

MEDICARE COMPLIANCE

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

Contents

- 3** AseraCare Settles FCA Case for \$1M Six Months After Court Ruling
- 4** CO: Departments Unilaterally Hiring Consultants Invites Risk, Duplication
- 5** Policy on Hiring External Auditors and Consultants
- 7** CMS Transmittals and *Federal Register* Regulations, Feb. 21-27
- 8** News Briefs

With More Scrutiny of Foreign Research Funding, Hospitals Try to Improve Disclosures

Compliance and IT at Tampa General Hospital are teaming up to try to identify emails that its researchers receive from foreign domains. The emails may be innocuous—international data sharing and collaboration are a mainstay of the research community—but the teaching hospital won't know unless it reviews them, and the stakes are higher now because the government has put foreign research support under a microscope, said Lynn Smith, research compliance officer. The email review would supplement its conflict-of-interest questions on foreign funding, but there will be more to come as monitoring evolves.

"We have to rethink how we manage this area going forward," she said.

All eyes are on foreign support in the wake of recent developments from the National Institutes of Health (NIH) and the Department of Justice (DOJ). In a recent notice, NIH reminded the "extramural community"—medical centers, hospitals and research institutions—they're required to report foreign "activities," including conflicts of interest. NIH also has instructed some of them to review specific researchers, which has led to a handful of resignations and terminations. Allegations of lying about foreign money can have serious consequences; DOJ said Jan. 28 it charged a Harvard University professor with making a false statement about his financial support from China.¹

"Faculty are under increased scrutiny and so are their institutions," said attorney Valerie Bonham, with Ropes & Gray in Washington, D.C., who isn't commenting on any specific cases. "There are concerns that economic and national security will be compromised

continued on p. 6

Mid-TPE Appeal Prevented Third Audit Round, 'But There Was No Explanation' From MAC

Targeted Probe and Educate (TPE) can be a zero-tolerance medical review strategy, which means a single claim denial could push providers from one round of audits to the next.

"There is no acceptable error rate," said Christine Hall, president of Stirling Global Solutions, at a Feb. 27 webinar sponsored by the Health Care Compliance Association.

But if providers appeal claim denials between rounds, they may be able to bring the audit to a close. It happened for Inova, a health system in northern Virginia, said Compliance Manager Ashley Henderson. The catch: the Medicare administrative contractor (MAC) may not tell you the audit is over, because appeals and TPE are in separate departments. "That was a new experience, but not an easy experience," she said. In the end, however, "it worked out well." The importance of communicating with the MAC is one of the lessons of that interaction with TPE, which many providers say is preferable to other audits, partly because there's generally not a tidal wave of audits, and because the MACs provide one-on-one education where they discuss specific errors with providers.

Henderson said Novitas, the MAC, audited claims for critical care services submitted by Inova physicians. "We were unsuccessful in round one and sent to

continued



HCCA

Managing Editor

Nina Youngstrom
nina.youngstrom@hcca-info.org

Copy Editor

Bill Anholzer
bill.anholzer@hcca-info.org

round two,” she said. Because the physicians were emphatic about the accuracy of the claims, Henderson filed an appeal. “We had six or seven claims denied in round two, and we appealed four or five of them, and that got us off TPE,” she said. “But there was no explanation. We didn’t receive notice we were no longer under audit, so we were waiting around anxiously for round three.” Eventually, Henderson called the MAC to ask about its third TPE round, and that’s when she found out the audit had been dropped because of the successful appeal. “They never sent us a letter,” she said. It’s a reminder of how vigilant compliance officers and physician advisors must be with TPE.

TPE is different from previous Medicare audits, including so-called probe and educate. Providers are selected because they’re a potential risk to Medicare and/or “vary significantly from their peers,” according to CMS’s questions and answers (Q&As) page on TPE.¹ That’s a departure from years of audits where all providers were swept in regardless of their billing rates. But Henderson said the two MACs she’s familiar with won’t reveal their methods for including Inova in a review. The MACs, Novitas and Palmetto, use vague language, such as “you have been selected based on our internal data analytics.” She has asked for more details, but they’re not forthcoming. “They say it’s proprietary.”

