

September 10, 2021



Leaning Objectives

- 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

Agenda

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



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."

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



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 "machine-readable" format
 - 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

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?



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"



For more information

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