HCCA
hcca-info.org

Compliance TODAY

A PUBLICATION OF THE HEALTH CARE COMPLIANCE ASSOCIATION

JANUARY 2018

Compliance and behavioral health

an interview with
Marla Berkow

Contents

January 2018

FEATURES

Compliance Today is printed with 100% soy-based, water-soluable inks on recycled paper, which includes 10% post-consumer waste. The remaining fiber comes from responsibly managed forests. The energy used to produce the paper is Green-e® certified renewable energy. Certifications for the paper include Forest Stewardship Council (FSC), Sustainable Forestry Initiative (SFI), and Programme for the Endorsement of Forest Certification (PEFC).

COLUMNS

DEPARTMENTS

by Arthur J. Fried, Melissa L. Jampol, and Chelsea E. Ott

Enforcement and regulatory concerns for hospitals in 2018

» Hospitals must be prepared to respond to a changing regulatory and enforcement environment in 2018, especially with respect to electronic health records (EHR), billing and coding, and OPPS and IPPS.

» Hospitals need to ensure that they have effective processes in place for employees to make complaints as well as to ensure that the complaints are thoroughly investigated and resolved objectively and decisively.

» With a continued emphasis by regulators on improper billing, hospitals should implement effective controls and monitor and audit their billing and provider arrangements to prevent improper billing, particularly of federal healthcare programs.

» In the event hospitals discover potential overpayments, they should seriously evaluate the repayment and self-disclosure requirements of federal and state law.

» Hospitals are training providers on the technical infrastructure, effective use of the EHR, and regulatory incentives, but they must be wary that an EHR system itself can cause false claims, or lead to false claims, if not properly implemented.

Arthur J. Fried *(afried@ebglaw.com) is a Member of the firm in the Health Care and Life Sciences practice in the New York office of Epstein Becker & Green, PC.* ***Melissa L. Jampol*** *(mjampol@ebglaw.com) is a Member of the firm in the Health Care and Life Sciences and Litigation practices in the New York and Newark offices of Epstein Becker & Green, PC.* ***Chelsea E. Ott*** *(cott@ebglaw.com) is a Law Clerk – Admission Pending at Epstein Becker & Green, PC in the Health Care and Life Sciences practice in the New York office.*

/in/arthurjfried */in/jampol* *bit.ly/in-ChelseaOtt*

The beginning of 2017 brought a new administration to the White House, along with some new and some familiar faces to executive agencies responsible for regulation and oversight of the hospital sector. Indeed, many positions in these agencies are still vacant or have only recently been filled. 2017 can thus be best categorized as a transition year, focused on forthcoming proposals for the significant payment and regulatory reform on the horizon in 2018.

Continued emphasis on individual accountability

The Yates Memorandum,[1] which was issued in September 2015, notified the healthcare community that there would be an increased focus on individual wrongdoers by the U.S. Department of Justice (DOJ).

The Trump Administration has not wavered from this message. Deputy Attorney General Rod Rosenstein repeatedly has emphasized that DOJ will continue to investigate and prosecute those persons responsible for significant corporate misconduct. Acting Assistant Attorney General Kenneth A. Blanco recently noted that False Claims Act (FCA) settlements and DOJ "indictments should send a clear signal to hospitals and healthcare institutions around the country that they and their management will be held accountable."[2]

One example of the Yates Memorandum in action was the April 2017 settlement by Norman Regional Health System, which involved a former hospital administrator and six physicians. The defendants were alleged to have improperly billed Medicare for

Fried

Jampol

Ott

services performed by radiological practitioner assistants, which required, but did not have, personal physician supervision. The administrator and physicians were forced to pay a share of the $1.6 million settlement.[3] Those in the hospital sector need to be more cognizant than ever that there may be a divergence of interests between the corporate entity and its employees during the course of a government investigation.

Significant False Claims Act enforcement expected to expand in 2018

The False Claims Act (31 U.S.C. §§ 3729—3733) continues to be DOJ's favorite tool for recovery of federal healthcare dollars. The government recovered $360 million from hospitals and clinics in FY 2016.

Although still often reliant on tips from whistleblowers, prosecutors are now able to harness the power of data analytics to identify healthcare fraud cases. For instance, the Fraud Section within DOJ's Criminal Division has an on-staff data analyst who is concerned "[n]ot simply [with] finding bills for dead patients or identifying the providers with the highest billings, but using her expertise to find investigative leads, identify strategic trends and corroborate fraud tips."[4]

In addition to monetary settlements, many entities also are faced with burdensome corporate integrity agreements (CIAs). Thirteen hospitals entered into CIAs in 2016. Hospitals should preemptively review their policies for compliance with the so-called "non-negotiable" terms that Health and Human Services (HHS) Office of the Inspector General (OIG) inserts into CIAs.