Report on Medicare Compliance (ISSN: 1094-3307) is published 45 times a year by the Health Care Compliance Association, 6500 Barrie Road, Suite 250, Minneapolis, MN 55435. 888.580.8373, hcca-info.org.

Copyright © 2020 by the Health Care Compliance Association (HCCA). All rights reserved. On an occasional basis, it is okay to copy, fax or email an article from *RMC*. Unless you have HCCA’s permission, it violates federal law to make copies of, fax or email an entire issue; share your subscriber password; or post newsletter content on any website or network. To obtain permission to transmit, make copies or post stories from *RMC* at no charge, please contact customer service at 888.580.8373 or service@hcca-info.org. Contact Aaron Black at aaron.black@hcca-info.org or 952.567.6219 if you’d like to review our reasonable rates for bulk or site licenses that will permit weekly redistributions of entire issues.

Report on Medicare Compliance is published with the understanding that the publisher is not engaged in rendering legal, accounting or other professional services. If legal advice or other expert assistance is required, the services of a competent professional person should be sought.

Subscriptions to *RMC* include free electronic delivery in addition to the print copy, as well as a searchable database of *RMC* content and archives of past issues at compliancecosmos.org.

To order an annual subscription to **Report on Medicare Compliance** (\$665 for HCCA members; \$765 for nonmembers), call 888.580.8373 (major credit cards accepted) or order online at hcca-info.org.

Subscribers to this newsletter can receive 20 non-live Continuing Education Units (CEUs) per year toward certification by the Compliance Certification Board (CCB)[®]. Contact CCB at 888.580.8373.

Don’t Bind the Records or Attach Sticky Notes

TPE reviews kick off with an audit of 20 to 40 claims—almost always 40, Hall said. Providers receive a notice of review (NOR) informing them they will receive an additional document request (ADR) and telling them to update information in the Provider Enrollment, Chain and Ownership System if there have been any changes. When ADRs come later, providers should only send one-sided documents and include signature logs to identify multiple providers. Missing signatures are one of the most reported errors, she said. “If a signature is missing, remember to attach a signature attestation to the document.”

Hall suggested providers include a cover sheet explaining what MACs will find in the packet. But she discouraged providers from binding the records with staples or paper clips or attaching sticky notes, and they shouldn’t highlight or alter language. “Sticky notes and tabs can become dislodged and lost or even reattached in a different location of the documents during the review process,” she explained. “A better solution would be including a cover sheet referencing the information intended on the sticky note or tab.”

Providers have 45 days to produce the documents “or claims are automatically considered denied,” Hall said. Thirty days later, the verdict will be returned. She said a single claim denial will trigger a second audit.

The same goes for a single denial in round two. Providers who pass the audit won’t be reviewed on the same topic for at least one year.

After education with the MAC, providers are given 45 to 56 days to improve before the second round of audits. “After that, the process starts over,” Hall said. If providers fail round three, the MAC refers them to the recovery audit contractors, zone program integrity contractor or unified program integrity contractor, “or CMS might place you on 100% prepayment review.”

Nationally, about 435,000 claims were reviewed in fiscal year 2019, according to the TPE FAQs, with about 60% accepted as billed. CMS said 13,500 providers and suppliers “were started on TPE.” Of them, less than 2% failed all three rounds of audits. There were 90,000 educational contacts (e.g., phone calls, face-to-face visits, webinar/e-visits, emails and letters) either during or after the review.

Evaluation and management (E/M) services are a common target across MAC jurisdictions, Hall said. A lot of them are reviewing initial and subsequent hospital visits and skilled nursing facility E/Ms, “and critical care seems to be repetitive by all the MACs.”

Denial Prevention Is the Best Medicine

Providers could help avoid TPE reviews by using data to monitor their billing. That includes outstanding accounts receivable and Part B comparative billing reports produced by the MACs and separately for CMS by a different contractor.²

To ensure NORs and ADRs get in the right hands, Inova “had a huge initiative to look at who does what with the letters,” Henderson said. “We’ve done a lot of work internally to streamline the process.” The patient financial services department made sure Medicare has the correct addresses for Inova hospitals. “Then compliance met with various departments (e.g., coding, patient financial services) to discuss which letters go where, and that’s how we spread the word” compliance facilitates the TPE process, she said.

