HCCA HEALTH CARE COMPLIANCE ASSOCIATION

Compliance TODAY

May 2016

A PUBLICATION OF THE HEALTH CARE COMPLIANCE ASSOCIATION

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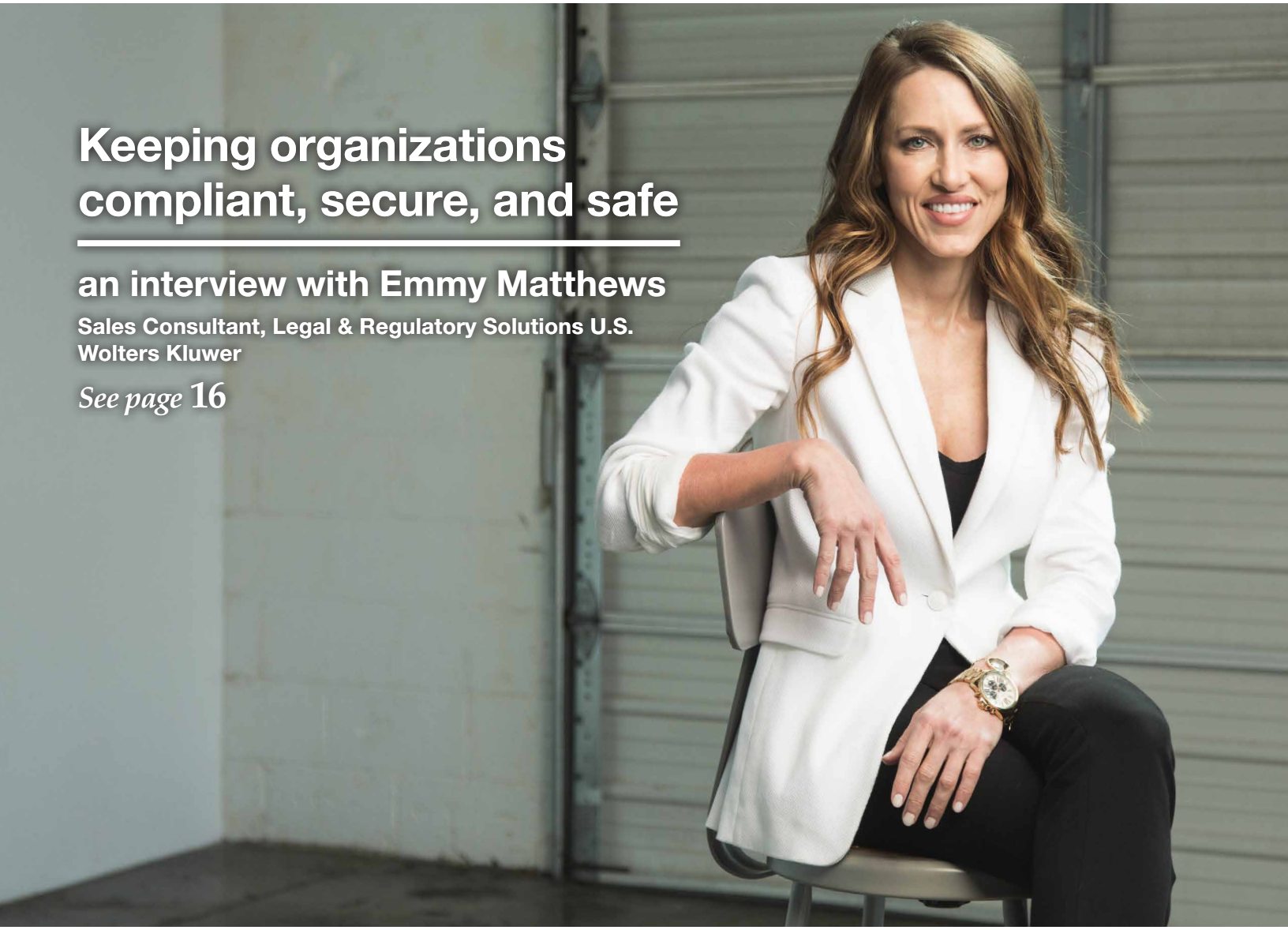

Keeping organizations compliant, secure, and safe

an interview with Emmy Matthews

Sales Consultant, Legal & Regulatory Solutions U.S.
Wolters Kluwer

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by Colin P. McCarthy, JD

The final 60-day rule is here: What healthcare providers need to know

» CMS released its final "60-day" rule on overpayments, six years after passage of the Affordable Care Act.
» Quantification is a required part of "identification" of an overpayment.
» Providers must use "reasonable diligence" (no more than six months) to investigate potential overpayments.
» The 60-day clock to refund starts to run after the overpayment has been investigated and quantified.
» CMS expects providers making repayments to use a 6-year lookback period.