Improper coding

Hospitals must be increasingly careful in their use of billing modifiers. Policies should be in place to ensure that healthcare professionals and billers properly code services, and internal audits should be routine to identify any red flags that require further investigation. Self-disclosure of potential wrongdoing can go a long way toward reducing the institution's exposure. Hospitals can look to various settlements during 2017 for examples of billing practices to avoid:

- In September 2017, a South Carolina hospital, AnMed Health, entered into a settlement with DOJ for $7 million to resolve claims that it improperly billed for physician services and evaluation and management (E/M) "up-coding." The hospital allegedly received inflated reimbursements for: (1) systematically "bill[ing] a minor care clinic as if it was an Emergency Department" and (2) "bill[ing] Emergency Department services as if they were provided by a physician" when they were performed by mid-level providers.[5]
- In June 2017, the University of Rochester (UR) settled a *qui tam* action involving the improper use of a billing modifier. The action settled for just over $100,000, but it is worth highlighting that UR's self-disclosure of the improper billing procedure to the government prior to the suit being unsealed resulted in a substantially reduced settlement amount.[6]

There are sure to be more cases brought in 2018 involving improper billing and coding. Indeed, OIG's current Work Plan focuses on the Two-Midnight Rule, which permits Medicare Part A payments for Medicare inpatient admissions when the admitting provider "expected the patient to require a hospital stay that crossed two midnights and the medical record supports that reasonable expectation."[7] The rules for converting an admission to outpatient status (Code 44) are also complex and easily misunderstood. OIG has significant recommendations for Centers for Medicare and Medicaid Services (CMS) in this area, aimed

at protecting patients from paying more than is necessary, while still providing the highest level of care.

Medicare Secondary Payer Act

In an area that seems ripe for enforcement in 2018, hospitals should also note potential FCA liability for claims under the Medicare Secondary Payer Act (MSP) [42 U.S.C. §§ 1395y(b)(2)(A)(i)-(iii)]. The MSP requires that if an individual has multiple sources of insurance, Medicare must be designated as the second payer (with limited exceptions). Medicare frequently withholds payment on claims related to accidents or injuries in order to determine if there is another primary insurer, such as Workers' Compensation, liability, or no-fault, such that Medicare should not be designated as the primary payer. Recent examples include:

- In January 2017, a court denied a hospital's motion to dismiss a FCA *qui tam* action that was brought by a former hospital patient account supervisor who alleged that the hospital systematically removed or omitted accident and injury information in order to be reimbursed for claims, for which Medicare otherwise would have withheld payment. This case has not yet been decided, but it is certainly one to watch.[8]
- In March 2016, a court found that allowing an insurer's policyholders to select a "health-first" option, without verifying whether a Medicare or Medicaid plan was implicated, and the subsequent improper submission of claims to the federal government, was a sufficient FCA pleading. The court found the alleged practice to be impermissible, even if the insurer ultimately paid the government back, because it allowed the insurer to "receiv[e] an interest free loan from the government…" Despite the lack of any overpayment in the long run, this approach demonstrates the increasing sophistication of FCA claims and the importance of thinking through ramifications of relying on information obtained from individuals without first reviewing it for compliance with applicable law.[9]

In 2018, hospitals can expect to see the government bring more MSP-related FCA investigations.

Teaching hospitals

A variety of issues are front and center for teaching hospitals in 2018, including two action items currently in the OIG Work Plan. First, under 42 C.F.R. § 412.105, interns and residents may not be counted as more than one full-time employee. However, OIG previously determined that these employees were repeatedly being billed for more than the permissible level. As a result, OIG is reviewing data provided by the Intern and Resident Information System to determine if hospitals received duplicate or excessive Graduate Medical Education payments. Given the OIG's emphasis in this area, teaching hospitals should review their controls to ensure that they are properly billing for intern and resident services.[10]

Second, teaching hospitals should also evaluate their policies on concurrent surgical procedures. Medicare prohibits teaching physicians from conducting two operations at the same time, unless the physician is present for all "critical parts" of each procedure.[11] At the end of 2016, the U.S. Senate Finance Committee issued a report urging hospitals to prohibit such concurrent surgeries.[12] The American College of Surgeons issued similar guidance urging surgeons not to conduct simultaneous surgeries, but if they do, to obtain the informed consent of the patients.[13] In response, many teaching hospitals proactively have revised their policies on simultaneous

surgeries. Although not a frequent area of CMS audits in the past, this issue is receiving increasing focus by DOJ and may have quality of care ramifications as well.