Henderson has gotten to know some of the reviewers at both MACs, who give her a courtesy call if documentation is missing. “If you have it, they will keep the claim open for 48 hours,” she said. The personal touch can make a big difference in a review because getting a response from someone random on the provider services number often takes days. “These individuals aren’t always familiar with the TPE process,” Henderson said.

Contact Hall at christine.hall.guru@gmail.com and Henderson at ashley.henderson@inova.org. ✧

Endnotes

1. CMS, “Targeted Probe and Educate (TPE) Q&A’s,” accessed February 28, 2020, <https://go.cms.gov/32vCINV>.
2. Nina Youngstrom, “CMS Sends Billing Outlier Reports to Part B Providers; Metrics Show How to Identify Them,” *Report on Medicare Compliance* 28, no. 31 (September 9, 2019), <http://bit.ly/2AEx35p>.

AseraCare Settles FCA Case for \$1M Six Months After Court Ruling

Almost six months after the U.S. Court of Appeals for the 11th Circuit ruled¹ in the false claims case against AseraCare Inc. that it takes more to prove false claims in a Medicare medical necessity case than a physician disputing patients’ eligibility for services after the fact, AseraCare announced Feb. 27 that it has reached a settlement with the Department of Justice. AseraCare, which operates about 60 hospices in 19 states, said it agreed to pay \$1 million.

“AseraCare is grateful to have reached this settlement with the Department of Justice and is proud that perseverance produced a benefit to the hospice industry that provides more clarity under the False Claims Act as a result of the opinion issued by the

Eleventh Circuit Court of Appeals on September 9, 2019,” it said in a statement.

The False Claims Act² (FCA) lawsuit 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. 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 court decision explained.

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. 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 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 decision said.

Court Gave DOJ Another Stab at Trial

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 and, 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.”

After a hearing, the district court granted summary judgment to AseraCare, throwing out the FCA lawsuit. DOJ appealed to the 11th Circuit, which gave DOJ another shot at trial. But it said DOJ needed to do more than expert armchair quarterbacking.

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.

The appeals court also considered the falsity in this case under the FCA. 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, the court said.

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 trial is moot now because of the settlement. ✦

Endnotes

1. Nina Youngstrom, “In AseraCare FCA Case, Court Says a Contrary Medical Opinion Is Not Enough,” *Report on Medicare Compliance* 28, no. 32 (September 16, 2019), <http://bit.ly/330Pdul>.
2. 31 U.S.C. §§ 3729-3733.

CO: Departments Unilaterally Hiring Consultants Invites Risk, Duplication

It always surprised Sue Shollenberger, director of corporate compliance-east at WellSpan Health in York, Pennsylvania, when she found out a department hired an external auditor or consultant on its own, without informing compliance or sharing the results. Things can go wrong when a department acts unilaterally, and the audit may be duplicative.

“The risk is, we can have pockets of people doing these and keeping the results to themselves, without the compliance department knowing they did them,” she said. “The consultant can find problems that are not properly addressed by the management of the department.” To avoid that, WellSpan Health has an updated policy on external reviews, and Shollenberger has emailed all managers to inform them to consult the policy before using outside auditors and consultants (see box, p. 5).¹

Hiring consultants and external auditors independently was risky for several reasons. For one thing, when an external auditor or consultant found an error, the department may fix it without necessarily considering the

bigger picture of Medicare’s 60-day overpayment refund rule and implementing corrective action. “If the error rate is greater than minimal, maybe we think of the six-year look-back period,” Shollenberger said. “Departments don’t know of the 60-day rule, and that doesn’t need to involve them, but they need to involve us.”

Also, there may be times when a department agrees with some audit results and disagrees with others. “You can agree to disagree, but you can’t dismiss the findings,” she explained. “You should have it documented that the consultant found 10 errors, we disagree with one of 10, and document why.” If you hire a quality consultant, there usually won’t be significant disagreement, but it’s always possible, Shollenberger said.

‘What Did You Know and When Did You Know it?’

