HOT TOPICS IN COMPLIANCE

GASCO Administrators Meeting

June 10, 2022

OVERVIEW OF RECENT TRENDS

- Vaccine Mandate
- No Surprises Act
- 21st Century Cures Act

EMERGING TRENDS IN HEALTHCARE

VACCINE MANDATE

BACKGROUND AND EFFECTIVE DATE

- On December 27, 2020, the No Surprises Act (NSA) was signed into law as part of the Consolidated Appropriations Act of 2021.
- The NSA became effective January 1, 2022.
- The NSA authorizes the Department of Health and Human Services (HHS), specifically Centers for Medicare and Medicaid Services (CMS), Department of Labor, and Department of the Treasury to issue additional rules and regulations related to the implementation and enforcement of the NSA.

WHO IS COVERED UNDER THE NSA?

- The NSA requirements apply to providers, facilities, providers of air ambulance services and health plans.
- The NSA protections generally apply to individuals enrolled in group or individual private health plans and Federal Employee Health Benefit Plans. The No Surprises Act protections do not apply to individuals covered under Medicare, Medicaid, Indian Health Services, VA and Tri-Care, as these programs contain their own similar provisions related to surprise medical bills.
- The NSA protections relating to the good faith estimate requirements and the patient-provider dispute resolution process apply to uninsured and self-pay patients.

WHAT IS A SURPRISE MEDICAL BILL?

- For purposes of the NSA, a surprise medical bill is an unexpected balance bill (a bill for the difference between what a person would pay for care in-network versus out-of-network), which in some instances may be the entire cost of the out-of-network care.
- Surprise medical bills occur when people with health coverage obtain medical care from a provider or facility outside their health plan's network without realizing the provider is out-of-network, due to lack of available in-network providers, or because they are seeking care during a medical emergency and are not able to verify coverage or make decisions based on coverage.

NSA – CMS RULE PART I

- On July 1, 2021, CMS issued an interim final rule titled: "Requirements Related to Surprise Billing; Part I" to place restrictions on surprise medical bills in the following circumstances:
  - patients in job-based and individual health plans who receive emergency care,
  - patients in job-based and individual health plans who receive non-emergency care from out-of-network providers at in-network facilities, and
  - air ambulance services from out-of-network providers.

NSA – CMS RULE PART II

- On September 30, 2021, CMS issued a second interim final rule titled: "Requirements Related to Surprise Billing; Part II".
- This second interim final rule provides additional restrictions on surprise medical bills, including:
  - Establishing an independent dispute resolution (IDR) process to determine out-of-network payment amounts between providers and health plans,
  - Requiring good-faith estimates of medical items or services for uninsured or self-paying patients,
  - Establishing a patient-provider dispute resolution process for uninsured or self-paying patients to determine payment amounts due to a provider under certain circumstances, and
  - Providing a way to appeal certain health plan decisions.

NSA – CMS RULE PART III

- On November 17, 2021, a third interim final rule was issued, and is still open for public comment, titled: "Prescription Drug and Health Care Spending".
- This rule primarily impacts group health plans, who will be required to submit certain information about prescription drug and health care spending, such as: most frequently dispensed drugs, costliest drugs, and enrollment and premium information.

GOOD FAITH ESTIMATE REQUIREMENTS FOR PROVIDERS

- Providers must follow the following timelines when providing an uninsured or self-pay patient with a good faith medical bill estimate:
  - Within 1 business day after scheduling or no later than 3 business days after scheduling, depending on scheduling; or
  - Within 3 business days after an uninsured or self-pay patient requests a good faith estimate.

GOOD FAITH ESTIMATE REQUIREMENTS FOR PROVIDERS (CONT.)

- The good faith estimate must include:
  - an itemized list of each item or service, grouped by each provider or facility offering care.
  - a paper or electronic copy of the good faith estimate, even if the provider also provides the good faith estimate over the phone or verbally in-person; and
  - the good faith estimate must use clear and understandable language.

IDR PROCESS FOR RESOLVING PAYMENT DISPUTES BETWEEN OUT-OF-NETWORK PROVIDERS AND HEALTH PLANS

- When a claim is made relating to a surprise medical bill and the health plan either denies the payment or pays less than anticipated, either the provider or health plan can choose to start an "open negotiation" period that lasts 30 business days.
- If the provider and health plan cannot agree on a payment rate during the "open negotiation" period, either can then choose to begin the federal independent dispute resolution (IDR) process to resolve the payment disagreement.

