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Leaning Objectives

- A. Understand basis and support for federal price transparency and surprise billing requirements;
- B. Identify strategies to monitor compliance and reduce enforcement risks;
- C. Learn about where the transparency trend is headed, including discussion of litigation challenging federal requirements

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Agenda

- How did we get here?
- The current requirements
- Monitoring Compliance
- Next Steps in Price Transparency

How did we get here?

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Statistics

- HHS: 66.5 percent of all bankruptcies were tied to medical issues.
 - "Medical issues," for this purpose, include high costs of health care or time out of work.
- HealthAffairs study (2017): large percentage of hospital visits result in a bill from an out-of-network provider, commonly referred to as a "surprise bill"*:
 - 20% of hospital inpatient admissions that originated in the emergency department (ED)
 - 14% of outpatient visits to the ED
 - 9% of ELECTIVE inpatient procedures
 - * It has become common to use the term "surprise bill" to refer to any out-of-network bill even if the patient consented to the use of an out-of-network provider through the provider's standard disclosure agreements.

Minnesota leading the way

- Minnesota Attorney General Agreement
 - Signed by all Minnesota hospitals in 2007, renewed multiple times
 - Requirements
 - Charity care policies and requirements
 - "Most Favored Insurer" rate for the uninsured
 - Limits on debt collection activity
- Good-faith estimate law (Minn. St. § 62J.81) first adopted in 2004
 - Providers required to "estimate the allowable payment the provider has agreed to accept from the consumer's health plan company for the services specified by the consumer ..."
 - For consumers without insurance, the provider must estimate
 - "the average allowable reimbursement the provider accepts as payment from private third-party payers ..." and
 - "the estimated amount the noncovered consumer will be required to pay."

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State Responses (cont.)

- Minnesota Surprise Billing Law (Minn. St. § 62Q.556) (2017)
 - Hold harmless for patients
 - Provider/Insurer dispute resolution process
 - Does not apply to emergency services or self-funded health plans
- Primary Care Price Transparency law (Minn. St. § 62J.812) (2018)
 - Providers to post 25 most frequently billing CPT codes over \$25
- Minnesota was/is not alone many states adopted measures to promote transparency

Initial Federal Efforts

- Internal Revenue Code 501(r)
 - Affordable Care Act required IRS to develop charity care and charge limits for non-profit hospitals and health systems
 - Requires hospital to create a Financial Assistance Policy (FAP)
 - Limits charges to FAP-eligible patients to the Amounts Generally Billed (AGB) (calculated based on payments from most payers)
 - Imposes restrictions on billing and collection activities
 - Cite: 79 FR 78953

Initial Federal Efforts

- Hospitals required to publish a list of their "standard charges." (42 U.S.C. § 300gg-18(e))
 - Old HHS definition of standards charges:
 - A standard list of all the billable services accounting for the cost of providing the service, other fees, and equipment needs
 - Essentially the chargemaster
 - The chargemaster price "is not what anybody pays ..."
 - Medicare sets its own rate, not included in the chargemaster
 - Payers negotiate discounts, either from the chargemaster rate or, more commonly now, prices are set through negotiation
 - Uninsured and under-insured patients are entitled to legal discounts (see, e.g., the Minnesota Attorney General Agreement) or eligible for discounts or charity care
 - Maybe if you are a Saudi Prince you may pay the chargemaster rate

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The current requirements

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Outline

- Balance Billing Limits (42 U.S.C.A. § 300gg-131)
- Hospital Price Transparency (84 FR 65524)
- Payer disclosure obligations (86 FR 36872)

New Federal Law and Regulations

- The No Surprises Act was part of the Consolidated Appropriations Act of 2021
 - Contained a number of new requirements for providers and health plans related to price transparency, most notably a national "surprise billing" solution that bans certain balance billing
 - Patient hold harmless
 - Dispute resolution for payers and providers
 - No rigid formula for rates n benchmark rate and Medicare/Medicaid based percentage
- New Federal Regulations expand the definition of "standard charges" and expand the scope of who must make disclosures:
 - New rules for hospitals
 - Federal rule issued November 27, 2019. Cite: 84 FR 65524
 - Finally took effect January 1, 2021
 - New rules for payers
 - Interim Final Rule (IFR) published July 13, 2021. Cite: 86 FR 36872
 - Health plan provisions mostly takes effect: January 1, 2022

Balance Billing Limits – Who and What is Covered?