Another pitfall is a department not sharing external audit findings with upper management. “It goes to ‘What did you know, and when did you know it?’” which could be important if the government investigates under the False Claims Act, she said. “Once a consultant gives you a finding, you have an awareness of problems.” The organization’s response must be documented. “You have to have it clean at the end,” Shollenberger said. “Otherwise, you’re vulnerable. You are now on notice you have this issue.” It would look bad if the HHS Office of Inspector General (OIG) comes in three years later and asks what you have been doing to correct the error and the answer is nothing. “I have always run my shop as if OIG could walk in any day, and you better have your documentation in order,” she said.

Hiring a consultant or external auditor without input from compliance also deprives it of the opportunity to broaden the review. “If we have an error in one hospital, we look at all hospitals [to see] if they have the same error,” she said. “We think broadly.”

Sometimes it’s unnecessary to go outside the organization, because the compliance department “may have the internal expertise to do it,” Shollenberger said. “I had a manager say, ‘I didn’t know you could do that for us.’ They’re busy in operations trying to serve patients and don’t think about it.”

Another reason to run the use of external auditors and consultants by the compliance department is it will vet them. Shollenberger said consultants and external auditors are put through background checks, including the HHS OIG List of Excluded Individuals and Entities.

Contact Shollenberger at sshollenberger@wellspan.org. ✦

Endnotes

1. “Policy on Hiring External Auditors and Consultants,” *Report on Medicare Compliance* 29, no. 8 (March 2, 2020).

Policy on Hiring External Auditors and Consultants

WellSpan Health in York, Pennsylvania, developed this policy to ensure its departments follow certain steps before hiring external auditors and consultants, said Sue Shollenberger, director of corporate compliance-east. Departments create risks if they independently hire auditors or consultants without looping in compliance and don't share results, she said (see story, p. 4). Contact Shollenberger at sshollenberger@wellspan.org.

WellSpan Health Manual of Administrative Policy

Policy # External and Consultant Review – Coding/Billing/Documentation

WellSpan Health adopts the following policy and procedure for the following specifically named entities:

- Apple Hill Surgical Center
- VNA Home Health and Services
- WellSpan Medical Equipment
- WellSpan Medical Group
- WellSpan Pharmacy
- WellSpan Philhaven
- WellSpan Surgery and Rehabilitation Hospital
- WellSpan Ephrata Community Hospital
- WellSpan Gettysburg Hospital
- WellSpan Good Samaritan Hospital
- WellSpan York Hospital

PURPOSE – To guide WellSpan Health employees when receiving external audit requests or considering externally hired consultants/ auditors to assess or address operational issues related to compliance with rules and regulations, including, but not limited to, documentation, billing, coding guidelines, and other rules or regulations governing healthcare services (OSHA, Human Resources, etc.).

POLICY AND PROCEDURE: Hiring External Consultants/Auditors

- I. It is best to determine, prior to engaging a consultant, that one is truly required. If department management believes that help is needed with coding, billing, or documentation, please consult with the Compliance Department directors regarding the following, when considering any compliance-related audits, reviews, or consultations:
 - A. What is the purpose of the review?
 - B. What potential compliance risks have been identified, requiring this review?
 - C. What expertise is available in-house?
 - D. If it is necessary to obtain outside expertise, what consideration was given to selecting the external consultant? Are they the best match for WellSpan?
 - E. Should the engagement be conducted under attorney-client privilege? General Counsel or an Associate General Counsel may be contacted to review.
- II. Ensure contract is developed in compliance with MAP policy #149 Contracting.
- III. Ensure that results from external reviews are reviewed by appropriate management oversight, ensure that any necessary billing corrections are made to accounts and/or paybacks made to payers, and ensure any necessary corrective actions are implemented.
 - A. Share actual draft and final written reports with appropriate department management. Also share with Corporate Compliance director if the review is related to documentation, billing, and/or coding guidelines or regulations.
 - B. Review report with appropriate management to determine if there is agreement with the consultant's results. Document results of that review. Most likely they will fall into one of three scenarios:

1. Agree with all findings and recommendations from the consultant, and report stands as final.
 2. Disagree with some findings/recommendations, and these are discussed with the consultant who agrees with us and revises the final report accordingly
 3. Disagree with some findings/recommendations. Consultant does not agree, and you agree to disagree. Document why you disagree with supporting rational and maintain this documentation with the consultant's report.
- C. Review report with appropriate management and determine if any corrective action needs to take place for any identified deficiencies. Items that may need corrective action or updates may include, but are not limited to:
 1. Policies and procedures may need to be reviewed and updated.
 2. Workflows may need to change.
 3. Bills may need to be corrected and/or paybacks of any overpayments may need to be made to payers.
 4. Education may need to be provided to staff.
 - D. Develop correction action plan (CAP), ensuring all identified deficiencies are addressed, and review with appropriate management.
 - E. Submit CAP to Corporate Compliance for review when the review is related to documentation, billing, and/or coding guidelines or regulations.
 - F. Implement CAP in a timely manner.
 - G. Review to ensure CAP is working as intended within one month of implementation.
 - H. Plan periodic monitoring for an appropriate length of time to ensure continued compliance. Discuss periodic monitoring plan with Corporate Compliance prior to implementation when the review is related to documentation, billing, and/or coding guidelines or regulations.
 - I. Implement periodic monitoring:
 1. Document review results.
 2. Share results with appropriate management.
 3. Share results with Corporate Compliance director when the review is related to documentation, billing, and/or coding guideline or regulations.
 4. Maintain review results for 10 years.

POLICY AND PROCEDURE: External Review Requests

For any other audit requests or review results received by the department, please notify Corporate Compliance immediately. Corporate Compliance reviews all external requests for audit, external requests for records, and external audit results. External audits usually have strict time frames regarding submission of medical records and appeal time frames. Additionally, lessons learned from audit results may be shared across WellSpan, for purposes of performance improvement.

SCOPE: This policy applies to all entities governed by WellSpan Health.

Foreign Research Support Is Scrutinized

continued from page 1

and taxpayer investment in research will be compromised by unauthorized foreign government access to intellectual capital." For example, if investigators fail to disclose foreign funding and other support for research, NIH worries "it's making a distorted funding decision because it doesn't have all the information it needs to make a decision about giving a grant to person A or person B," she said.

In this environment, compliance officers have a "valuable opportunity" to work with investigators to educate them and improve compliance, Bonham said. It's a delicate balance, however. "University compliance officers are not set up as law enforcement shops," she said. But they can use their compliance chops—reviewing and updating policies when new guidance is released, as expected soon, and validating information from principal investigators, among other things.

With NIH grants, Bonham said there are three "reporting pathways the government is concerned about" in terms of foreign influence in research:

- ◆ **Financial conflicts of interest:** NIH set forth conflict of interest reporting requirements in regulations updated in 2011. Reporting is a two-stage process: The investigator reports a significant financial interest to the institution, which decides whether it must be managed or eliminated. Then the institution reports the financial interest to NIH if it's identified as a conflict of interest.
- ◆ **Other support:** According to the terms and conditions for NIH grants in the NIH Grants Policy Statement,² investigators must disclose everything that supports their research. "It's a broad concept" and includes lab space, materials and personnel (e.g., visiting, voluntary and adjunct professors), Bonham said.
- ◆ **Foreign components:** Also located in the Grants Policy Statement, these requirements are grant specific. NIH must preapprove research activity outside the U.S. if it constitutes a significant part of NIH-funded research. Human subjects research, for example, is clearly in the bucket of "significant," she said. "What's less clear is activity that will result in co-authorship, which NIH says 'may' represent 'significant' parts of a project."

Scientist Allegedly Caused Harvard to Lie to NIH

Allegations of lying to investigators about funding from China is at the heart of the indictment of Charles Lieber, the chair of Harvard University's chemistry and chemical biology department, on one count of making a materially false statement in connection with his affiliation with Wuhan University of Technology (WUT) in China. Lieber allegedly caused Harvard to falsely

tell NIH that he had "no formal association with WUT" after 2012, the DOJ alleged.

