Report on
# Medicare Compliance

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

Contents



## Fake Nurse Diplomas Lead Organizations to Check Licensure; New Process May Be Needed

When Kim Danehower, corporate compliance officer at Baptist Memorial Health Care Corp. in Nashville, Tennessee, read about Operation Nightingale—a Department of Justice-HHS Office of Inspector General enforcement action that exposed the sale of 7,600 fake nursing diplomas and transcripts—her heart sank.[1] More than a third of the people who bought their degrees passed their licensing exams and were licensed as registered nurses (RNs) or licensed practical nurses (LPNs), with grave implications for patient safety and risk management at the facilities where they work. Danehower and other compliance professionals are facing both the urgency of determining whether any of the nurses with ill-gotten licenses are employed at their facilities and a forward-looking review of the way they vet RNs and LPNs.

"That is horrifying," she said. "We are trying to figure it out. It's a work in progress." So far, Danehower has received a bit of welcome news from Arkansas, one of the three states in which her health system operates: none of the nurses who bought fraudulent degrees have Arkansas licenses, according to the state nursing board. She's still awaiting word from the two other states, Tennessee and Mississippi. Whatever happens with these nurses, this mess is an alert "to shore up processes and work closely with human resources and employment services" to have a good understanding of how credentialing works and to audit and monitor it. "We have rallied the troops and made sure the C-Suite knows," Danehower said. But there's still the question of traveling nurses from staffing agencies. "We don't have complete control over validation," she noted.

*continued on p. 6*

## Self-Disclosure Leads to Settlement for Nine Alleged Violations; Genetic Testing Is Theme

In a grab-bag settlement with the HHS Office of Inspector General (OIG), Paradigm Diagnostics Inc. in Arizona agreed to pay $3.43 million to settle allegations that it overbilled Medicare for genetic testing, waived patient copays and paid various kickbacks to physicians and a clinical decision support software manufacturer for patient referrals. The settlement stemmed from Paradigm's self-disclosure to OIG.

It's unusual to see so many seemingly unrelated items in the same settlement, attorneys said. It makes sense, however, for organizations to put all known compliance concerns in a self-disclosure where possible, said attorney Asher Funk, with Goodwin in Washington, D.C. "You don't want to disclose only one issue when a bunch of other concerns are hanging out there," Funk said. It's much better "to put everything on the table in an effort to reach a global resolution." Then again, the government usually takes the position that paying kickbacks leads to overutilization, so allegations may be linked, he said. "One of the most tried and true theories the government pursues is the interplay between improper remuneration and allegedly medically unnecessary care," Funk said, although it's unclear what happened here. Three attorneys for Paradigm didn't respond to *RMC*'s request for comment.

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"This is a little bit novel to me," said attorney Bob Wade, with Nelson Mullins in Nashville, Tennessee. It's partly a successful compliance story because Paradigm identified and reported problems, but he questions why there were so many compliance issues to resolve.

The settlement, which was obtained through the Freedom of Information Act, is broken down into two parts. The first part addresses allegations that Paradigm submitted claims to Medicare for items or services it knew were false or fraudulent, which subjects them to civil money penalties. Specifically, the company allegedly submitted false Medicare claims:

- That included consult and surgical pathology services that weren't performed from October 2018 through April 2020.
- For genetic testing using "stacked" codes from June 2016 through Nov. 20, 2019. Funk said that while it's unclear, the codes were probably duplicative (i.e., reimbursed individually and again as part of a panel). "Coding for genetic testing is very complex," he noted. "There are hundreds of CPT codes."
- For breast cancer testing that wasn't provided as claimed because Paradigm billed for the testing under the code for full gene sequencing from June 2016 through December 2017 when it was only doing partial gene sequencing.
- For genetic testing within 14 days after an inpatient or outpatient hospital discharge from May 31, 2016, through April 2020. Medicare payments for lab tests are folded into the MS-DRG and APC if specimens are tested within 14 days of discharge. "It's part of a composite payment because testing happened so close to the episode of care," Funk noted. However, labs are permitted to keep specimens longer and run tests at a later date.

In the second part of the settlement, OIG alleged that Paradigm "offered or paid remuneration to certain individuals and entities, and solicited or received remuneration from certain individuals and entities." OIG specifically alleged Paradigm:

- Waived copayments that beneficiaries should have paid between May 31, 2016, and April 2020.
- Paid or agreed to pay remuneration to a clinical decision support software manufacturer for referrals to Paradigm ($150 per genetic test) from January 2018 to January 2020.
- Paid remuneration to 17 physicians in the form of meals and refreshments between May 31, 2016, and June 2020.
- Paid remuneration to physicians in the form of compensation (e.g., registry payments) to 17 physicians and physician-affiliated entities between May 31, 2016, and March 2020.

