

# MEDICARE COMPLIANCE

Weekly News and Compliance Strategies on Federal Regulations,  
Enforcement Actions and Audits

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## In AseraCare FCA Case, Court Says a Contrary Medical Opinion Is Not Enough

In a long-awaited decision, a federal appeals court said Sept. 9 that it takes more to prove false claims than a physician disputing the eligibility of patients for Medicare services after the fact.

With this caveat, the U.S. Court of Appeals for the 11th Circuit is giving the Department of Justice (DOJ) another chance to take AseraCare Inc., a hospice provider, to trial in a False Claims Act (FCA) case. But DOJ needs to do more than expert armchair quarterbacking.

The ruling is pretty good news for providers on the medical necessity and FCA fronts. "Providers have always been comfortable with the statement that if clinicians make good-faith judgments about the eligibility of a patient for a particular service, as long as that judgment was in good faith, it wouldn't be second guessed afterward. The court agreed with that," says attorney Christopher Donovan, with Foley & Lardner in Boston. "You can't just roll out another expert who disagrees with your certification." But the appellate court also ruled that hospice claims could be false if there's evidence that physicians rubber-stamped certifications, as a witness alleges in the AseraCare case, says attorney Jesse Witten, with Drinker Biddle in Washington, D.C. "It's a difficult decision to sort out because there's something for everybody," he says.

*continued on p. 6*

## Hospital Settles OCR Case on Patient Access; Some Pockets of Risk, Confusion Persist

A patient's uphill battle to get a copy of her medical records has led to another resolution agreement between a covered entity (CE) and the HHS Office for Civil Rights (OCR), which says the case is a first under its new Right of Access Initiative.

Bayfront Health St. Petersburg in Florida paid \$85,000 to OCR and adopted a corrective action plan to settle a potential violation of HIPAA's right of access provision, which requires CEs to give patients their records within 30 days. OCR alleged that Bayfront, a Level II trauma and tertiary care center, didn't provide a mother timely access to records about her unborn child. The mom complained to OCR, which had to shake the records loose from Bayfront nine months after she made her first request.

A patient's right to access his or her records is a cornerstone of the HIPAA Privacy Rule, and OCR imposed its first civil monetary penalty ever in a case about violating it. In 2011, Cignet Health of Prince George's County, Maryland, paid \$4.3 million for violating 41 patients' rights by denying their access to medical records. They separately requested them in vain and individually filed complaints with OCR, which investigated. "During the investigations, Cignet refused to respond to OCR's repeated demands to produce the records," OCR said. "On April 7, 2010, Cignet produced the medical records to OCR, but otherwise made no efforts to resolve the complaints through informal means."

*continued*



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The Cignet and Bayfront cases aside, CEs generally seem to have the patient-access requirement under control, some experts say. “I don’t think there’s widespread noncompliance with this requirement,” says former OCR acting deputy director Iliana Peters, who was also senior advisor for HIPAA compliance and enforcement. But there are “areas of potential noncompliance” and some confusion about the right of access, particularly with respect to the judicial and administrative process, says Peters, with Polsinelli in Washington, D.C. She predicts clarity will come through enforcement. There’s also controversy around charges, which is at the heart of a lawsuit against HHS.

In the Bayfront case, OCR says a patient complained that she asked the hospital for her fetal heart monitor records starting in October 2017 and had not received them by the time she complained to OCR in August 2018. When OCR investigated, Bayfront said when the patient first asked for the records, they couldn’t be located. Her counsel then requested the records twice in 2018, and Bayfront first gave counsel an incomplete set and then a complete set. “Complainant’s counsel shared the records with her and, as a result of OCR’s investigation, on February 7, 2019, Bayfront provided Complainant with the fetal heart monitor records directly,” the resolution agreement states.

Bayfront didn’t admit liability, and a spokesperson didn’t respond to a request for comment. HHS did not elaborate on its Right of Access Initiative.