According to the criminal complaint, Lieber, the principal investigator of the Lieber Research Group at Harvard, works on "science and technology at the nanoscale" and has received \$15 million in funding from NIH and the Department of Defense (DOD) since 2008. An affidavit from FBI Special Agent Robert Plumb said Lieber also "was a 'strategic scientist' at WUT and a contractual participant in China's Thousand Talents Plan for significant periods between at least 2012 and 2017." China uses its Thousand Talents Program to recruit scientific talent to further the country's scientific development, prosperity and national security. WUT paid Lieber \$50,000 a month for at least three years and about \$150,000 in living and personal expenses, as well as \$1.5 million to establish a research lab at WUT, the affidavit alleged.

In early 2015, Harvard independently learned of the WUT-Harvard Joint Nano Key Laboratory at WUT and Lieber's role as director, according to the affidavit. Harvard told Lieber that improperly using the Harvard name and logo violated university policy, and he allegedly "falsely told Harvard officials WUT was using Harvard's name and logo without his knowledge and consent," although he admitted doing research there.

DOD investigators asked Lieber in April 2018 whether he had disclosed foreign research collaboration to DOD. "Lieber said he was familiar with China's Thousand Talents Plan, but that he had never been asked to participate in the program...he also told investigators he 'wasn't sure' how China categorized him. I believe these statements were false because" Lieber signed a three-year Thousand Talents agreement with WUT on July 21, 2012, the FBI affidavit alleged.

Lieber allegedly caused Harvard to tell NIH "that Lieber 'had no formal association with WUT' after 2012, but that 'WUT continued to falsely exaggerate' Lieber's involvement with WUT in subsequent years," the affidavit said. "Lieber also caused Harvard to tell NIH that Lieber 'is not and has never been a participant in' China's Thousand Talents Plan." None of that was true, the affidavit alleged. Lieber is on administrative leave from Harvard, according to Bloomberg news. Harvard didn't respond to RMC's request for comment.

NIH Warns of Foreign 'Influence'

This is a fraught environment for foreign support. Institutions could lose their grants or grant eligibility if they don't comply with reporting requirements, and their reputation takes a blow if their professors or other members of a research team share sensitive data with a foreign power without appropriate approvals.

NIH Director Francis Collins said in a 2018 letter³ sent to about 10,000 institutions that it's "aware that some foreign entities have mounted systematic programs to influence NIH researchers and peer reviewers." He said NIH expects them to "work with your faculty and with your administrative staff to make sure that, in accordance with the NIH Grants Policy Statement, all applications and progress reports include all sources of research support, financial interests, and relevant affiliations." In July 2019, NIH posted a reminder that the extramural community must "report foreign activities...."⁴ Then things got more personal. NIH sent 180 letters to organizations about their researchers' relationships with foreign governments, "and we have only seen a handful in the news," said Julie Hamilton, a managing director at Deloitte Advisory. "So there are definitely more to come."

NIH's warnings led Moffitt Cancer Center in Florida to review employees' collaborations with research institutions in China, and in December 2019, Moffitt announced the resignation of its then-CEO, Dr. Alan List, and then-center director, Thomas Sellers, "for violations of conflict of interest rules through their work in China," according to its website.⁵ "Moffitt found several compliance violations that also prompted separation of four additional researchers." Preliminary findings of its review, which focused on employees' participation in China's Thousand Talents Program, have been shared with the federal government, Moffitt said, adding, "There is no indication Moffitt research was compromised or patient care affected."

Institutions with NIH grants "need to be taking any NIH communications, including their letter, very seriously," said Denise Hall-Gaulin, a principal with PYA. Research compliance has become increasingly risky, and it "takes a lot more legwork to ensure compliance with all regulatory requirements. This is such a new increase in focus by the government, trying to get your arms around how to put best practice controls in place is not very well established."

Policies, Education May Need a Refresher

There are several moves for compliance officers to make to help protect their organizations in this area. They should check their policies to ensure "they are current with guidance about the meaning of the three reporting duties," Bonham said. For example, NIH clarified its definition of "other support" in July 2019,⁶ and the Joint Committee on the Research Environment (JCORE) "is expected to come out with recommendations for federal science funders" soon.

