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News for North Carolina Hospitals
from the Health Law Attorneys of Poyner Spruill LLP

Final CMS Rule on the Reporting and Returning of Medicare Overpayments Is a Wake-Up Call for Physicians

by Wilson Hayman

Effective March 14, 2016, a final rule published in February 2016 by the Centers for Medicare and Medicaid Services (CMS) implements the 60-day rule included in the Affordable Care Act (ACA) (31 U.S.C. § 1320a-7k(d)). ACA requires providers and suppliers who receive Medicare funds to *report and return overpayments by the later of either (1) 60 days after the date on which the overpayment was identified, or (2) the date any corresponding cost report is due, if applicable.* Hospitals must also notify in writing the Secretary of DHHS, the state, an intermediary carrier, or contractor to whom the overpayment is returned of the reason for the overpayment. In addition, ACA provides that any overpayment retained by a person after the deadline is a violation that potentially triggers the provisions of the Federal False Claims Act, with substantial civil penalties plus treble the amount of damages sustained by the government due to the acts of that person, Civil Monetary Penalties and exclusion from federal health care programs.

The final rule addresses several concerns raised by providers about the proposed rule published on February 16, 2012. It clarifies the meaning of overpayment "identification" that triggers the 60-day period for the reporting and repayment of overpayments, and it reduces the "lookback" period for overpayments to providers from 10 years to six years. At the same time, it serves as a wake-up call for hospitals to implement these particular requirements of the ACA as enunciated in the new rule. We will answer some of the most important questions about the significance of the final rule for physicians in this article.

To What Providers and Overpayments Does the Final Rule Apply?

The final rule applies only to Medicare Part A and Part B providers and suppliers, including hospitals. CMS has previously published separate rules covering the reporting and returning of overpayments for Medicare Part C and Part D, and a final rule concerning Medicaid overpayments has not yet been published. For hospitals that file cost reports with the Medicare program for Medicare Part A inpatient and outpatient services, the overpayments must be reported and returned by the date any corresponding cost report is due. For other services such as physician, lab, CORF and home health services reimbursed under Medicare Part B, the overpayments must be reported and returned by 60 days after the date on which the overpayment was identified.

The rule defines "overpayment" as *any* funds that a person has received or retained under the Medicare program to which the person is not entitled to retain. It includes payments for claims that lack sufficient documentation or medical necessity, primary payments by Medicare when a primary payment from a non-Medicare payer has been received, and even overpayments caused by a Medicare contractor or that were otherwise outside of the provider's control.

When is an Overpayment Identified?

For Medicare Part B services, CMS in its commentary indicates that the *60-day time period begins* either (a) when the provider has completed reasonable diligence in investigating a potential overpayment and "identified" an overpayment, or, (b) if the provider failed to conduct reasonable diligence but had in fact received an overpayment, the day the provider first received credible information of a potential overpayment. The final rule provides that a provider has "identified" an overpayment "when the person has, or should have through the exercise of reasonable diligence, determined that *the person has received an overpayment and quantified the amount of the overpayment.*" It thus clarifies that the process of determining and quantifying an overpayment must be completed before the 60-day period begins. CMS also indicates that reasonable diligence and a timely, good faith investigation of credible information *may require up to six months from receipt of the credible information* before the overpayment is "identified." Added to the 60-day period, this permits a total of up to eight months for due diligence, and CMS has acknowledged that extraordinary circumstances may require additional time. Written documentation of this process should be retained to demonstrate compliance with the rule.

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WHAT DOES THE "REASONABLE DILIGENCE" STANDARD MEAN IN IDENTIFYING OVERPAYMENTS?

"Reasonable diligence" according to CMS *requires* both (1) proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments, and (2) investigations conducted in good faith and in a timely manner by qualified individuals in response to obtaining credible information of a potential overpayment. To exercise reasonable diligence under this standard, CMS considers it necessary for a hospital to have an effective compliance program that monitors the accuracy and appropriateness of the hospital's Medicare claims.

WHAT DOES THIS STANDARD MEAN FROM A PRACTICAL STANDPOINT?