Also, a pharmaceutical manufacturer offered to pay Paradigm $15,000 for every referral of a person for a clinical trial from January 2017 through December 2018.

This set of allegations, which OIG called the anti-kickback conduct and physician self-referral conduct, subjects the company to civil monetary penalties. Paradigm was accepted into OIG's Self-Disclosure Protocol (SDP) in January 2022.[1] It didn't admit liability in the settlement.

## No Beating Around the Bush With the AKS

Whatever happened, Wade noted how important self-disclosure is once overpayments are identified. "If you don't self-report, it is considered to be a reverse false claim," he said. "Individuals involved in those issues are considered" accountable for reverse false claims. Also, a "high number of compliance issues points to the need to conduct compliance effectiveness reviews periodically," Wade said.

When multiple compliance issues are identified, counsel for a provider may package them in a single self-disclosure, Funk said. If it's necessary to self-

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disclose an actual or potential Anti-Kickback Statute (AKS) violation to the SDP—OIG won't accept Stark Law self-disclosures unless the AKS has been implicated as well—providers should prepare to acknowledge fault. "You have to admit there might be a colorable violation to be accepted into the Self-Disclosure Protocol," Funk said. "You can't scoff and say, 'We did everything right.'"

For example, Funk helped a rural hospital with a self-disclosure after it came to light that a physician wasn't charged rent for office space on a strip of land he sold the hospital. The deal had nothing to do with referrals and the physician eventually paid rent, but an acquisition set in motion the self-disclosure, Funk said. A large health system decided to buy the hospital and during the transaction it discovered the free rent and insisted on a self-disclosure before closing the deal. Because of OIG's updated SDP language, which states that "OIG will not accept any disclosing party into the SDP that fails to acknowledge clearly that the disclosed arrangement constitutes a potential violation of the AKS and, if applicable, the Stark law," Funk said that "you can't come to OIG and be defiant." That's why the hospital's submission had to acknowledge the free rent to a referral source could be an inducement for referrals, although "that was not the hospital's intent."

### Genetic Testing 'Is a Huge Risk Area'

Genetic testing, also a significant part of the settlement, "is a huge risk area," Funk said.

"Compliance is not easy from a billing perspective," Funk said. Medicare doesn't cover genetic tests that are predictive or screening tests unless they were specifically authorized by statute, he said. Only diagnostic tests for certain conditions are covered. Some are addressed in a national coverage determination (90.2), which applies to next generation sequencing, as well as "a patchwork" of local coverage determinations (LCDs), "which are all a bit different," Funk said.[2] "There are many sources of guidance," and keep in mind that Medicare only covers a narrow set of tests and there are requirements for each type of test that depend on your Medicare administrative contractor. On top of that, there are hundreds of codes for genetic testing, adding to the compliance minefield.

The risk may also be reflected in the growth of Medicare Part B payments for genetic tests, which quadrupled between 2016 and 2019, according to a December 2021 Data Brief from OIG.[3] The number of genetic tests paid for by Medicare rose by 230%.

"It's an area of growth because we are seeing increasingly useful technologies to help with cancer and other conditions," Funk said. "But you are also seeing certain abuses and a lot of it is being facilitated by labs paying recruiters who are getting patients in the door because they provide remuneration to doctors who order potentially unnecessary testing. Those prototypical schemes are driving utilization, a lot of which is being facilitated by telehealth."

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**Endnotes**

1. U.S. Department of Health & Human Services, Office of Inspector General, *OIG's Health Care Fraud Self-Disclosure Protocol*, updated November 8, 2021, https://bit.ly/3HgLUEf.
2. Centers for Medicare & Medicaid Services, "Next Generation Sequencing (NGS)," National Coverage Determination, last accessed February 9, 2022, https://go.cms.gov/3DWrYGH.
3. U.S. Department of Health & Human Services, Office of Inspector General, *HHS OIG Data Brief: Trends in Genetic Tests Provided Under Medicare Part B Indicate Areas of Possible Concern*, A-09-20-03027, December 2021, https://bit.ly/3lkZ8JL.

## FCA Recoveries Drop; Lawyers See Other Data as More Significant

Settlements and recoveries from the False Claims Act (FCA) yielded $2.2 billion in the fiscal year ending Sept. 30, the Department of Justice (DOJ) said Feb. 7.[1] Health care cases made up the lion's share of the recoveries—$1.7 billion, with about half of the dollars coming from a whistleblower-driven FCA settlement with the pharmaceutical manufacturer Biogen.[2] Although $2.2 billion is a significant drop from the $5.6 billion recovered the previous year, attorneys say false claims enforcement is going strong, and there's more telling information in the data than the total dollar amount. DOJ also noted the number of settlements and judgments (351) is the second highest ever.