They also may want to look at their disclosure forms. "Compliance officers need to review the annual conflict of interest survey to ensure there's an explicit question that asks if there's foreign support," said Kaitlin McCarthy, a senior manager at Deloitte Advisory.

Everyone should be queried, including executives, Hamilton added. "Researchers have always had expectations they report 'other support,' but I think NIH is saying they have to be more explicit in what they are looking for from the academic community," she noted.

When there's a question about the information provided by investigators, Bonham recommends taking extra steps to validate it. "If a faculty member says, 'I don't have an affiliation with Institution X,' but the publication history indicates they do, that should give us reason to question it." Institutions may also want to have a preapproval process for researchers and other employees who travel internationally for work, Hamilton added.

At Tampa General Hospital, which has a separate research compliance office, investigators are asked about their financial interests when they submit a new protocol and on annual renewal, Smith said. "From a research perspective, we ask whether they have an interest in the sponsor of research," she explained. The institutional review board asks the same question. She tracks the answers on a spreadsheet so she can verify them against the CMS Open Payments database, but obviously that stops at the border. "We have to do surveillance in different ways because the traditional ways to respond are not sufficient," Smith said.

CMS Transmittals and Federal Register Regulations, Feb. 21-27

Transmittals

Pub. 100-04, Medicare Claims Processing Manual

- Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code (CARC), Medicare Remit Easy Print (MREP) and PC Print Update, Trans. 4536 (Feb. 21, 2020)
- Quarterly Update for the Temporary Gap Period of the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP) - April 2020, Trans. 4532 (Feb. 21, 2020)
- July 2020 Healthcare Common Procedure Coding System (HCPCS) Quarterly Update Reminder, Trans. 4534 (Feb. 21, 2020)
- Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - April 2020 Update, Trans. 4540 (Feb. 27, 2020)

Pub. 100-20, One-Time Notification

- International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs) - July 2020 Update, Trans. 2439 (Feb. 21, 2020)
- Implementation of Additional Requirement to add Healthcare Common Procedure Coding System (HCPC) and Current Procedural Terminology (CPT) - HCPC/CPT as Paired Items of Service for Prior Authorization and Medicare Claims Processing for Part A, Part B, DME, and Home Health and Hospice, Trans. 2438 (Feb. 21, 2020)

Federal Register

Proposed Regulations

- Medicare Program: Comprehensive Care for Joint Replacement Model Three-Year Extension and Changes to Episode Definition and Pricing, 85 Fed. Reg. 10516 (Feb. 24, 2020)

Even if the question is on your disclosure form, it's a good time to review the reporting and management process, Hamilton and McCarthy said. It needs to be robust, with input from researchers and scientists. Whether a certain kind of foreign support creates a conflict can be complicated and requires careful analysis, they said.

If conflict of interest programs are not monitoring potential research faculty conflicts, there could be gaps in reporting, said Kristen Lilly-Davidson, with PYA. She also thinks compliance officers should be included in critical strategic decisions that impact the compliance of research programs. "It's important for research leadership to understand potential compliance risks that may be wrapped around the research initiatives, whether it's grant funding, export controls or strategic partnerships," she said.

Compliance officers also should get the word out about reporting foreign affiliations and support.

Education is a centerpiece because "you are always dependent on investigators to disclose," said Tracy Popp, senior director of clinical research at Tampa General Hospital. The message would be: "Conflicts are not necessarily bad. They can be managed. But if you are going to commit time to [another] institution, it better be OK with the institution that employs you. And

if you are going to be paid for research by a foreign country, it better be OK with NIH," Smith said. She will also caution investigators and physicians that they may be targeted by foreign governments.