- Who is Covered?
 - A participant, beneficiary, or enrollee ...
 - with benefits under a group health plan or group or individual health insurance coverage offered by a health insurance issuer ...
 - furnished during a plan year beginning on or after January 1, 2022
- What is Covered?
 - Emergency services (for which benefits are provided under the plan or coverage) with respect to an emergency medical condition
 - Covers services provided at:
 - a nonparticipating facility, or
 - by a nonparticipating provider
 - Locations covered:
 - emergency department of a hospital, or
 - independent freestanding emergency department

Balance Billing Limits – Consent

- Consent allowed for services by an out-of-network provider at an in-network facility (42 U.S.C.A. § 300gg-132) (subject to limits)
- Limits:
 - Appointment for services made 72 hours in advance
 - Written notice in paper or electronic form, as selected by the patient, in 15 most common languages
 - Clearly states that consent is optional and patient may receive the services from a participating provider at an in-network cost-sharing rate
 - Provide a list of participating providers who are able to provide the services (if any)
 - Provide a good-faith estimate of the amount that will be charged to the patient
 - Provides notice of prior authorization or other care management limitations that may apply
- No consent allowed for:
 - emergency services
 - Ancillary Services (Anesthesiology, Pathology, Radiology, Neonatology, lab services)

Balance Billing Limits – Provider Disclosure

- Additional Disclosure requirements for providers
 - Providers must create a "one-page notice" outlining the federal balance billing requirements, any applicable state law requirements, and information on how to file a complaint with the federal or state government (42 U.S.C.A. § 300gg-133);
 - Provide a good-faith estimate of total expected charges (42 U.S.C.A. § 300gg-136); and
 - Provide details on Patient-Provider dispute resolution process for the uninsured individuals (300gg-137).

Balance Billing Limits – Payer/Provider Negotiation

- Balance subject to negotiation/arbitration
 - Process:
 - Plan makes initial payment or denial,
 - Provider objects to payment amount,
 - negotiations occur,
 - if unresolved by negotiation subject to "Baseball style arbitration" (subject to certain factors)
 - Arbitration factors (300gg-111(c)(5)(C)):
 - Submitted offers from both parties,
 - training and expertise of the providers,
 - market share of the provider,
 - quality and outcomes
 - Factors that cannot be considered (300gg-111(c)(5)(D)):
 - Billed charges
 - · usual and customary charges, or
 - public payor rates

Balance Billing Limits – State Preemption

- State law preemption and deference:
 - state law is preempted if it "prevents the application" of the No Surprises Act
 - This is the same preemption standard used by HIPAA and ACA
 - Permits states to impose stricter requirements

Hospital Price Transparency

- The Rule requires two hospital disclosures:
 - Disclose the "standard charge" for every "item or service" where a standard charge has been established in a <u>"machine-readable" format</u>
 - Provide a separate consumer-friendly list of 300 "Shoppable Services"
 - Alternative for Shoppable Services: Provide access to a "price estimator" that provides information for the CMS defined shoppable services plus at least 225 additional Shoppable Services

Hospital Price Transparency – Machine Readable

- "Standard charge" defined:
 - Gross charges -
 - meaning the chargemaster price
 - Cash discount prices -
 - "generally applicable price the hospital would accept from a cash-paying customer"
 - The payer-specific negotiated charge, for every payer with whom the hospital has negotiated a price for the service
 - The de-identified maximum negotiated charge
 - The de-identified minimum negotiated charge

Hospital Price Transparency – Machine Readable

- "Every 'item and service'" defined:
 - Includes any item, DRG, or "service package" where a price has been negotiated
 - Include facility fees, room and board, and other fees
 - Include costs of services from employed providers, but not contracted providers

Hospital Price Transparency – Machine Readable

- Other requirements
 - Each hospital location must publish a list, unless a health system has a uniform rate
 - Each item needs a plain language description of service and a code
 - Display must be searchable
 - List must be public and not behind paywall, registration requirement, or require any information from the viewer
 - File must be updated at least annually.