CMS indicates that when a hospital or other provider receives information about a potential overpayment, the provider has a duty to make a reasonable inquiry. Such information may include, among others things, notice from a government agency, the hospital's discovery of a billing error that results in increased reimbursement, the discovery of services provided by an unlicensed or excluded individual, or an increase in the provider's Medicare revenue for no apparent reason. If the reasonable inquiry reveals an overpayment, then the provider has 60 days to report and return the overpayment. If the provider fails to make a reasonable inquiry conducted with all deliberate speed, then the provider could be found to have acted in reckless disregard or deliberate ignorance of whether he or she had received an overpayment. Failure to conduct reasonable diligence per se is not a violation of the statute, but failure to report and return an overpayment in fact received, and that the provider should have identified, renders the provider liable. Providers need to calculate an overpayment amount that is reliable and accurate, and may use statistically valid sampling methodologies and extrapolation to calculate the overpayment amount.

For Medicare Part A services, a hospital normally must return the overpayment at the time the cost report is filed. Sometimes CMS makes interim payments to a hospital through the cost year and the hospital reconciles these payments with covered and reimbursable costs at the time the cost report is due. The final rule creates the following two exceptions to the rule that the applicable reconciliation occurs with the hospital's submission of a cost report:

- When a hospital receives more recent CMS information that affects the Supplemental Security Income (SSI) ratio used in calculating the disproportionate share hospital (DSH) payment adjustment, the provider is not required to return any overpayment resulting from the updated information until the final reconciliation of the hospital's cost report occurs; and
- When the hospital knows that an outlier reconciliation will be performed, the hospital is not required to estimate the change in reimbursement and return the estimated overpayment until the final reconciliation of that cost report has been settled.

However, if a hospital self-identifies an overpayment after applicable reconciliation and the filing of a cost report, the hospital must follow this rule and return the overpayment within 60 days by the filing of an amended cost report.

WHAT IS THE SIGNIFICANCE OF THE SIX-YEAR LOOKBACK PERIOD?

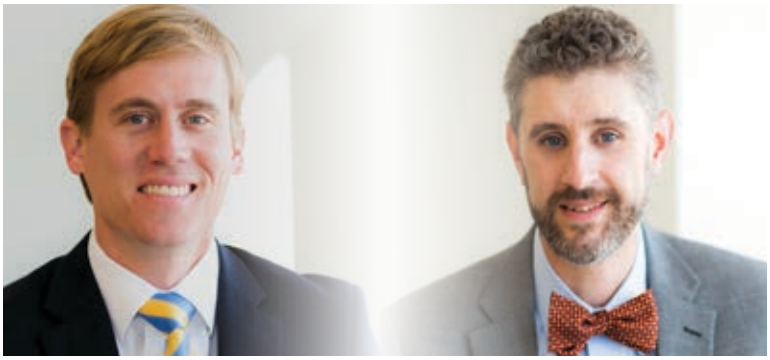
The final rule establishes a lookback period of six years after the date the overpayment was received, a change from the 10-year lookback period in the proposed rule. A hospital must report and return the overpayment only if the hospital, using reasonable diligence, identifies the overpayment within six years of the date the overpayment was received. It is important for hospitals to review and revise their policies as needed to address this lookback period because the current Condition of Participation for hospitals regarding medical records retention only requires a retention period of five years. CMS has indicated that it will also amend its reopening rules so that a contractor will be able to reopen and revise its initial determination related to any overpayment reported and returned during the six-year lookback period in this final rule. This means that upon receiving findings of a Recovery Audit Contractor (RAC) audit (or other Medicare audit) that identifies overpayments, a hospital may have a duty to determine and quantify overpayments going back six years, prior to the three-year period covered by the RAC audit. Similarly, if a Medicare Administrative Contractor identifies an overpayment during a cost report audit, the hospital has a responsibility to conduct reasonable diligence on other cost reports in the lookback period to determine if it has received an overpayment for years not covered by the audit.

HOW ARE PHYSICIANS TO REPORT AND RETURN OVERPAYMENTS?

The final rule states that hospitals should use the existing, most applicable process, including claims adjustment, credit balance (for hospitals), self-reported refund, or other appropriate process, to satisfy the obligation to report and return overpayments. The most applicable process could also include amending or reopening a previously filed cost report. Hospitals may request a voluntary offset from the contractor instead of submitting a check with the overpayment reporting form.