IDR PROCESS FOR RESOLVING PAYMENT DISPUTES BETWEEN OUT-OF-NETWORK PROVIDERS AND HEALTH PLANS (CONT.)

- The parties will jointly select a third-party certified IDR entity to resolve the payment amount dispute. If the parties are unable to mutually agree on a certified IDR entity then HHS will select one. HHS will publish a list of certified IDR entities on its IDR portal: https://www.cms.gov/nosurprises
- Patients are not involved in this IDR process and their cost-sharing is limited to the in-network costs for the service.

INFORMATION BLOCKING RULE

- What is Information Blocking?
- Pursuant to the 21st Century Cures Act Final Rule, information blocking is a practice that:

INFORMATION BLOCKING RULE (CONT.)

- Except as required by law or covered by an exception, is likely to interfere with access, exchange, or use of EHI; and
  - If conducted by a health information technology developer, health information network or health information exchange, such developer, network or exchange knows, or should know, that such practice is likely to interfere with access, exchange, or use of EHI; or
  - If conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with the access, exchange, or use of EHI, unless an exception applies.

INFORMATION BLOCKING RULE EXCEPTIONS

- The Information Blocking Rule includes the following exceptions:
  - Preventing Harm - Health Center holds a reasonable belief the withholding of EHI will substantially reduce a risk of harm to patient;

INFORMATION BLOCKING RULE EXCEPTIONS (CONT.)

- Privacy - Health Center is required by a state or federal law to withhold EHI to satisfy a precondition (such as a patient consent or authorization) prior to providing access, exchange, or use of EHI, and the precondition has not been met;
- Security - withholding information directly relates to safeguarding the confidentiality, integrity, and availability of EHI;

INFORMATION BLOCKING RULE EXCEPTIONS (CONT.)

- Infeasibility – Health Center is unable to fulfill request due to uncontrollable events (disaster, public health emergency, public safety incident, etc.) segmentation or infeasibility of circumstances;
- Health IT Performance – temporary unavailability of EHI due to IT activities (i.e. temporary server shut down);

INFORMATION BLOCKING RULE EXCEPTIONS (CONT.)

- Content and Manner – requirements for content or manner of EHI request has not been met;
- Fees – Health Center may charge reasonable fees consistent with federal and state limitations so long as they are consistently applied, and
- Licensing – temporary delays related to negotiating licensing agreements.

PRESIDENT BIDEN'S ORDER AND THE DOJ

- According to President Biden's Executive Order of July 9, 2021, many agencies, including the DOJ, are asked to scrutinize and enforce antitrust laws already in place, with the goal of protecting Americans through ensuring competition in healthcare.

PRESIDENT BIDEN'S ORDER AND DOJ ACTION (CONT.)

- Lack of competition in healthcare increases prices and reduces access to quality care has occurred in four major areas of healthcare:
  - Prescription Drugs
  - Hearing Aids
  - Hospitals
  - Health Insurance

PRESIDENT BIDEN'S ORDER PRESCRIPTION DRUGS

- Directs the Food and Drug Administration to work with states to safely import prescription drugs from Canada, pursuant to the Medicare Modernization Act of 2003.
- Directs HHS to increase support for generic and biosimilar drugs, which provide low-cost options for patients.
- Directs HHS to issue a comprehensive plan within 45 days to combat high prescription drug prices and price gouging.
- Encourages the FTC to ban "pay for delay" and similar agreements by rule.

PRESIDENT BIDEN'S ORDER CONSOLIDATION OF HOSPITALS

- Underscores that hospital mergers can be harmful to patients and encourages the Justice Department and FTC to review and revise their merger guidelines to ensure patients are not harmed by such mergers.
- Directs HHS to support existing hospital price transparency rules and to finish implementing bipartisan federal legislation to address surprise hospital billing.

PRESIDENT BIDEN'S ORDER CONSOLIDATION IN THE HEALTH INSURANCE INDUSTRY

- Directs HHS to standardize plan options in the National Health Insurance Marketplace so people can comparison shop more easily.

QUESTIONS?

Any additional questions can be emailed to:
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Please let us know if you need any assistance amending the policy to fit the demands of your facility.

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THANK YOU

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