What was striking is the 40% increase in the number of matters that DOJ initiated on its own instead of taking the ball from whistleblowers—296 last year, up from 212 in 2021, said Matthew Krueger, former U.S. Attorney for the Eastern District of Wisconsin. "That's really remarkable," said Krueger, with Foley & Lardner LLP in Milwaukee, Wisconsin. The 40% increase is across all industries (see box for health care-specific FCA data, p. 5). It probably means DOJ is pursuing more cases based on data analytics, tips from law enforcement partners and COVID-19 relief fund (e.g., Provider Relief Fund, Paycheck Protection Program) audits or investigations that don't originate with whistleblowers, Krueger said.

"There is still a high number of qui tams being filed and they remain the bread and butter of DOJ's False Claims Act docket," he noted. "DOJ's public statements

signal that it still welcomes qui tams, but the data show that DOJ is also finding more cases on its own."

Attorney Jeb White, president of Taxpayers Against Fraud in Washington, D.C., said "some people are attacking DOJ" because of the drop in FCA recoveries, but they're always skewed by large-dollar cases and timing. In FY 2021, for example, a large chunk of DOJ's health care FCA recoveries came from a $2.8 billion settlement with Purdue Pharma in connection with opioid prescriptions that allegedly were medically unnecessary and tainted by kickbacks.[3] "A case could settle next week and change the narrative" of the reduction in FCA recoveries, White said.

He noted the FCA is working as intended when the law was put in place during the Civil War. It's designed to supplement the government's enforcement by incentivizing private plaintiffs to go after fraud.

### Payouts in Intervened Cases Drop

There was also an increase in the number of whistleblower cases in which DOJ declined to intervene. White sees that as a maturation of the qui tam relator's bar and the ability of whistleblowers to move forward without the government against the backdrop of DOJ's limited resources. Qui tam attorneys would prefer to have DOJ intervention, especially because "it has an effect on the jury," but they are prevailing in cases without it, he said. Biogen, which settled FCA allegations it paid kickbacks to physicians to induce them to prescribe Biogen drugs in the form of speaker honoraria, speaker training fees or consultant programs, is a prime example. It led to the largest whistleblower award ever.

"The fact the government is initiating more cases will bear fruit later," White noted. FCA lawsuits take five or 10 years to resolve. "The thing that concerns me is that the dollar amount in intervened cases was at an 18-year low," he said—$776.7 million in 2022 versus $561.7 million in 2004.

Here are a few of the 2022 health care cases DOJ highlighted:

- SHC Home Health Services of Florida LLC and related entities (collectively Signature HomeNow) paid $2.1 million to settle false claims allegations over home health services provided in Florida. The case arose from a tip to the HHS Office of Inspector General's hotline and a whistleblower complaint. The qui tam complaint alleged Signature billed Medicare for beneficiaries who weren't homebound, didn't need skilled care, didn't have valid or appropriate plans of care and/or didn't have proper face-to-face encounters with patients, according to the U.S. Attorney's Office for the Western District of Kentucky.[4]
- Providence Health & Services in Washington agreed to pay $22.69 million to settle false claims allegations, the U.S. Attorney's Office for the Eastern District of Washington and the state attorney general said. The settlement focused on alleged false claims submitted to Medicare, Medicaid and other federal health care programs for neurosurgery performed by two neurosurgeons at Providence St. Mary Medical Center (SMMC) in Walla Walla. Employees had raised concerns that the surgeons "endangered the safety of SMMC patients" and didn't adequately or correctly document certain procedures, diagnoses and complications. Both surgeons were allowed to resign.[5]
- Flower Mound Hospital, a partly physician-owned hospital in Texas, agreed to pay $18.2 million to settle false claims allegations. DOJ alleged that when the hospital—doing business as Texas Health Presbyterian Hospital Flower Mound—repurchased the shares of physician owners who were 63 years old or older, it sold the shares to other physicians in a way that fueled false claims allegations. The hospital allegedly took referrals into account when choosing new physician buyers and deciding how many shares they would get in violation of the Anti-Kickback Statute.[6]