### There’s Some Confusion Around Processes

Under the HIPAA Privacy Rule, CEs are required to give people access to their protected health information (PHI) in one or more “designated record sets” upon request (45 C.F.R. § 164.524). CEs have 30 days to produce the records, although OCR encourages them to respond as fast as possible. In terms of charges, CEs and the business associates operating on their behalf may charge patients a reasonable, cost-based fee for a copy of their PHI. According to May 2016 OCR guidance, *Individuals’ Right under HIPAA To Access their Health Information*, the fee may only include the cost of supplies, postage and labor. The guidance described the methods that may be used to calculate the fee. They are actual labor costs (e.g., for copying) and applicable supplies; average costs, “as long as the types of labor costs included are the ones which the Privacy Rule permits to be included in a fee”; and a flat fee that doesn’t exceed \$6.50 per request.

There may be some confusion around the different processes that hospitals and other CEs have for releasing medical records, Peters tells RMC. When patients request their own records, in person, by email or through a portal, it should be straightforward. She and other privacy experts say they haven’t seen CEs run afoul of this too often. There’s a right of patient access, and it’s unambiguous, Peters explains. But if an attorney requests the records with the patient’s authorization, HIPAA permits the disclosure but doesn’t require it. “Those are two different processes that people often get mixed up,” she says.

Beyond that are litigation matters. “There are several different ways that people deal with litigation that have different requirements,” Peters says. For example, a court order requires disclosure, but for subpoenas, “it’s not a slam dunk,” she notes. “There are all these different issues that surround medical record production that complicate the access to medical records.”

The presence of a business records affidavit sometimes makes the difference in whether CEs are required to disclose PHI and how fast they have to do it, says attorney Richelle Marting, with the Forbes Law Group in Overland Park, Kansas. When attorneys request medical records with a business records affidavit, they are using it for litigation, she says. “We typically view that as the attorney’s request to enable the production of records into evidence,” which falls under the HIPAA provision on authorizations (42 C.F.R. § 164.508), not the patient right of access, says Marting,

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who is also a part-time hospital privacy officer. “That’s the informal consensus. Nobody has clear guidance whether that’s right or wrong.”

A wrinkle with patient access is the tension between privacy and security compliance when patients ask providers to send their medical records to an app that’s not secure versus a reputable, secure app, Peters says. “The provider has to manage whether to send very sensitive data in an unsecure way to comply with the patient request,” she explains. This may come up with patients who have chronic conditions and “want to be empowered in a good way to use their medical information and interact with the provider, but they could be walking into a security issue. It’s on the provider to work with patients, but providers don’t necessarily have the bandwidth to help patients get medical records to a strange new app they want to use.”

Peters also clarified that despite OCR making a distinction in the announcement about the Bayfront resolution agreement between the mother’s medical records and the unborn child’s medical records, patients are entitled to access the medical information in their own file. “It doesn’t matter whether it implicates a third person,” she says. “I’m worried people might think there’s a distinction. If it’s in my medical records, it is my information, and I get a copy of it.” It’s important for CEs to understand that as genetic testing becomes more routine.

### **Warning Signs About Patient Access**

Fees for records are another fraught area in patient access. They’re at the heart of a lawsuit filed against HHS by CIOX Health, a medical records release company, over how much CEs and business associates are allowed to charge for copies of PHI under HIPAA (“HIPAA Court Battle Heats Up Over Fees for Copying PHI; BA Challenged OCR Guidance,” *RMC* 27, no. 19).

When a ruling comes, it could give CEs clarification on when they can charge more for releasing medical records than the limited cost-based fees in the 2016 OCR guidance. CIOX also wants the court to stop enforcement of OCR’s guidance on the grounds that it’s essentially a regulation that hasn’t gone through the proper rulemaking process. But whether there will be a ruling is open to question: HHS has filed a motion with the U.S. District Court for the District of Columbia to dismiss the lawsuit.

Complying with patient requests for records hasn’t been a problem, says Barbara Duncan, HIPAA privacy officer at Stormont Vail Health in Topeka, Kansas. Occasionally a patient or attorney complains they were never received, she says. If that happens, the health system re-sends the records, this time by certified mail. Many patients request and retrieve their own PHI through the patient portal.

There are indications of trouble with patient access. Early results of the “Patient Record Scorecard,” a new initiative to rate how well CEs comply with the right of access to medical records, are not rosy. Of 51 organizations that received a records request, just nine rated five stars as part of the project launched by Ciitizen Corp., a health care records start-up firm initially focused on assisting patients with cancer. Among the aspects measured were how quickly records were sent and whether patients were able to get them in the “form and format” of their choosing, as required under HIPAA, according to a story in *RMC*’s sister publication, *Report on Patient Privacy*.