Although several of the changes made to the proposed rule are favorable to providers, the final rule creates a duty of reasonable diligence requiring providers to proactively monitor receipts and practices, as well as a duty to respond to credible information of a possible overpayment in a timely manner. Hospitals must incorporate these duties into a strong compliance program or risk substantial penalties if overpayments from any source are ultimately found.

Wilson Hayman's practice focuses on health care law, civil law, administrative law, compliance with the Stark law, Anti-Kickback statute, and other federal and state laws. He is editor of *Corridors* and may be reached at 919.783.1140 or whayman@poynerspruill.com.



Coming Soon to Your Inbox! Phase 2 of OCR's Audit Program for HIPAA Compliance

by David Broyles and Matt Fisher

On March 21, 2016, the Office of Civil Rights (OCR) in the Department of Health and Human Services (HHS) announced that it was ready to begin Phase 2 of its audit program for HIPAA compliance, which will include auditing business associates, besides covered entities, as mandated by the HITECH Act. Phase 2 follows the first phase of OCR's audits and will continue to focus on assessing the compliance efforts of covered entities and business associates, identifying undiscovered risks and vulnerabilities, and pinpointing best practices adopted in the industry. The Phase 2 audits will initially comprise desk audits, which are projected to be complete by the end of 2016, and will be followed by on-site audits.

How the Process Works

The first point of contact in this process will be an email sent by OCR with a request that contact information be provided for a given covered entity or business associate. OCR will request timely responses so it can then send a pre-audit questionnaire asking for basic information about each organization. Specific information about the audit protocols will come later. OCR will likely use the basic information it gathers in these initial contacts with group organizations so that organizations similar in size, operations, affiliations, and other characteristics receive similar audit questions that reflect their operational traits. OCR plans to also compile publicly available information about covered entities and business associates that do not respond to its requests for information, so failing to respond will clearly not insulate an organization from OCR's scrutiny.

According to OCR, ALL covered entities and business associates are eligible to be audited during the Phase 2 audits. The initial round of desk audits will focus on covered entities, followed by a round of desk audits that will focus on business associates. The on-site audits that follow will focus more on compliance with the specific privacy and security requirements under HIPAA, regardless of the organization's classification as a covered entity or business associate.

The OCR Road Map for Phase 2 Audits

In the early part of the Phase 2 audits, OCR will ask covered entities to identify their business associates and to provide contact information for each business associate. OCR has not announced how it plans to compile the list of contact points for the initial emails. As it combs through its list of covered entities and business associates, OCR may use the contact information to target other entities, resulting in the contact point for smaller organizations being any person within the organization who has contact with another organization that has provided data to OCR. This means it is critical that all staff of every organization know there may be an email contact from OCR. OCR has posted a sample contact information request letter on the HHS website at http://tinyurl.com/hnh6uze.

What this Means to Providers and Business Associates

Including business associates as primary audit targets in the Phase 2 audits is likely due to the massive number of vendors that provide services to covered entities relating to protected health information (PHI). Nearly 33 million medical records containing PHI being stored or otherwise handled by business associates have been exposed since 2009.

OCR's approach with the Phase 2 audits should put business associates on notice that responsibility for compliance with the privacy and security rules under HIPAA – and their responsibility for data breaches – will be aggressively enforced going forward. In addition, when covered entities and business associates are negotiating their business associate agreements and any other HIPAA-related agreements, the parties should ensure that all rights and duties under the agreements are aligned with the strengthened privacy and security rules, including audit rights

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Draft Carefully: North Carolina Supreme Court Affirms Strict Blue Pencil Doctrine Still Applies to Non-Competes

by Caitlin Goforth

North Carolina courts traditionally recognized their limited power in amending terms of unenforceable non-compete agreements. The "blue pencil" rule permits a court to enforce restrictions that are reasonable, while striking those deemed to be unreasonable. This striking power has always been limited to just that, striking. The courts will not write in any language to make an unenforceable agreement enforceable, and the language of the document must make sense on its own after any deletions. However, a decision by the North Carolina Court of Appeals called into question this doctrine when it ruled a court could rewrite contract terms where the parties expressly gave the court permission to do so in the agreement. Recently, the North Carolina Supreme Court overruled the Court of Appeals, reinstating the traditional rule.