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**Endnotes**

1. U.S. Department of Justice, Office of Public Affairs, "False Claims Act Settlements and Judgments Exceed $2 Billion in Fiscal Year 2022," news release, February 7, 2023, https://bit.ly/3DRAreg.
2. U.S. Department of Justice, Office of Public Affairs, "Biogen Inc. Agrees to Pay $900 Million to Settle Allegations Related to Improper Physician Payments," news release, September 26, 2022, https://bit.ly/3CrVjZ3.
3. U.S. Department of Justice, Office of Public Affairs, "Justice Department Announces Global Resolution of Criminal and Civil Investigations with Opioid Manufacturer Purdue Pharma and Civil Settlement with Members of the Sackler Family," news release, October 21, 2020, http://bit.ly/37uLgno.
4. U.S. Department of Justice, U.S. Attorney's Office for the Western District of Kentucky, "Home Health Company Operating in Florida Pays $2.1 Million to Resolve False Claims Allegations," news release, May 5, 2022, http://bit.ly/3Ig1hzy.
5. Nina Youngstrom, "Providence Settles FCA Allegations of Unnecessary Neurosurgery," *Report on Medicare Compliance* 31, no. 15 (April 25, 2022), http://bit.ly/3Xg4bbv.
6. Nina Youngstrom, "'Uptick' Is Seen in Joint Venture FCA Cases; CIAs Offer Checklist," *Report on Medicare Compliance* 31, no. 17 (May 9, 2022), http://bit.ly/3lr9GHl.

## False Claims Act Recoveries, Broken Down by Year and Number of Whistleblower-Initiated Cases

The Department of Justice on Feb. 7 announced more than $2.2 billion in False Claims Act settlements and judgments in the fiscal year ending Sept. 30, 2022 (see story, p. 3).[1]

### Fraud Statistics - Health and Human Services[2]
Oct. 1, 1986 - Sept. 30, 2022
Civil Division, U.S. Department of Justice