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The healthcare industry has been waiting for almost six years to receive final guidance on the "60-day" rule provisions of the Affordable Care Act. On February 12, 2016, the Centers for Medicare & Medicaid Services released its final rule on reporting and returning overpayments.[1] The final rule contains some industry-favorable revisions to CMS's original proposed 60-day rule regulations.


McCarthy

The Affordable Care Act requires Medicare providers to report and return overpayments within 60 days of the date the provider "identified" the overpayment or the date of any corresponding cost report due, if applicable. CMS issued a proposed rule four years ago that received immense pushback from healthcare providers and their counsel. Under the proposed rule, providers were left with more questions than answers on the meaning of when an overpayment has been "identified" and were shocked to learn that they faced a potential 10-year lookback period for making repayments. Thankfully, CMS carefully considered more than 200 industry comments, recognized some of the flaws with its proposals, adopted a more practical and industry-friendly definition of "identified," and shortened the lookback period in the final rule.

Meaning of "identified"

Initially, CMS proposed to define "identified" as "actual knowledge of the existence of the overpayment or [acting] in reckless disregard or deliberate ignorance of the overpayment." This definition did not give providers and their counsel clear direction on when the 60-day clock started ticking. In the final rule, CMS adopted a more practical standard proposed by many industry commenters: an overpayment is "identified" when a "person has, or should have through the exercise of reasonable diligence, determined that the person received an overpayment *and quantified* the amount of the overpayment." (emphasis added).

With this new standard, providers will be able to more easily calculate their deadline for reporting and returning overpayments. However, providers should not interpret this

change to mean that they have an unlimited amount of time to "quantify" the overpayment and stall the repayment process. CMS created a "reasonable diligence" standard, meaning that providers who stick their head in the sand will face False Claims Act (FCA) liability.

In August 2015, the first judicial interpretation of the 60-day rule was less forgiving than CMS's definition. In that FCA case, *Kane v. Healthfirst*, the court agreed with the government's position that the 60-day clock starts to run when a provider is "put on notice that a certain claim may have been overpaid." CMS's new definition of "identified" provides a national standard and clarity for the industry, rather than requiring providers to rely on case law.

A "reasonable diligence" standard

CMS's proposed rule acknowledged that providers may need time to investigate potential overpayments, but stated that CMS expected providers to do so with "all deliberate speed." CMS failed to define what this standard meant, again adding confusion and uncertainty for providers attempting to comply with the 60-day deadline. In the final rule, CMS changed its language and used a standard of "reasonable diligence." CMS stated that "reasonable diligence" is "demonstrated through the timely, good faith investigation of credible information, which is at most 6 months from receipt of the credible information, except in extraordinary circumstances." This benchmark gives providers a clear deadline for conducting investigations in response to compliance hotline reports, internal audits, and other credible information on potential overpayments. The 6-month standard takes into account the time and resources typically needed to conduct a thorough investigation, including legal counsel, external auditors, and statistical sampling. Providers should document their investigative efforts to demonstrate compliance with the 6-month benchmark.

Lookback period

When CMS released its proposed 60-day rule, providers were outraged that the agency would require a 10-year lookback period, which is the outer limit on the FCA's statute of limitations. CMS responded to industry comments that the 10-year lookback period was unduly burdensome and revised the lookback period to 6 years. The 6-year lookback period is consistent with the most common FCA statute of limitations. Many industry commenters suggested that CMS should use the existing reopening period (4 years) as the lookback period, but CMS stated that the 6-year lookback would "appropriately address many of [providers'] the concerns about burden and cost."

Procedures for reporting and returning overpayments

In the final 60-day rule, CMS acknowledged that overpayments may need to be reported in different ways, depending on the nature of the overpayment (e.g., credit balances, cost reporting issues, etc.). Therefore, CMS stated that providers may use the "applicable claims adjustment, credit balance, self-reported refund, or other reporting process set forth by the applicable Medicare contractor to report an overpayment." Additionally, use of the OIG's Self-Disclosure Protocol or the CMS Voluntary Self-Referral Disclosure Protocol would satisfy the requirements of the 60-day rule.

Conclusion

Healthcare providers and their compliance officers and counsel have been diligently working over the past several years to comply with the 60-day rule without clear guidance from CMS. Now, CMS has provided bright-line standards that will help providers understand their obligations during the repayment process.

The final 60-day rule became effective on March 14, 2016.

1. 81 Fed. Reg. 7654 (Feb. 12, 2016). Available at http://1.usa.gov/1Rp0Opu