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## **Va. Hospital Settles CMP Case Over Physician Recruitment Incentive**

Mary Washington Hospital in Fredericksburg, Virginia, has agreed to pay \$50,000 to settle a civil monetary penalty case over physician recruitment. The HHS Office of Inspector General alleged the hospital paid a medical group a recruitment incentive for a physician from January 1, 2017, through February 28, 2019, and transformed it into remuneration under the Stark Law and Anti-Kickback Statute by not recovering some of the money, according to the settlement.

Mary Washington Hospital reported the problem to the OIG and was accepted into its Self-Disclosure Protocol in March 2019. OIG contended the hospital paid remuneration, which created a financial relationship with the medical group, and then submitted claims for designated health services that resulted from prohibited referrals in violation of the Stark Law. The hospital didn’t admit liability in the settlement, and its attorney didn’t respond to requests for comment.

Hospitals often give physicians incentives, including loans, income guarantees and malpractice insurance subsidies, to recruit them to the service area. The Stark Law has an exception for physician recruitment incentives under certain conditions. For example, the hospital can’t obligate the physician to refer all patients to the recruiting hospital or link the incentives to the volume or value of referrals. Incentives may flow through physician practices, although there

are strings attached. If a recruitment arrangement takes the form of an income guarantee, the amount is limited to practice expenses that are the “actual additional incremental costs attributable to the recruited physician,” according to the Stark regulations.

**Stark Tripwire: Loan Forgiveness**

Stark may get stepped on when physicians leave before the expiration of the forgiveness term, typically two to four years, says attorney Bob Wade, with Barnes & Thornburg in South Bend, Indiana. If the recruited

physician hasn’t completed the forgiveness period of the loan or other recruitment dollars, the loan may be subject to repayment. The physician may balk, and possibly have a legitimate argument for doing so. Maybe he or she feels the hospital didn’t abide by the contract (e.g., failed to promote the practice or pay the incentives on a timely basis), and the hospital has to decide whether it’s worth taking the physician to court, Wade says.

The hospital still has a Stark challenge: “You have to interpret the financial arrangement under the recruitment

**Stark Compliance Tool: Keeping Track of Incremental Expenses**

The Stark Law exception for physician recruitment has strings attached for incentives that hospitals run through physician practices. If a recruitment arrangement takes the form of an income guarantee, the amount is limited to practice expenses that are the “actual additional incremental costs attributable to the recruited physician,” according to the Stark regulations (see story, p. 3). Here is a tool that can help hospitals track and document their incremental expenses, says attorney Bob Wade, with Barnes & Thornburg in South Bend, Indiana. Contact him at bob.wade@btlaw.com.

**INCOME GUARANTEE MONTHLY REPORT**

Month: \_\_\_\_\_

Recruited Physician: \_\_\_\_\_

Group Name: \_\_\_\_\_

REVENUE: \$ \_\_\_\_\_ (Medicare)  
 \$ \_\_\_\_\_ (Medicaid)  
 \$ \_\_\_\_\_ (Commercial)  
 \$ \_\_\_\_\_ (Self-Pay)  
 \$ \_\_\_\_\_ (Total Revenue)

**INCREMENTAL EXPENSES:**

Type of Incremental Expense	Amount	Reason Expense is Incremental
Office Space		
Medical Equipment		
Office Equipment		
Medical Supplies		
Office Supplies		
Medical Personnel Salary		
Medical Personnel Benefits		
Administrative Personnel Salary		
Administrative Personnel Benefits		
Physician Malpractice Insurance		
Physician Benefits		
Billing Services		
Advertising/Marketing		
TOTAL INCREMENTAL EXPENSES	\$ _____	

TOTAL REVENUE: \$ \_\_\_\_\_  
 TOTAL INCREMENTAL EXPENSES: \$ \_\_\_\_\_  
 MONTHLY NET: \$ \_\_\_\_\_  
 MONTHLY INCOME GUARANTEE AMOUNT: \$ \_\_\_\_\_  
 MONTHLY NET: \$ \_\_\_\_\_  
 AMOUNT OWED BY/CREDITED TO HOSPITAL: \$ \_\_\_\_\_

exception separately from other potential exceptions, like the employment exception," he says. Here's how that can go: After weighing the costs and benefits of suing the physicians for the money, the hospital may decide to settle, and the settlement may fit under the isolated transaction exception, Wade says. That exception allows for one-time compensation arrangements. "It's possible to argue prospectively, when you enter into the settlement, that Stark is not implicated" because the recruited physician is no longer a referral source for the hospital. However, all referrals will need to be considered, including the referrals from the recruited physician and the referrals from physicians in the practice that the recruited physician is affiliated with.