In *Beverage Sys. Of the Carolinas, LLC v. Associated Beverage Repair, LLC*, two companies in the beverage service industry entered into negotiations for the sale of a business. Both parties signed a non-compete agreement that included geographic terms. In an attempt to be proactive, the agreement explicitly allowed a court to rewrite unreasonably broad portions should any enforceability issues occur in the future. After the parties executed the non-compete, a business dispute arose, and the enforceability of the agreement became a central issue.

The trial court determined the non-compete was overly broad in geographic scope and therefore unenforceable. Even though the agreement specifically allowed for the court to rewrite certain provisions in order to save the non-compete, the trial court refused.

On appeal, the North Carolina Court of Appeals reversed the trial court's ruling. The Court of Appeals agreed with the trial court that the non-compete was unreasonable because the geographic scope was too broad. However, while the appelate court recognized the limitations of the blue pencil doctrine, it determined that the strict rule did not apply. The parties' consent in the agreement for the court to rewrite problematic geographical terms trumped the blue pencil doctrine. This ruling would allow a court to step in and rewrite terms of a non-compete that would be binding between the parties.

In its recent decision reversing the Court of Appeals, the North Carolina Supreme Court reverted to the old rule. In its decision, the court held, "parties cannot contract to give a court power that it does not have." Where terms of a non-compete are deemed unenforceable, the court will not take on the "role of scrivener" or act as the parties' "guardian." The court said making judges create reasonable terms that the parties should have agreed to at the time of execution is "mischief." Thus, in North Carolina, courts are limited to striking or enforcing terms in the non-compete that were drafted by the parties themselves.

The reaffirmation of the strict blue pencil rule increases the importance of careful drafting when preparing non-competes governed by North Carolina law. Companies using non-competes with overly broad restrictions – whether too broad in geography, time, or activities – cannot rely on the courts to fix their problems for them. In particular, any use of boilerplate non-compete language or language from agreements used in other states may result in an unenforceable agreement. Companies and their attorneys should be sure each non-compete is carefully drafted and no broader than necessary to protect legitimate business interests.

Caitlin Goforth practices in the areas of employment law and litigation. She represents employers in litigation under all federal and state employment laws, including cases involving harassment, discrimination, retaliation, and wage and hour issues. Caitlin may be reached at cgoforth@poynerspruill.com or 919.783.2987.

Don't Be a Target – Retirement Plan Fees and Expenses

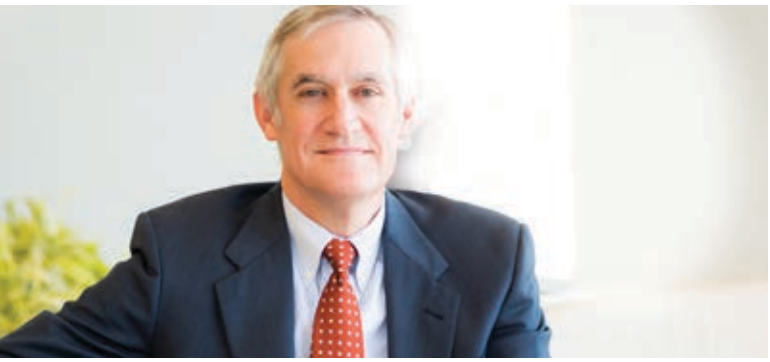
by Nancy Brower

A number of challenges are being initiated by the plaintiffs' bar and U.S. Department of Labor investigators in the area of retirement plan asset charges and retirement plan expenses. Some hospitals and other employers have had to pay many millions of dollars to settle these cases. Retirement plan sponsors and other plan fiduciaries (e.g., investment or administrative committees) should take heed of this trend and consider taking the following actions:

- Establish a Process for Evaluating Administrative Expenses. Retirement plan fiduciaries need to review and thoroughly understand the asset management fees and administrative expenses that are being paid from retirement plan assets to verify those fees and expenses are reasonable. Determining the reasonableness of fees requires evaluating what other providers charge in the marketplace for similar services to similarly sized and situated plans. Employers may evaluate the reasonableness of compensation by requesting proposals from multiple vendors, engaging a benchmarking service or hiring a consultant with expertise in plan fee arrangements. Because of the constantly changing nature of the marketplace, this task must be performed on a regular basis. Depending on the size of the plan, services involved and applicable external factors, employer-fiduciaries should consider benchmarking provider fees. if not annually at least every two to three years and whenever plan circumstances have changed significantly. They should also make sure that the analysis takes into account all of the compensation the plan's providers are receiving, including indirect compensation derived from the plan's investment funds.
- Evaluate Asset Share Class and Type of Investment in Light of the Size of the Plan's Assets. The plan's fiduciaries should determine whether the retirement plan is invested in the lowest fee share class available to the retirement plan, and if not, should consider and document why it was prudent for a different share class to be utilized. For plans with significant assets, retirement plan fiduciaries should be prepared to justify a decision to use a mutual fund instead of a lower-cost vehicle, like an exchange-traded fund, a collective trust fund or separately managed account.
- Document the Decision-Making Process Relating to Fees and Expenses. It is difficult to prove that the fiduciaries are engaged in a prudent decision-making process if there is no record of the documentation reviewed by the fiduciaries or the advice they obtained in evaluating retirement plan fees and expenses. Note that plan fiduciaries need to demonstrate not only that they obtained the fee and expense information, but that they prudently and thoroughly analyzed it. Documentation should include minutes or notes regarding the decision along with a copy of the information that the fiduciaries considered in their analysis.

The bottom line: hospitals as retirement plan fiduciaries should assume they will be challenged on the retirement plan's investment fees and administrative expenses. Plan fiduciaries should take whatever steps are necessary so they can later demonstrate with substantiating documentation that they evaluated all of the fees and expenses and that the fees and expenses were reasonable compensation for the services provided and the amount of assets invested.

Nancy Brower practices in the area of employee benefits and represents public, private, governmental, and nonprofit employers. She has significant experience designing and documenting retirement plans and executive compensation plans, as well as providing administrative advice on these plans. Nancy may be reached at nbrower@poynerspruill.com or 704.342.5275.



Statistical Sampling in FCA Case Under Review by 4th Circuit Court of Appeals

by Todd Hemphill

The issue of using statistical sampling in federal False Claims Act (FCA) cases has come to the fore in the 4th Circuit Court of Appeals, following a U.S. District Court decision denying its use in a case brought in South Carolina against a network of 24 nursing home providers (collectively, Agape).

The case, *U.S. ex rel. Brianna Michaels and Amy Whitesides v. Agape Senior Community, et al.*, was brought in 2012 by two former employees of Agape as relators (plaintiffs) under the whistleblower provisions of the FCA. The plaintiffs alleged that Agape engaged in a scheme to submit claims to Medicare, Medicaid and Tricare for hospice and nursing home inpatient services that were false because the care was not medically necessary or the certifications required to obtain reimbursement were falsified. As with all FCA cases, the U.S. government investigated the allegations to determine whether it would intervene in the case on behalf of the private party plaintiffs. The government ultimately elected not to do so, and the plaintiffs and defendants moved forward with discovery. As a result of a dispute between the parties regarding the scope of discovery, the matter came before U.S. District Court Judge Joseph F. Anderson, Jr. on the question of whether the plaintiffs would be permitted to prove liability and damages based on a statistical sampling model.

In the context of health care fraud and abuse, the process of statistical sampling takes a sample of claims relating to a small group of patients that are reviewed to determine which of the sampled claims are allegedly false. The results of that analysis of the sample may then be extrapolated to the much larger universe of claims and patients to prove a plaintiff's claim of liability and damages under the FCA. In the *Agape* case, Judge Anderson noted the case presented well over 50,000 individual unrelated claims, involving medical charts of between 10,000 and 20,000 nursing home patients. Nevertheless, despite the extensive amount of time that would be required for the parties to review and present all of those claims at trial, Judge Anderson determined that statistical sampling would not be appropriate in this case, because:

1. Each claim asserted in the case presented the question of whether services furnished to nursing home patients were medically necessary.
2. Answering the question for each of the patients would involve a highly fact-intensive inquiry involving expert testimony after a review of each patient's medical chart.
3. The medical charts of each patient for which the false claims were alleged were intact and were available for review by the parties.

