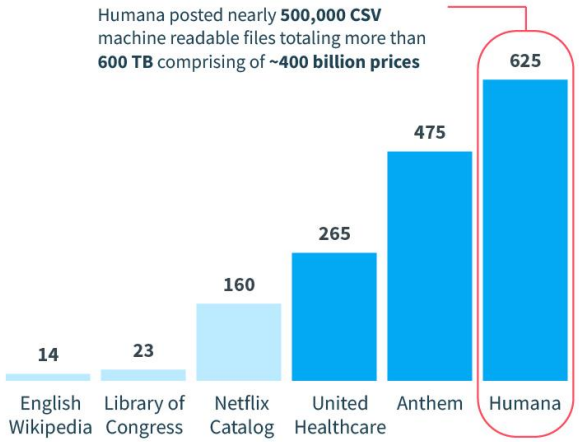
Clarify

The total number of prices (Payer x Plan x Provider x Code) could reach > 1 Trillion prices

UnitedHealthcare
265 TB dump of ~100,000,000,000 prices



Payer posted data volume
compared to other databases (TB)



Price transparency at scale

Resources needed to scrape and process include tens of thousands of dollars of disk space and extensive engineering time

Equally as challenging as aggregating and processing such a large scope of data is identifying insights

A platform that aggregates data to provide actionable insights, with granular price level detail, will be needed for all consumers

Source: Study conducted by Clarify on payer databases in 2022

10. HIPAA Rules

- January 2021 and December 2022 proposed rules
  - Access and fees - overhauling individual access rights, clarifying fees for access, and expanding the existing regulatory framework
  - Notice of Privacy Practices - eliminating written acknowledgement of receipt of notice of privacy practices and updating content requirements.
  - Changes to “minimum necessary” and “health care operations” - addressing uses and disclosures of PHI for care coordination and case management.
  - Shifting from “professional judgment” to “good faith” standard for certain disclosures
  - Uses and disclosures to avert threats to health or safety: shifting disclosure threshold from situations involving “serious and imminent” threat to those involving “serious and reasonably foreseeable” threat
  - Rationalizing 42 CFR Part 2 (SUD records) requirements and HIPAA Privacy Rule

Our Next Healthcare Regulatory Round-Ups:

April 26: FY2023 IPPS Proposed Rule +MA Final Rule

May 10: No Surprises Act