Contact Bonham at valerie.bonham@ropesgray.com, Hamilton at julhamilton@deloitte.com, Popp at tpopp@tgh.org, Smith at lynnsmith@tgh.org, Hall-Gaulin at dgaulin@pyapc.com, Lilly-Davidson at klilly-davidson@pyapc.com and McCarthy at kaimccarthy@deloitte.com. ♦

Endnotes

1. Department of Justice, "Harvard University Professor and Two Chinese Nationals Charged in Three Separate China Related Cases," news release, January 28, 2020, <http://bit.ly/2T24yJ0>.
2. "NIH Grants Policy Statement," NIH, last updated December 5, 2019, <http://bit.ly/32zKalq>.
3. Francis Collins, letter, August 20, 2018, <http://bit.ly/396YQLo>.
4. NIH, "Reminders of NIH Policies on Other Support and on Policies related to Financial Conflicts of Interest and Foreign Components," Notice Number: NOT-OD-19-114, July 10, 2019, <http://bit.ly/2I0ROvU>.
5. Moffitt Cancer Center, "Moffitt Cancer Center CEO, Center Director Resign after Compliance Review," news release, December 18, 2019, <http://bit.ly/2PtOfiQ>.
6. Michael Lauer, "Clarifying Long-Standing NIH Policies on Disclosing Other Support," *Open Mike* (blog), July 11, 2019, <http://bit.ly/2VozHYF>.

NEWS BRIEFS

◆ **Diversicare Healthcare Services Inc. has agreed to pay \$9.5 million to settle false claims allegations over Medicare billing for therapy services at its skilled nursing facilities (SNFs) that weren't necessary, reasonable or skilled**, the Department of Justice (DOJ) and U.S. Attorney's Office for the Middle District of Tennessee said Feb. 28.¹ From Jan. 1, 2010, through Dec. 31, 2015, the government alleged Diversicare submitted claims for ultra-high levels of therapy despite evidence, for example, "the frequency and duration of physical or occupational therapy were not reasonable or necessary for the patient" and the intensity was inappropriate. Diversicare also allegedly "submitted forged, photocopied, or pre-signed physician signatures on pre-admission evaluation certifications required in the submission of claims to TennCare for nursing facility services." Diversicare didn't admit liability in the settlement.

◆ **CMS has posted a new edition of its Medicare quarterly provider compliance newsletter.**² Two billing errors are addressed: lumbar sacral orthosis and Herceptin—multidose vial wastage, dose vs. units billed.

◆ **California urologist Mark Wilfred Tamarin was sentenced to 71 months for billing Medicare for \$700,000 worth of medically unnecessary and nonexistent treatments**, "sometimes billing for purported patient visits miles apart and occurring at the exact same time," the U.S. Attorney's Office for the Central District of California said Feb. 24.³ He was found guilty of wire fraud and attempted health care fraud in July. From 2009 to January 2013, Tamarin, a partner in

Advanced Urology Medical Offices, "ordered two to three times the number of post-void residual (PVR) tests and renal ultrasounds for urology patients in comparison to his three medical partners," the U.S. attorney's office said. "Tamarin ordered these tests before speaking with or seeing a patient despite the fact that the tests themselves only were appropriate in limited medical circumstances." He also treated patients at Kindred Hospital, a sub-acute medical center in Ladera Heights, for patients with serious medical problems. He billed for patients visits that never happened.

◆ **Clarification:** Mercy Medical Center in Canton, Ohio, is the correct name of the hospital mentioned in the Feb. 24 story⁴ in RMC on HIPAA transaction sets. RMC mistakenly added "Humana" to the name of the hospital.

Endnotes

1. Department of Justice, "Diversicare Health Services Inc. Agrees to Pay \$9.5 Million to Resolve False Claims Act Allegations Relating to the Provision of Medically Unnecessary Rehabilitation Therapy Services," news release, February 28, 2020, <http://bit.ly/2Pudsg8>.
2. CMS, "Guidance to Address Billing Errors," *Medicare Quarterly Provider Compliance Newsletter* 10, no. 2 (January 2020), <https://go.cms.gov/3909X8Z>.
3. Department of Justice, U.S. Attorney's Office for the Central District of California, "Urologist Sentenced to Nearly Six Years in Prison for Fraudulent Billings of Nonexistent Patient Visits and Unnecessary Tests," news release, February 24, 2020, <http://bit.ly/2uthP3M>.
4. Nina Youngstrom, "HIPAA Transaction Sets May Be a Route to Reduce Payer Downcoding, Unbundling," *Report on Medicare Compliance* 29, no. 7 (February 24, 2020), <http://bit.ly/2Pxt4y4>.