Thus, while the review could conceivably involve thousands of claims and patients, Judge Anderson was satisfied that those claims should be adjudicated individually, rather than using an extrapolation from a statistical sample that may not accurately reflect the non-sampled cases.

Following Judge Anderson's initial ruling on the statistical sampling issue, the plaintiffs and Agape entered into settlement discussions without the government's involvement. They ultimately reached an agreement whereby Agape would pay the plaintiffs $2.5 million in settlement of all claims. The settlement was then submitted to the government for approval, as all FCA settlements must be approved by the court and the U.S. Department of Justice (the Government). The government rejected the settlement, based in large part on its own statistical sampling analysis that put the value of the case at $25 million.

The plaintiffs and Agape objected to the Government's refusal to approve the settlement, but Judge Anderson ruled that the plain language of the FCA required the Government's approval, despite the fact that it had not intervened in the case and despite the fact that he had already found that a statistical sampling methodology — which formed the basis for the Government's objection — could not be used in the case to determine liability or damages.

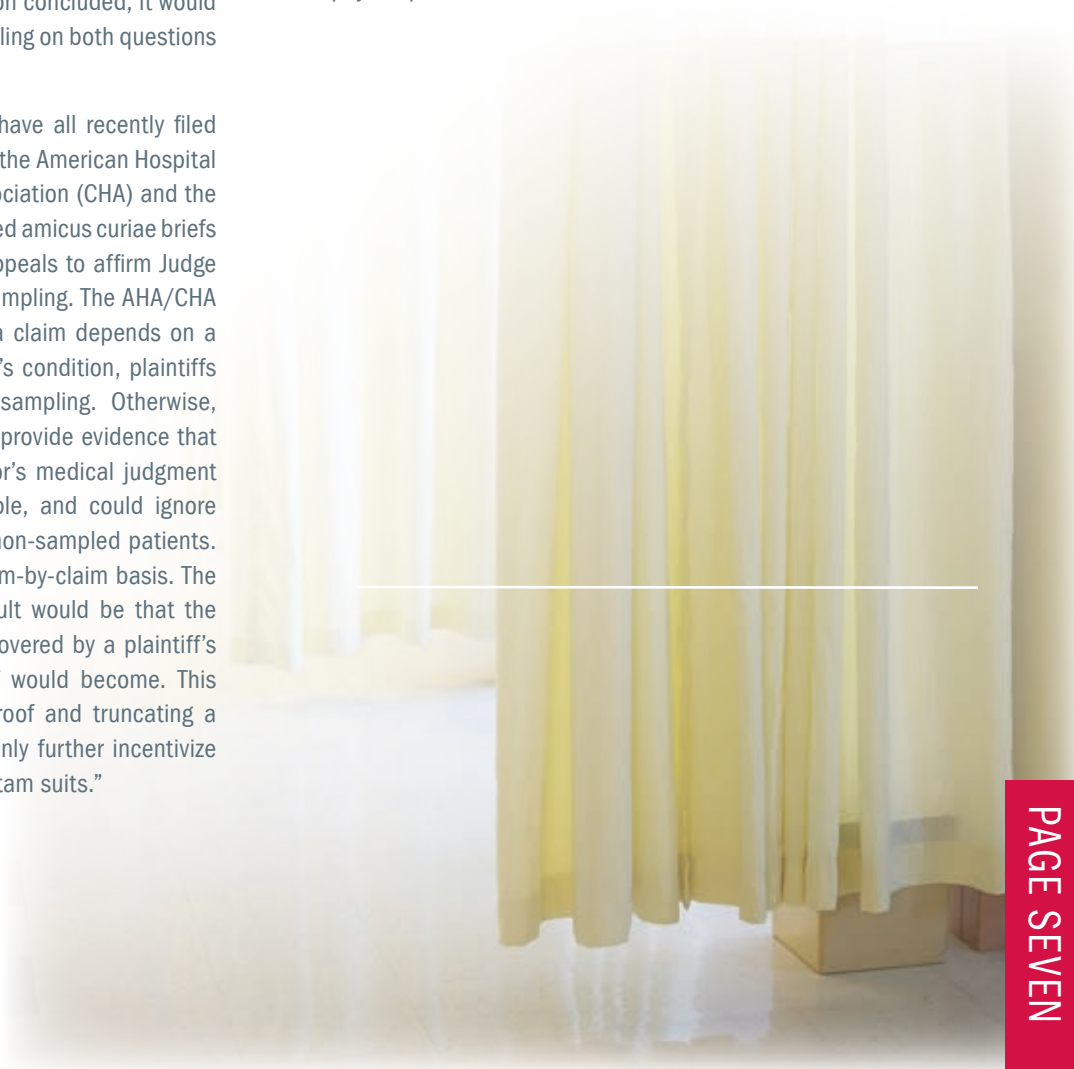
However, rather than move forward with the trial, Judge Anderson certified both of his rulings for immediate appeal, reasoning first that if the Government's objection is overturned by the Court of Appeals and, upon remand, Judge Anderson determined that the objection was unreasonable, the case would end with an amicable settlement. Conversely, Judge Anderson reasoned that if the trial proceeds without the use of statistical sampling in determining liability or damages, the parties would face a trial of monumental proportions, involving a staggering outlay of expenses by the parties, which would possibly be unnecessary if the Court of Appeals reversed his rejection of the plaintiffs' proposed statistical sampling methodology. Thus, Judge Anderson concluded, it would be much more judicially efficient to have a ruling on both questions before starting the trial.