### **Tread Carefully With Income Guarantees**

Income guarantees for physicians who join a physician practice can be a slippery slope to noncompliance. With an income guarantee, the hospital covers the gap between revenue and expenses for a period of time when the recruited physician is new to the practice (e.g., two years). After that, "there's a forgiveness period," Wade says. As long as the physician stays in the service area, the hospital will forgive the loan on a pro rata basis, potentially all the way to zero. But there could be Stark trouble if that's not the case. For example, if the amount owed after the initial two-year guarantee period is \$240,000 and the physician stays long enough to reduce it to \$120,000, "someone has to repay the remaining \$120,000 because it was a loan given to the group," he says. The hospital is in dangerous Stark Law and Anti-Kickback Statute territory if it writes off the rest of the debt because there is still an ongoing referral relationship with the group.

Physicians may be mistakenly overpaid by the hospital because of recruitment incentives, Wade says. There are many ways this can happen, but usually the income guarantees were not "incremental," he says (see box, p. 4). To qualify for the Stark recruitment exception, hospitals face some limits on the income guarantees they give recruited physicians who join physician practices. Only incremental costs must be included, which means the actual additional cost allocated by the practice for the physician. Suppose the office rent for three existing physicians is \$10,000 a month, and the practice allocates \$2,500 a month for the new recruit without renting additional space. "They can't do that under Stark because it's not incremental. They didn't rent more space due to the recruited physician joining the practice," Wade says.

If the hospital realizes during a compliance review it has a Stark problem, that doesn't necessarily mean it will be able to recover the money from the practice. Even if it sues, the physician group will say,

"Judge, look at the contract. It didn't qualify the word 'expenses' by saying 'incremental.' The Stark Law obligation is a billing obligation. That's the hospital's fault, not our fault." Where does that leave the hospital? Perhaps facing a self-disclosure to CMS's Self-Referral Disclosure Protocol.

Another way that hospitals overpay practices through recruitment incentives is guaranteed tuition payments, Wade says. The monthly payments may be \$10,000 according to the contract with the recruit, for example, but the doctor submits an invoice for \$15,000 because that's his or her obligation, and the accounts payable department writes the check. In this case, the hospital paid more than it was required to pay in the recruitment contract. Again, what is the hospital going to do? Take the doctor to court?

Front-end monitoring is the best way to prevent Stark Law recruitment violations, he says. "The recruitment agreement has to be very explicit," he says. It's helpful to have preprinted forms for income guarantees or tuition reimbursement that conform to the contract. Wade recommends assigning one person in accounts payable who understands what should be paid under the physician recruitment exception. When the physician invoices come in for the income guarantee and other incentives, that person should be able to recognize whether the payment requests are consistent with the exception and the hospital contract. "It's preferable to have an upper-level person monitoring this because you have a lot of moving parts."

Contact Wade at [bob.wade@btlaw.com](mailto:bob.wade@btlaw.com). ✦

### **CMS: 'Blanket Distribution of Notices' Can Confuse Beneficiaries**

Conversations about why they are outpatients, not inpatients—a mostly artificial distinction for payment purposes—sometimes means taking patients down the rabbit hole, and utilization reviewers and case managers don't relish them.

"It's very difficult explaining the difference between observation and inpatient to a patient," says Kim Romoser, manager of utilization review and appeals at WellSpan Health in York, Pennsylvania. "Regardless of how it is worded, they do not understand. No one has ever said, 'Oh, I get that. It makes perfect sense.' I do my best to try to explain in laymen's terms." Patients protest. They are in a hospital bed, so how is it possible they aren't inpatients? "They question and question, and it is just at the point where they say, 'OK, if a physician said so, I guess that is OK,' and there's resignation: 'Well, I don't like it. If that's the rules, then I don't have any type of recourse.'"

