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PULSE

FTC Finalizes Updates to Health Breach Notification Rule

The final rule clarifies its applicability to health apps and other similar technologies not covered under HIPAA.

In a move to bolster consumer privacy in the digital health landscape, the Federal Trade Commission recently announced significant updates to the Health Breach Notification Rule (HBNR). These revisions aim to modernize the rule, ensuring its applicability to emerging technologies like health apps while expanding the scope of information that covered entities must disclose in the event of a data breach.

The HBNR, originally established to safeguard personal health records (PHRs) and related entities not governed by the Health Insurance Portability and Accountability Act (HIPAA), now extends its reach to encompass a broader array of health apps and connected devices.

"Protecting consumers' sensitive health data is a high priority for the FTC," said Samuel Levine, director of the FTC's Bureau of Consumer Protection. "With the increasing use of health apps and connected devices, the updated HBNR will ensure it keeps pace with changes in the health marketplace."

Following a period of public feedback initiated in May 2023, the FTC finalized changes to the HBNR, addressing key areas:

1. **Revised Definitions:** The updated rule clarifies the applicability of the HBNR to health apps and similar technologies, introducing new definitions such as "covered health care provider" and "health care services or supplies."
2. **Clarification of Breach of Security:** It defines a "breach of security" to include unauthorized acquisitions of identifiable health information resulting from data security breaches or disclosures.
3. **Expansion of Notification Requirements:** Covered entities are now required to notify the FTC alongside affected individuals, particularly in breaches involving 500 or more individuals. This notification must occur within 60 calendar days of discovering a breach. *Continued on pg 2*

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4. **Enhanced Consumer Notice Content:** The rule mandates expanded content in breach notifications, including identifying third parties acquiring unsecured PHR identifiable health information.
5. **Utilization of Electronic Notification:** The updated rule permits the expanded use of electronic means, such as email, for providing breach notifications to consumers.
6. **Improved Readability:** Changes have been made to enhance the rule's clarity and readability, facilitating compliance among covered entities.

Alongside the rule updates, the FTC has taken action against companies violating the HBNR. Recent enforcement actions against entities like GoodRx and Easy Healthcare.

The commission's decision to finalize the rule was not without dissent, with Commissioners Melissa Holyoak and Andrew N. Ferguson voting against its publication. However, Chair Lina M. Khan, along with Commissioners Rebecca Kelly Slaughter and Alvaro Bedoya, issued a statement in support of the revisions, emphasizing their importance in protecting consumer interests.

The finalized rule is set to take effect 60 days after its publication in the *Federal Register*.

Consumer Frustration Mounts Over Health Care Payments

A recent survey by JPMorgan highlights a shift toward electronic payment methods in the health care industry and mounting consumer tensions about bill payments.

A recent survey conducted by JPMorgan reveals a significant disconnect between consumers and providers in the health care payment landscape. According to the report, health care consumers are often left confused and frustrated by the bill payment process, while providers face challenges associated with delays and collection costs.

The survey, which gathered insights from both patients and providers, sheds light on several key issues. One notable finding is that 44% of patient respondents expressed disappointment with slow refund processes. Additionally, 24% of respondents expressed a desire for more flexibility in how their refunds are delivered, while 23% indicated a preference for receiving advance notice before receiving their refund.

"Consumers are often frustrated and confused by their payment experience, while providers face long delays and high costs to collect," according to the report. "Consumers and providers do not find this dynamic sustainable."

To address these challenges, some consumers are turning to installment payment plans offered by health care providers. According to the findings, 80% of providers now offer fee-free payment plans, allowing patients to pay off balances over time. This trend reflects a growing recognition of the need for more flexible payment options within the health care industry.

Additionally, data from the survey reveals a shift towards electronic payment methods, with claims payers increasingly utilizing the ACH network for healthcare payments. According to Nacha, which manages the ACH network, health care claim payments rose by 5.8% in the third quarter of last year, reaching 122 million transactions. This trend continued into the following quarter, with health care claim payments increasing by 7.7% to 127 million transactions.

In response to these challenges, JPMorgan has been ramping up its efforts to address health care payment issues, particularly as it pertains to business-to-business clients in the sector. The banking giant has been focusing on embedded payments, catering to the unique needs of the health care industry and other sectors alike.

Download the report here.

NEWS & NOTES

AMGA Urges Congressional Action to Safeguard Medicare Providers and Patients

The American Medical Group Association (AMGA) is sounding the alarm, urging congressional leaders to prioritize stability and value in health care. Facing significant Medicare Part B reimbursement cuts over the past years, providers risk dire consequences, including furloughs and service disruptions for Medicare patients. AMGA emphasizes the need for Congress to prevent further payment reductions and extend incentives for value-based care models, crucial for multispecialty medical groups to maintain quality care delivery. Additionally, as the looming threat of Pay-As-You-Go (PAYGO) rules casts a shadow over Medicare, AMGA stresses the urgency for policymakers to address these issues by Dec. 31, 2024. Recommendations include extending Advanced Alternative Payment Model incentives and reforming the Medicare Shared Savings Program. Moreover, AMGA opposes changes to Medicare Advantage policies that could adversely affect patient care and provider stability. Their plea extends to maintaining telehealth waivers and enacting legislation for pharmacy benefit manager reform, essential for improving data exchange and easing financial burdens on Medicare beneficiaries.