The plaintiffs, Agape and the government have all recently filed briefs with the Court of Appeals. In addition, the American Hospital Association (AHA), the Catholic Health Association (CHA) and the American Health Care Association (AHCA) filed amicus curiae briefs in support of Agape, asking the Court of Appeals to affirm Judge Anderson's ruling disapproving statistical sampling. The AHA/CHA joint brief argues that when the falsity of a claim depends on a doctor's medical judgment about a patient's condition, plaintiffs cannot prove liability through statistical sampling. Otherwise, plaintiffs in such cases would only have to provide evidence that there was no reasonable basis for a doctor's medical judgment for treatment of the patients in the sample, and could ignore individual treatment issues present in the non-sampled patients. Therefore, liability must be proved on a claim-by-claim basis. The joint brief further argues that the end result would be that the larger the number of patients and claims covered by a plaintiff's allegations, the lower his burden of proof would become. This "combination of lowering the burden of proof and truncating a defendant's ability to defend itself would only further incentivize the filing of questionable and meritless qui tam suits."

The ACHA brief also focuses on the need for a claim-by-claim analysis where the FCA claims are "based on physicians' medical judgments concerning their patients' conditions, prognoses, and medical needs." ACHA goes on to argue that allowing plaintiffs in this type of case to prove liability for unspecified claims using statistical sampling would essentially shift the burden of proof to providers to have to disprove the elements of FCA liability for each such unspecified claim.

The parties are now awaiting a hearing date for oral arguments on the appeal.

Todd Hemphill's practice focuses on health care strategic planning issues, assisting clients in developing health care development strategies under the Certificate of Need law, negotiating health care transactions, litigating Certificate of Need awards and denials, licensure and certification issues, including appeals challenging certification and licensure survey decisions and penalties. Todd may be reached at 919.783.2958 or themphill@poynerspruill.com.



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(similar to those of OCR) among and between the entities. A business associate and its subcontractors are viewed as one and the same under HIPAA, so the same contracting principles should apply liability flows to all downstream parties that a business associate subcontracts with regarding its work under an agreement with a covered entity.

Recent OCR enforcement actions, including one settlement of $1.55 million that stemmed from a covered entity's failure to enter a business associate agreement and institute an organization-wide risk analysis related to PHI (see http://tinyurl.com/zlnhclt), show how costly failing to pay close attention to your organization's privacy and security practices – including emails from OCR in your inbox – can prove to be.

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