But the conversation is required by law when hospitals give patients the Medicare Outpatient Observation Notice (MOON), which explains they are outpatients receiving observation services, not inpatients. Hospitals are required to deliver the MOON to patients who receive 24 hours or more of observation services and to notify them within 36 hours after physicians have written the observation order.

That's not to be confused with the Important Message from Medicare (IM), which notifies inpatients of their right to appeal the discharge. Apparently, some hospitals give both notices to the same patients. That makes no sense because they serve different purposes, says Ronald Hirsch, M.D., vice president of R1 RCM. In fact, CMS frowns on it. "We generally explain to providers/hospitals that 'blanket' distribution of notices can be confusing to beneficiaries when not related to an impending inpatient admission/discharge," CMS said in a recent email to Hirsch, who shared it with RMC. "In addition, some beneficiaries will call the [quality improvement organization] to appeal when they are not eligible and are frustrated and more confused when the QIO realizes and conveys there is no actual inpatient stay/impending discharge to appeal."

### **There's Risk of Termination**

The Medicare conditions of participation for hospitals require them to notify patients of their rights. "Noncompliance with this requirement places the hospital at risk of termination from the Medicare program," CMS said in the email. "This requirement is assessed by onsite surveyors from the State Survey Agencies or CMS-approved hospital accrediting organizations. Separately there may be applicable State laws and noncompliance with State requirements may terminate licensure."

Hospitals have to deliver the first IM to the patient within two days of admission, and a follow-up no later than two days before discharge. The second IM isn't necessary if the first is given within two days of discharge.

Every hospital faces the challenge of ensuring patients get required notices, including IMs, MOONs and advance beneficiary notices, Hirsch says. "What some hospitals have chosen to do because of the complicated workflow is to give every notice to every patient on the premise that no one reads the notices anyway. As long as they have a signed copy in the charts in case they get audited, they are happy," he says. "But to me that is problematic. Patients who will be placed in observation who get the IM and read it, or family who reads it, will think they have appeal

rights, and that's a problem because they don't" on the observation side.

### **Registration Delivers MOON, First IM**

The best practice is not to give every notice to the same patient just in case, Hirsch says. The order for the status should triage and alert the person who delivers the form, who should check with the nurse to ensure the patient is in good enough condition to understand the information on the form, he says. For example, the nurse may say the patient just received a dose of pain medication and to check back in a few hours.

At WellSpan, registration staffers give patients the MOON when the physician orders observation. They are also responsible for delivering the initial IM after the physician orders inpatient admission. "When the IM process first started, case management was doing it, but it was very difficult because we weren't necessarily 24/7, so we transitioned to registration staff, and that works very well," Romoser says. However, if the patient is reclassified as observation after being admitted, case management delivers the IM.

The discharge IM also is delivered by case management, and it generates more questions than the initial IM. Patients want to know what their recourse is if they don't feel ready for discharge. They can appeal to QIOs, which will generate another form, the Detailed Notice of Discharge.

Where it gets hazy is whether to issue another discharge IM if the QIO agrees the patient isn't ready for discharge, Romoser says. It doesn't happen often, but "the care team gets together and discusses the patient's plan," she says. "When the physician writes a new discharge order, we issue a new IM. We're erring on the side of caution."

Contact Romoser at [kromoser@wellspan.org](mailto:kromoser@wellspan.org) and Hirsch at [rhirsch@r1rcm.com](mailto:rhirsch@r1rcm.com). ✦

### **AseraCare Decision Raises FCA Bar**

*continued from page 1*

Where the chips ultimately fall is up to a jury, unless the two sides settle. However it turns out, the message is that "the government can't demonstrate falsity just because there are two physicians having a good-faith disagreement," Witten says.

AseraCare operates about 60 hospices in 19 states and admits around 10,000 patients, most enrolled in Medicare. For patients to be eligible for the Medicare hospice benefit, a physician must certify that the patient is terminally ill, with a life expectancy of six months or less. Physicians certify patients for hospice care for 90 days, with recertification every 60 or 90 days.