| FY | NEW MATTERS[3] | | SETTLEMENTS AND JUDGMENTS[4] | | | | | RELATOR SHARE AWARDS[5] | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | NON[6] QUI TAM | QUI TAM | | | | | | |
| | NON QUI TAM | QUI TAM | TOTAL | WHERE U.S. INTERVENED OR OTHERWISE PURSUED | WHERE U.S. DECLINED | TOTAL | TOTAL QUI TAM AND NON QUI TAM | WHERE U.S. INTERVENED OR OTHERWISE PURSUED | WHERE U.S. DECLINED | TOTAL |
| 1987 | 12 | 3 | 11,361,826 | 0 | 0 | 0 | 11,361,826 | 0 | 0 | 0 |
| 1988 | 5 | 7 | 2,182,675 | 355,000 | 0 | 355,000 | 2,537,675 | 88,750 | 0 | 88,750 |
| 1989 | 19 | 16 | 350,460 | 5,099,661 | 0 | 5,099,661 | 5,450,121 | 50,000 | 0 | 50,000 |
| 1990 | 27 | 11 | 10,327,500 | 903,158 | 0 | 903,158 | 11,230,658 | 119,474 | 0 | 119,474 |
| 1991 | 19 | 12 | 8,670,735 | 5,420,000 | 0 | 5,420,000 | 14,090,735 | 861,401 | 0 | 861,401 |
| 1992 | 26 | 15 | 9,821,640 | 2,192,478 | 0 | 2,192,478 | 12,014,118 | 446,648 | 0 | 446,648 |
| 1993 | 22 | 38 | 12,523,165 | 151,760,404 | 0 | 151,760,404 | 164,283,569 | 22,946,101 | 0 | 22,946,101 |
| 1994 | 42 | 75 | 381,470,015 | 6,280,815 | 240,000 | 6,520,815 | 387,990,830 | 1,113,597 | 72,000 | 1,185,597 |
| 1995 | 26 | 87 | 96,290,779 | 84,061,789 | 1,620,000 | 85,681,789 | 181,972,568 | 14,337,982 | 465,800 | 14,803,782 |
| 1996 | 20 | 177 | 63,059,873 | 49,236,698 | 2,340,000 | 51,576,698 | 114,636,572 | 8,707,168 | 667,400 | 9,374,568 |
| 1997 | 48 | 269 | 351,440,027 | 578,987,081 | 92,500 | 579,079,581 | 930,519,608 | 58,852,605 | 20,250 | 58,872,855 |
| 1998 | 35 | 276 | 40,107,920 | 251,824,167 | 2,526,075 | 254,350,242 | 294,458,162 | 46,863,357 | 187,015 | 47,050,372 |
| 1999 | 28 | 315 | 88,000,792 | 396,402,128 | 1,366,699 | 397,768,827 | 485,769,619 | 45,174,556 | 317,829 | 45,492,385 |
| 2000 | 35 | 212 | 208,899,015 | 723,152,746 | 333,457 | 723,486,203 | 932,385,218 | 115,397,403 | 87,343 | 115,484,746 |
| 2001 | 34 | 181 | 435,849,179 | 931,262,922 | 14,991,554 | 946,254,475 | 1,382,103,654 | 143,904,700 | 3,735,500 | 147,640,200 |
| 2002 | 22 | 194 | 74,454,427 | 937,841,186 | 23,407,571 | 961,248,757 | 1,035,703,184 | 150,280,717 | 4,008,686 | 154,289,403 |
| 2003 | 27 | 215 | 541,929,810 | 1,304,920,314 | 2,880,785 | 1,307,801,099 | 1,849,730,909 | 284,074,368 | 722,233 | 284,796,601 |
| 2004 | 28 | 273 | 34,816,447 | 470,335,081 | 5,775,062 | 476,110,142 | 510,926,589 | 95,920,149 | 1,625,129 | 97,545,278 |
| 2005 | 35 | 270 | 204,821,548 | 906,656,836 | 6,671,593 | 913,328,429 | 1,118,149,977 | 120,989,298 | 1,900,095 | 122,889,393 |
| 2006 | 19 | 216 | 1,050,520,714 | 1,227,114,221 | 16,229,540 | 1,243,343,761 | 2,293,864,475 | 163,167,984 | 3,921,996 | 167,089,981 |
| 2007 | 30 | 199 | 465,052,993 | 929,615,846 | 152,456,640 | 1,082,072,486 | 1,547,125,480 | 157,860,623 | 2,497,177 | 160,357,799 |
| 2008 | 64 | 231 | 162,972,022 | 1,005,797,375 | 6,852,571 | 1,012,649,946 | 1,175,621,969 | 192,433,605 | 1,522,164 | 193,955,770 |
| 2009 | 36 | 279 | 240,061,424 | 1,368,411,522 | 30,283,452 | 1,398,694,974 | 1,638,756,398 | 155,440,550 | 8,669,822 | 164,110,372 |
| 2010 | 42 | 385 | 549,097,732 | 1,955,805,336 | 16,366,232 | 1,972,171,568 | 2,521,269,301 | 335,084,132 | 4,639,804 | 339,723,936 |
| 2011 | 42 | 417 | 178,287,545 | 2,183,142,674 | 88,291,393 | 2,271,434,067 | 2,449,721,612 | 446,890,505 | 24,055,563 | 470,946,068 |
| 2012 | 31 | 417 | 561,373,967 | 2,580,255,899 | 37,838,668 | 2,618,094,567 | 3,179,468,534 | 296,518,575 | 10,598,793 | 307,117,368 |
| 2013 | 30 | 504 | 61,354,329 | 2,573,568,951 | 122,854,972 | 2,696,423,924 | 2,757,778,253 | 474,900,353 | 29,569,605 | 504,469,958 |
| 2014 | 34 | 471 | 89,054,490 | 2,282,799,137 | 75,322,326 | 2,358,121,462 | 2,447,175,952 | 385,057,130 | 13,397,186 | 398,454,316 |
| 2015 | 27 | 426 | 160,758,915 | 1,492,103,005 | 477,123,065 | 1,969,226,070 | 2,129,984,985 | 272,916,832 | 133,278,440 | 406,195,271 |
| 2016 | 96 | 504 | 97,354,415 | 2,552,466,698 | 75,145,688 | 2,627,612,387 | 2,724,966,802 | 464,489,816 | 20,481,847 | 484,971,663 |
| 2017 | 71 | 495 | 32,627,357 | 1,668,286,326 | 446,222,506 | 2,114,508,832 | 2,147,136,189 | 301,070,938 | 123,637,553 | 424,708,490 |
| 2018 | 61 | 448 | 568,069,015 | 1,871,758,567 | 172,958,622 | 2,044,717,189 | 2,612,786,204 | 286,640,878 | 27,091,647 | 313,732,524 |
| 2019 | 59 | 449 | 700,838,735 | 1,623,696,829 | 284,329,091 | 1,908,025,920 | 2,608,864,654 | 231,928,954 | 69,026,440 | 300,955,394 |
| 2020 | 122 | 459 | 402,745,794 | 1,295,390,759 | 180,079,049 | 1,475,469,808 | 1,878,215,602 | 230,136,355 | 48,094,625 | 278,230,979 |
| 2021 | 102 | 389 | 3,591,166,587 | 1,074,269,163 | 454,044,509 | 1,528,313,672 | 5,119,480,259 | 168,559,467 | 54,937,327 | 223,496,794 |
| 2022 | 93 | 371 | 106,369,498 | 641,697,050 | 1,013,116,617 | 1,654,813,666 | 1,761,183,164 | 115,525,911 | 296,535,477 | 412,061,388 |
| **TOTAL** | **1,469** | **9,306** | **11,594,083,366** | **35,132,871,824** | **3,711,760,235** | **38,844,632,059** | **50,438,715,425** | **5,788,750,879** | **885,764,744** | **6,674,515,623** |