Read more here.

OIG Asks CMS to Improve Medicare Rate-Setting Procedures

A recent report from the Office of the Inspector General (OIG) highlights deficiencies in Medicare's rate-setting procedures for clinical diagnostic lab tests during public health emergencies like the COVID-19 pandemic. The report reveals that existing procedures hindered Medicare Administrative Contractors (MACs) from setting adequate rates to cover the costs of COVID-19 viral testing for all laboratories, leading to delays and missed opportunities for vital information gathering. Moreover, communication gaps among stakeholders exacerbated the problem, indicating a need for improved procedures and legislative support. OIG's recommendations urge CMS to establish better communication channels among stakeholders and enhance rate-setting procedures for new tests during emergencies. These improvements would require new legislative authority, as current statutes lack provisions for expedited rate-setting processes.

Read the report.

HHS Implements New Dispute Resolution Process for 340B Drug Pricing Program

The rule addresses conflicts between covered entities and pharmaceutical companies over drug discounts.

The Department of Health and Human Services (HHS) recently introduced a revamped Administrative Dispute Resolution (ADR) process under the 340B Drug Pricing Program, marking a significant step toward resolving longstanding disputes between hospitals and pharmaceutical companies.

The 340B program, intended to assist safety-net health care providers in serving vulnerable populations, has often been a source of contention, with disagreements arising over the eligibility of hospital pharmacies and reimbursement cuts. The newly established ADR process provides covered entities and pharmaceutical manufacturers with a platform to address issues such as overcharging, duplicate discounts, and diversion. A panel of experts from the Office of Pharmacy Affairs within the Health Resources and Services Administration (HRSA) will oversee the resolution of claims, ensuring a fair and equitable process.

One of the key features of the revised ADR process is its accessibility. Recognizing the resource constraints faced by many covered entities, HHS has designed the process to be more administratively feasible and timely. Unlike the previous iteration, which posed challenges for small, community-based organizations, the revised process aims to level the playing field by streamlining procedures and lowering barriers to entry.

Additionally, the new process emphasizes the importance of good faith efforts in resolving disputes prior to resorting to formal adjudication. By encouraging dialogue and cooperation between parties, HHS aims to minimize the need for lengthy legal proceedings and promote amicable resolutions. Manufacturers are also required to conduct audits of covered entities before filing claims, further facilitating transparency and accountability.

In response to the final rule, stakeholders have expressed cautious optimism. The American Hospital Association (AHA) lauded the improvements in the ADR process, particularly highlighting the clarity in defining overcharge claims and the opportunity for reconsideration of decisions.

Similarly, 340B Health welcomed the clarification regarding the scope of ADR claims, while advocating for additional enhancements such as the exclusion of Medicaid-managed care claims and stricter timelines for decision-making.

Read the rule here.

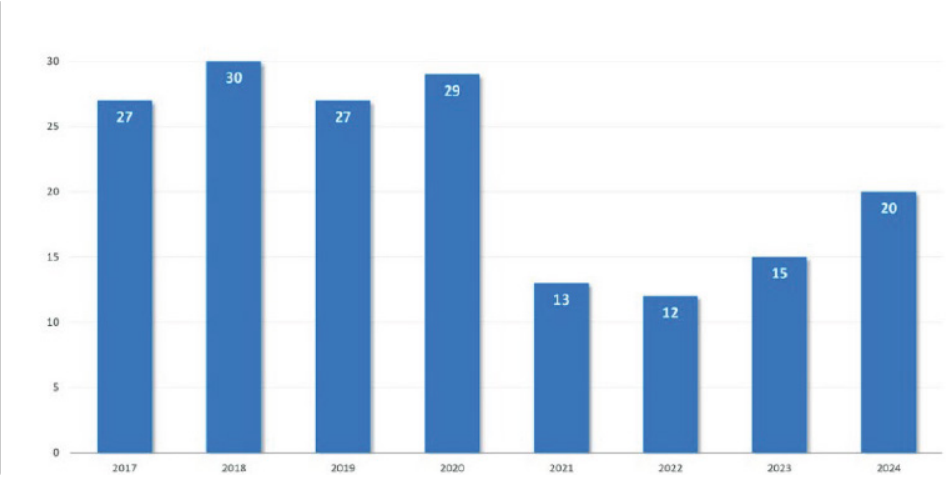
DATAWATCH

Hospital Merger & Acquisition Activity Hits Q1 High in 2024

In a surge reminiscent of pre-pandemic levels, hospital merger and acquisition (M&A) activity reached a peak in the first quarter of 2024, according to the latest edition of Kaufman Hall's M&A Quarterly Activity Report.

The report found there were 20 total transactions generating $12 billion in 2024, marking the highest first-quarter total since 2020. With four mega mergers among the total announced transactions, the average size of the seller (or smaller party) remained at a high level of $598 million, exceeding the year-end averages for every year since 2017 except for 2021 and 2022.

Number of Q1 Announced Transactions by Year, 2017 - 2024



Source: *Kaufman Hall & Associates M&A Quarterly Activity Report: Q1 2024.* https://tinyurl.com/25j38yxb

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