The FCA lawsuit against AseraCare was set in motion by three former AseraCare employees, and DOJ intervened, filing its own complaint. It alleged that AseraCare submitted documentation that supported Medicare claims for hospice patients who were not terminally ill.

In making its case, DOJ focused on a sample of 223 patients whose medical records and clinical histories were reviewed by its primary expert witness, Dr. Solomon Liao. He identified 123 who allegedly were ineligible for the hospice benefit when AseraCare was paid for their care, according to the appeals court decision.

There were no allegations, however, that AseraCare billed for fake patients or forged certifications, or that its employees lied to certifying physicians or withheld key information on patient conditions. In fact, AseraCare has comprehensive documentation of the patients' medical conditions, and its certifications of terminal illness were signed by the right medical staff. "Rather, the Government asserted that its expert testimony — contextualized by broad evidence of AseraCare's improper business practices — would demonstrate that the patients in the sample pool were not, as a medical fact, terminally ill at the time AseraCare collected reimbursement for their hospice care," the appeals court decision stated.

But things got a little strange. The judge agreed to bifurcate the trial, with one phase to decide on falsity under the FCA and the second phase to determine knowledge of the falsity.

### **It Was a Battle of the Experts**

At trial, Liao testified that the medical records of the relevant AseraCare patients didn't support the terminal illness certifications because they didn't show a life expectancy of six months or less, although he said his testimony reflected his after-the-fact review of supporting documentation. AseraCare then offered rebuttal testimony from its physicians. "The question before the jury was instead which doctor's interpretation of those medical records sounded more correct," the appellate court decision explained.

The jury found that AseraCare submitted false claims for 104 of the 123 patients.

Before moving on to the second phase of the trial, AseraCare asked the district court to throw out the jury's findings as a matter of law because it had made a mistake in its jury instructions, and the district court agreed to order a new trial. Also, on its own, the district court decided to consider whether DOJ had enough admissible evidence, aside from a difference of medical opinions, "to show that the claims at issue are objectively false as a matter of law." The district court warned

that "the Government's proof under the FCA for the falsity element would fail as a matter of law if all the Government has as evidence of falsity in the second trial is Dr. Liao's opinion based on his *clinical judgment* and the medical records that he contends do not support the prognoses for the 123 patients at issue in Phase One."

After a hearing, the district court granted summary judgment to AseraCare, throwing out DOJ's FCA lawsuit. DOJ appealed to the 11th Circuit, which affirmed the district court's decision to grant a new trial and vacated the post-verdict grant of summary judgment for AseraCare.

The 11th Circuit said the appeal "requires us to consider how Medicare requirements for hospice eligibility — which are centered on the subjective 'clinical judgment' of a physician as to a patient's life expectancy — intersect with the FCA's falsity element." The question is whether AseraCare's certifications that patients were terminally ill met Medicare's statutory and regulatory requirements for reimbursement. If not, the claims could be false under the FCA.

The appeals court reviewed the legal standard for the falsity of hospice claims, including the hospice eligibility framework, and concluded that "none of the relevant language states that the documentary record underpinning a physician's clinical judgment must prove the prognosis as a matter of medical fact. Indeed, CMS has recognized in crafting the implementing regulations that '[p]redicting life expectancy is not an exact science.'" CMS indicated that as long as clinical judgments are "well-founded," they should be deferred to.

The appeals court also considered the falsity in this case under the FCA. There are two "species": the

## **CMS Transmittals and Federal Register Regulations, Sept. 6-12**

### **Transmittals**

#### **Pub. 100-04, Medicare Claims Processing Manual**

- October 2019 Update of the Ambulatory Surgical Center (ASC) Payment System, Trans. 4389 (Sept. 6, 2019)

#### **Pub. 100-20, One-Time Notification**

- Additional Instructions to Hospitals on the Election of a Medicare-Supplemental Security Income (SSI) Component of the Disproportionate Share (DSH) Payment Adjustment for Cost Reports that Involve SSI Ratios for Fiscal Year (FY) 2004 and Earlier, or SSI Ratios for Hospital Cost Reporting Periods for Patient Discharges Occurring Before October 1, 2004, Trans. 2357 (Sept. 6, 2019)

### **Federal Register**

#### **Final Rule with Comment Period**

- Medicare, Medicaid, and Children's Health Insurance Programs; Program Integrity Enhancements to the Provider Enrollment Process, 84 Fed. Reg. 47794 (Sept. 10, 2019)

legitimacy of the physician's clinical judgment and "the legitimacy of AseraCare's statement that a clinical judgment has been properly made."