### Endnotes

1. U.S. Department of Justice, Office of Public Affairs, "False Claims Act Settlements and Judgments Exceed $2 Billion in Fiscal Year 2022," news release, February 7, 2023, http://bit.ly/3DRAreg.
2. The information reported in this table covers matters in which the Department of Health and Human Services is the primary client agency.
3. New Matters refers to newly received referrals, investigations and qui tam actions.
4. Settlements and judgments include common law recoveries arising out of our False Claims Act investigations.
5. Relator share awards are calculated on the portion of the settlement or judgment attributable to the relators' claims, which may be less than the total settlement or judgment. Relator share awards do not include amounts recovered in subsection (h) or other personal claims. See 31 U. S. C. 3730(h).
6. Historically, non qui tam settlements and judgments did not include matters separately handled by the United States Attorneys' Offices, as the Civil Division did not maintain that data. However, beginning Oct. 1, 2019, non qui tam settlements and judgments include settlements and judgments occurring on or after Oct. 1, 2019, in matters separately handled by the United States Attorneys' Offices when those settlements and judgments have been reported to the Civil Division.

## Sample Checklist for Compliance Policy Management

This tool appears in the Complete Compliance and Ethics Manual 2023.[1]

### Sample Compliance Policy Management Checklist

| Topic | Task | Function Responsible | Next Steps | Completion Date |
|---|---|---|---|---|
| **Policy approval process** | Create "policy on policies" that defines approval process for policies, including any intermediary approval requirements and who has final approval authority | | | |
| | Outline policy approval process steps and approval "gates," including approval by policy owner, Legal, and final approver (e.g., senior management and/or compliance governance committee) | | | |
| | Communicate policy approval policy and process to relevant stakeholders | | | |
| **Policy drafting** | Create standard policy format | | | |
| | Identify risk(s) for which a policy is needed (i.e., which risk will this policy help mitigate?) | | | |
| | Determine scope of persons affected by the risk (e.g., size of audience, geographical locations, job functions, departments) to determine policy audience | | | |
| | Identify relevant subject matter expert(s) to assist in drafting of new policy | | | |
| | Create initial draft of policy using standard policy format and identified policy audience | | | |
| | Assign policy owner (may be the subject matter expert) | | | |
| | Circulate initial draft for comment from relevant stakeholders | | | |
| | Create final policy draft and submit through policy approval process | | | |
| | Following approval, determine whether translations will be needed and if so, obtain them | | | |
| **Policy implementation** | Determine appropriate communication method based on urgency and audience, including consideration of any translations needed for communication pieces | | | |
| | Create communication plan with rollout dates and effectiveness measures | | | |
| | Draft communication pieces and submit for approval through corporate communications approval process | | | |
| | Once approved, obtain any needed translations | | | |
| | Launch policy communication campaign and assess effectiveness | | | |
| | Ensure new policy is posted to policy library and easily accessible to all affected persons | | | |
| **Policy maintenance** | Create versioning protocol to track revision dates and versions of policies | | | |
| | Assign an owner for each policy | | | |
| | Choose a review cadence for review of each policy based on comparative risk | | | |
| **Policy review** | Review policies based on a set review cadence for each (e.g., annually) | | | |
| | Ensure subject matter expert/policy owner conducts content review for each policy to ensure adequate risk mitigation | | | |
| | Conduct legal review for each policy to ensure policy language is adequate and current | | | |
| | Document all revisions, including reasoning/basis for each change | | | |
| | Implement versioning protocol to track and communicate current version and replace/archive outdated versions | | | |

### Endnotes

1. Society of Corporate Compliance & Ethics, "Sample Compliance Policy Management Checklist," *Complete Compliance and Ethics Manual 2023* (Eden Prairie: Society of Corporate Compliance & Ethics, 2023), http://bit.ly/3YGqGHE.

## Fake Nurse Documents May Spur Change

*continued from page 1*

According to the U.S. Attorney's Office for the Southern District of Florida, 25 people have been charged with wire fraud in connection with an alleged scheme to sell fraudulent nursing degrees and transcripts from three accredited Florida-based nursing schools to people in search of nursing licenses and jobs as RNs and LPNs/licensed vocational nurses (LVNs). More than 7,600 RN and LPN/LVN phony diplomas were issued by the now-defunct nursing schools: Siena College, the Palm Beach School of Nursing and Sacred Heart International Institute. Thirty-seven percent of the nursing-school graduates—2,812—passed their state licensing exams and were licensed.