Hospital Price Transparency – "Shoppable Services"

- More detail on "shoppable services"
 - A service that can be scheduled in advance
 - Must post at least 300 services:
 - 70 services defined by CMS
 - 230 selected by the provider
 - Must be posted separately from the machine-readable list
 - Hospital must identify and group the ancillary services customarily provided as part of, or in conjunction with, each shoppable service
- Price Estimator Tool is an acceptable alternative
 - Must include all 70 CMS-specified services (if the hospital provides those services)
 - Prominent display on the website
 - Accessible without a charge to, or registration by, the consumer
 - Allows a consumer to estimate the amount they will be obligated to pay

Payer disclosure obligations - Summary

- Interim Final Rule includes requirements related to:
 - patient cost-sharing protections,
 - notice and consent standards for waivers,
 - rules for calculating the qualifying payment amount (QPA),
 - disclosure requirements,
 - significant restrictions on Air Ambulance service charges. and
 - complaints processes.

Payer disclosure obligations – Coverage and Limits

- Applies if the plan provides or covers any benefits for emergency services
- Prohibits the Plan from denying coverage based on prior authorization requirements, whether the provider is in-network, or any other term or condition
 - Exceptions: rule allows denial based on requirements related to coordination of benefits, or a permitted affiliation or waiting period.
- Limits consumer cost-sharing amounts for emergency services
 - An amount determined by an applicable All-Payer Model Agreement under section 1115A of the Social Security Act.
 - If there is no such applicable All-Payer Model Agreement, an amount determined under a specified state law.
 - If neither of the above apply, the lesser amount of either the billed charge or the qualifying payment amount, which is generally the plan's or issuer's median contracted rate.

Monitoring Compliance

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Risks of Non-compliance

- Financial penalties
 - Balance Billing: If patient is sent a prohibited bill, Civil Money Penalties of up to \$10,000 "per violation"
 - Price Transparency: Current hospital penalty for non-compliance is \$300 per hospital per day
- Poor patient/consumer relations
 - Extensive coverage of compliance (or non-compliance) in media
 - Consumer demand for information
 - Will a patient choose a different provider based on the quality/volume of information disclosed?
- Always a risk of more significant enforcement

Price Transparency Enforcement

- Complaint-Based CMS has set up easy mechanism to submit a complaint
- CMS Enforcement letters requiring a written hospital response within specified timeframe
- Additional Enforcement is coming:
 - Increased financial penalties
 - CMS proposed rule to increase daily penalties up to \$5,500 per day large facilities
 - CMS also considering increased penalties for intentional or severe violations
 - False Claims Act enforcement/False Certification Liability
 - When submitting a claim, providers are certifying that they have complied with ancillary legal requirements
 - The circuit courts are divided on the extent to which the implied false certification theory can give rise to FCA liability.

Areas of Enforcement Focus

- Are patients being balance billed or charged higher cost-sharing than appropriate?
 - Are providers sending inappropriate bills to collection?
- Price Transparency
 - Are the posted prices the actual contract price (excluding value-based purchasing discounts)?
 - Is the data being reported current?
 - How difficult is it for the public to access the information?
 - Is it easily findable from the hospital website?
 - Is the hospital publishing it in a format that blocks it from being included in search engine searches?
 - Are there unreasonable service interruptions, off-line periods?

Next Steps in Price Transparency

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Litigation Challenges

- Hospital and Insurance Company industry groups challenged the rules in federal court
 - The government rules survived the legal challenge. American Hospital Association v. Azar, 983 F.3rd 528 (D.C. Circ. 2020)

Continued Challenges for Providers

- Substantial price variation
 - Sites of service
 - Comparing one geographic region to another
 - Substantial variation on services within a market are hard to explain
- Patients are often unaware of existing price transparency tools or do not use them; Policymakers have only slightly more awareness than the general public
- Price transparency only provides part of the story to patients
 - Patient share of price is confusing
 - High-deductible plans, coverage limits, out-of-pocket limits
- Does promoting price comparison result in decline in focus on quality of care?
- Media, medical bill of the month, "Why I'm Obsessed with Patients' Medical Bills"

Questions/Comments

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