There isn't anything in the statutory or regulatory framework to indicate that a clinical judgment about a patient's prognosis is invalid because an unaffiliated physician reviewing the records later disagrees, and there isn't necessarily Medicare noncompliance if the only flaw is an absence of certainty the patient will die in six months.

### Other Ways to Show Objective Falsity

But there are other ways to show objective falsity, such as physicians signing certifications without reviewing the medical records. Without showing objective falsehood, "the FCA is an inappropriate instrument to serve as the Government's primary line of defense against questionable claims for reimbursement of hospice benefits," the appeals court stated.

The appeals court remanded the case to the district court for a new trial, and said it has to consider all

the evidence. Some had been excluded because of the bifurcated trial. DOJ has witnesses who will testify that AseraCare physicians allegedly signed hospice certifications without reviewing documentation. A "former employee testified that signing certifications had become so rote for one physician that he 'would nod off' while signing," the appeals court decision said.

When the case goes back to trial, the government has a "substantial burden of proof," Donovan says. It has to show not just that the hospice patient was ineligible but that the physician who signed the certification knew it or that the medical records weren't reviewed.

Witten says "the message for hospice providers is they need to ensure the physician is certifying patient life expectancy is not longer than six months and that they truly reviewed the clinical information before they made that judgment."

Contact Donovan at [cdonovan@foley.com](mailto:cdonovan@foley.com) and Witten at [jesse.witten@dbr.com](mailto:jesse.witten@dbr.com). View the decision at <http://bit.ly/2ISLazQ>. ✦

## NEWS BRIEFS

◆ **Philip Esformes, the former owner of a network of assisted living facilities and skilled nursing facilities in Florida, was sentenced to 20 years in prison Sept. 12 after being found guilty in the largest health fraud scheme ever charged by the Department of Justice (DOJ).** From January 1998 to July 2016, Esformes bribed physicians to admit patients to his facilities, where they often didn't get proper services or received medically unnecessary services. "Esformes concealed the poor conditions and scheme from authorities by bribing an employee of a Florida state regulator for advance notice of surprise inspections scheduled to take place at his facilities," DOJ said. He personally benefited from the fraud to the tune of \$37 million, and used the money for "extravagant purchases, including luxury automobiles and a \$360,000 watch." Visit <http://bit.ly/2ISFTs4>.

◆ **Geoffrey Girnun, an associate professor in the Department of Pathology and director of cancer metabolomics at the Renaissance School of Medicine at Stony Brook University (SBU) in New York state, was charged with theft of state and federal government funds, wire fraud and money laundering,** the U.S. Attorney's Office for the Eastern District of New York said Sept. 12. Girnun allegedly submitted fake invoices to SBU for research equipment from sham companies he set up to conceal his theft of funds from cancer-related research grants awarded by the National Institutes

of Health (NIH) and SBU. He used the \$200,000 he allegedly stole to pay his mortgage and for other personal expenses. Visit <http://bit.ly/2mfoPNk>.

◆ **Without mentioning a time frame, CMS Administrator Seema Verma said revisions to the Stark regulations are underway.** "We're not done dismantling antiquated government rules. Our new CMS office on burden reduction will focus on several areas. First, we've heard your concerns about the Stark Law, and a revision to the rule is in process," she said during a speech to an American Hospital Association regional policy board meeting. "We're also aware that prior authorization is a difficult issue. It is an important tool, but it can result in delays in patient care as well as burden." The Stark update was expected this past summer based on earlier CMS announcements. Visit <https://go.cms.gov/2kLajwb>.

◆ **In a new report, the HHS Office of Inspector General says CMS could use data from the Comprehensive Error Rate Testing (CERT) contractor to identify high-risk home health agencies (HHAs) "as a part of a multifaceted approach that includes targeted probe-and-educate reviews as well as aspects of its Fraud Prevention System to further reduce improper payments."** CERT data for 2014 through 2017 already identified 87 high-risk HHAs, which showed an improper payment rate of about 78%. Visit <https://go.usa.gov/xVNkC>.