It's hard to wrap your head around the scope of the scheme, said Christa Bernacchia, senior manager and director of credentialing services for BerryDunn. "It's

something you can't script, almost like Hollywood. Things like this unfortunately happen, but on a much smaller scale," she said. "At the end of the day, I hope this doesn't mar the great work that 99% of nurses are doing."

The challenge for health care organizations is that nurses generally don't face the same degree of scrutiny as clinicians like physicians and advanced practice providers (APPs), Bernacchia said. "This will be a game-changer for everyone," she said. "Medical staff professionals need to have an eye on this, along with folks from compliance, risk management and legal."

Magnifying the fraudulent licensure situation is the fact that 39 states participate in the nursing licensure compact, said Robyn Hoffmann, senior manager of compliance and credentialing at BerryDunn, who is an RN. It makes it easier for nurses who are licensed in one state to get their license in another. "The intent of the compact is to increase the number of nurses who can serve across states," Hoffmann explained. Nurses with licenses based on counterfeit education may be licensed in more than one state because of the compact, she noted. The compact was mentioned in the indictments of the people allegedly involved in the scam.

### 'There Is So Much to Learn'

"There are a lot of legal and law enforcement actions that are going to happen as Operation Nightingale unfolds, but a serious risk management and quality improvement type of analysis needs to take place," she said. "There is so much to learn to make sure something like this doesn't happen again."

Consider the implications for the different levels of screening. Nurses are the "hubs of the organization that make everything go," but screening isn't as thorough as with physicians and APPs, such as nurse practitioners and physician assistants, Hoffmann said.

Physicians and APPs are subject to primary source verification, Bernacchia said. For example, when a nurse midwife applies for privileges, someone on the medical staff or at an outside credentialing firm verifies every piece of information from a primary source "and makes sure you are who you say you are," she explained. "We pull all your credentials, confirm education, training and license, and check license sanction and liability history." That information is reviewed internally within organizations, often going through multiple levels of review, based on organizational structure, policy and bylaws.

RNs and LPNs don't face that extent of vetting because they aren't members of the hospital medical staffs, and in an ambulatory or other health care setting, may be vetted less, Bernacchia said. Their license should be verified on a state database, their resumes should be reviewed for work history and education and their names should be run through the List of Excluded Individuals and Entities for possible exclusion from federal health care programs, she said.

There are extra hoops to jump through if medical professionals or nurses attended a program or school that later shut down, Bernacchia said. Usually there's contact information provided online for closed programs or schools, but that may not always be the case, and it leaves employers between a rock and a hard place. Depending on the organization, credentialing teams or human resources "have to think critically and be resourceful and look at alternate ways of verifying education," she noted.

### Other Safeguards From The Joint Commission

After health care workers are hired, the Joint Commission requires role-specific orientation, which is another safeguard, Hoffmann said. Ambulatory care settings, for example, should have a checklist to confirm nurses can safely execute and document critical functions, such as phlebotomy, nebulizer treatments, infusions and injections, and are capable of disinfecting health care equipment. "These skills should also be re-evaluated on an annual basis and documented in the nurse's training file," Hoffman noted.

## CMS Transmittals and *Federal Register* Regulations, February 3-February 9

### Transmittals

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

- April 2023 Quarterly Update to HCPCS Codes Used for Skilled Nursing Facility (SNF) Consolidated Billing (CB) Enforcement, Trans. 11,849 (Feb. 9, 2023)
- Internet-Only Manual (IOM) Updates to Pub. 100-04, Chapter 12 for the New Hospital Inpatient or Observation Care Code Family, Nursing Facility Visits Code Family, Billing the Substantive Portion of a Split (or Shared) Visit, Changes for Prolonged Services, and Updates to the IOM with Policies Finalized for Office/Outpatient E/M Visits in the CY2020 and CY2021 Final Rules, Trans. 11,842 (Feb. 9, 2023)
- Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - April 2023 Update, Trans. 11,848 (Feb. 9, 2023)
- Update to the Internet Only Manual (IOM) Publication (Pub.) 100-04, Chapter 18, Section 10.2.2.1, to Clarify the Payment Method on Vaccines for Critical Access Hospitals (CAHs), Trans. 11,843 (Feb. 9, 2023)

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

- New State Codes for North Carolina and other States, Trans. 11,838 (Feb. 6, 2023)

**Pub. 100-07, State Operations Provider Certification**

- Revisions to State Operations Manual (SOM), Appendix PP, Trans. 211 (Feb. 3, 2023)

**Pub. 100-08, Medicare Program Integrity**

- First Policy Change Request Regarding Implementation of the Provider Enrollment, Chain and Ownership System (PECOS) 2.0, Trans. 11,839 (Feb. 9, 2023)

In light of what Operation Nightingale uncovered, Hoffmann thinks organizations would benefit from using a quality improvement methodology like The Joint Commission's tracer to evaluate a nurse's performance all the way through an episode of care. The director of nursing or nurse manager would determine whether the nurse carried out a physician order or administered an injection, for example, "in a reasonable and prudent way and that they have the skills to safely render care," she explained. "The tracer technique could also be used after the fact within an organization to help it identify how a non-licensed individual was inadvertently hired."

There are other potential ripple effects of the dummied documents. Some RNs and LPNs with ill-gotten licenses may decide to move up the nursing ladder. "Having your license is the building block to be able to go back to nursing school and get a master's degree and advanced licensure," Bernacchia said.

### Indictments Sketch Out Sale of Degrees

People allegedly involved in the scheme were named variously in three indictments and two criminal informations. For example, Charles Etienne, the president of Sacred Heart International Institute, was charged with conspiracy to commit mail fraud and wire fraud. According to the criminal information, Etienne and his co-conspirators sold 588 fake diplomas and transcripts that indicated the buyers had finished the necessary coursework to get nursing degrees when that wasn't the case. They allegedly mailed the phony documents to the buyers and to state licensing agencies.

Another indictment names 14 people in connection with the Palm Beach School of Nursing, which said online that it offered an "Associate in Science" degree to prepare students for Florida Board of Nursing for Registered Nurse Education and meet eligibility for the RN licensing exam. The defendants—who include the director of nursing, the registrar and the director of finance—are accused of recruiting people through interstate wire communications who wanted RN or LPN credentials and distributing fraudulent diplomas and transcripts to them for licensure and employment. Palm Beach School of Nursing was terminated in 2017 by the Florida Board of Nursing, according to the indictment.

All people named in charging documents are innocent until proven guilty.

Although the indictments don't explain how the law enforcement agencies exposed the scam, Hoffmann said "there are 7,600 different stories and each one is worthy of a tracer." They raise questions about "safety in the work environment and robust credentialing processes." How did the person get hired? What kinds of documents did the health care organization require? Were the people with fraudulent licenses identified when their clinical skills were evaluated during new-hire orientation? Where are the breakdowns in the system? Some of the same questions should be asked about qualifying to sit for the state licensing exam, she said.

In a statement, the National Council of State Boards of Nursing said, "Nursing regulatory bodies in affected states have been investigating individual cases and are taking appropriate action, in accordance with their state laws and due process, that includes loss of license."[2]

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**Endnotes**

1. U.S. Department of Justice, U.S. Attorney's Office for the Southern District of Florida, "Fraudulent Nursing Diploma Scheme Leads to Federal Charges Against 25 Defendants," news release, January 25, 2023, http://bit.ly/3HMPqr1.
2. NCSBN, "The National Council of State Boards of Nursing (NCSBN) Statement on Operation Nightingale," January 26, 2023, https://bit.ly/40F5iEG.

## NEWS BRIEFS

◆ **Beyond Reps Inc. d/b/a IronRod Health and Cardiac Monitoring Services (IronRod) agreed to pay $673,200 to settle false claims allegations over remote cardiac monitoring services**, the U.S. Attorney's Office for the Western District of New York said Feb. 3.[1] IronRod, which is based in Phoenix, Arizona, allegedly used technicians who lacked required credentials to conduct remote cardiac monitoring readings between Jan. 1, 2018, and April 30, 2021. The U.S. attorney's office also alleged "IronRod misrepresented that it performed services in New York State in order to obtain higher reimbursements from Medicare for remote cardiac monitoring services" between June 1, 2018, and Aug. 20, 2018. The case was set in motion by a whistleblower.

◆ **CMS said Feb. 9 it incorrectly returned home health claims with telehealth services if providers didn't include an in-person visit with the same revenue code (reason code 31869), according to MLN Connects**.[2] CMS told providers to resubmit the claim if it was returned.

**Endnotes**

1. U.S. Department of Justice, U.S. Attorney's Office Western District of New York, "Cardiac Monitoring Company Settles Fraudulent Billing Allegations," news release, February 3, 2023, http://bit.ly/3HQqi2H.
2. Centers for Medicare & Medicaid Services, "What's the Comprehensive Error Rate Testing Program?" MLN Connects, February 9, 2023, http://bit.ly/3YYgLh9.