In addition to sound policies and regular monitoring and audits, hospitals may consider enhanced compliance measures, such as empowering anesthesiologists to alter the time of the procedure if the surgeon is not adequately available; and permitting fellows, residents, and assistants to commence a procedure only if the surgeon is not also performing the key parts of another surgery. These can be incorporated into the surgical "time outs" that have gained widespread acceptance.

Improper financial arrangements with physicians

As always, hospitals must ensure that relationships with providers meet the requirements of the Anti-Kickback Statute (AKS) and the Stark Law or face multi-million dollar high-stakes litigation:

- In September 2017, a Los Angeles hospital, Pacific Alliance Medical Center, agreed to repay $42 million to settle allegations that it violated both the AKS and the Stark Law when it paid above-market prices for office space in referring physicians' offices and participated in marketing arrangements that resulted in undue benefits to the physicians' practices.[14]
- In May 2017, two Missouri providers, St. John's Regional Health Center and its affiliate, St. John's Clinic, settled a FCA case alleging that they violated the AKS and Stark Law for $34 million. After an infusion center was converted into a hospital outpatient department to take advantage of 340B drug discounts, a "margin replacement" compensation model was implemented in order to make the physicians whole for any income they would lose as a result of the change. The government alleged that the compensation was calculated "by working backwards from a desired level of overall compensation," as opposed to taking into account actual work performed, clinic expenses, or the cost of malpractice insurance.[15] In addition to the monetary settlement, the providers entered into a CIA.[16]

HIPAA enforcement

The Health Insurance Portability and Accountability (HIPAA) Breach Notification Rule (45 C.F.R. §§ 164.400-414) requires HIPAA covered entities and their business associates to provide notification to affected individuals following a breach of unsecured PHI without unreasonable delay, and in no case later than 60 days following the discovery of a breach. From January 1 to November 1, 2017, the Office of Civil Rights (OCR) received reports of 199 breaches of unsecured PHI, each affecting 500 or more individuals.[17] In order to minimize liability, hospitals must protect PHI by ensuring that they are routinely performing adequate risk assessments and incorporating remedial measures indicated by these assessments, and responding to breaches by taking appropriate disciplinary action with respect to employees who act negligently or improperly. One HIPAA settlement in 2017 totaled $5.5 million and included a robust corrective action plan.

Hospital-ambulance swapping arrangements

Providers participating in swapping arrangements came under scrutiny in two recent settlements, demonstrating a new enforcement trend. For example, four hospitals affiliated with Hospital Corporation of America in the Houston area were required to pay $8.6 million to settle allegations that the "hospitals received kickbacks from various ambulance companies in

exchange for rights to the hospitals' more lucrative Medicare and Medicaid transport referrals."[18] Regent Management Services LP, which owns 11 nursing facilities in Texas, paid $3 million for similar allegations.[19] Additional settlements are expected in 2018.

Developing regulatory issues

Currently, leadership at CMS is shaking up the Center for Medicare and Medicaid Innovation (CMMI). The CMS Administrator, Seema Verma, is seeking informal "feedback on a new direction to promote patient-centered care and test market-driven reforms that empower beneficiaries as consumers, provide price transparency, increase choices and competition to drive quality, reduce costs, and improve outcomes."[20] The number of mandatory geographic areas participating in the Comprehensive Care for Joint Replacement (CJR) model has been reduced from 67 to 34. In addition, CMS is proposing to: (1) allow CJR participants in the other 33 areas to participate on a voluntary basis and (2) cancel the Episode Payment and Cardiac Rehabilitation incentive payment models, which were scheduled to begin on January 1, 2018.[21]

Additionally, 2018 is likely to bring cuts to a number of Medicare and Medicaid programs.

Medicaid Disproportionate Share Hospitals (DSH) payments

Federal law mandates that states pay DSH payments to qualifying hospitals serving a large number of Medicaid and uninsured patients. On July 27, 2017, CMS issued a notice of proposed rulemaking regarding DSH allotment reductions for FY 2018 to FY 2025.[22]

Hospital Outpatient Prospective Payment System (OPPS) and Inpatient Prospective Payment System (IPPS) rules

CMS is updating policies relating to the Hospital Value-Based Purchasing Program, the Hospital Readmissions Reduction Program, and the Hospital-Acquired Condition Reduction Program.[23] Under IPPS, CMS is providing a market basket update that will apply to the rate of increase limits for certain hospitals excluded from the IPPS that are paid on a reasonable cost basis subject to these limits for FY 2018.[24]

Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)

The Quality Payment Program (QPP) will continue with "pick your pace" for the new payment system's data reporting and also expand exemption of physicians from mandatory participation. The proposed 2018 rulemaking continues to emphasize flexibility, particularly as it relates to the Merit-based Incentive Payment System (MIPS). Although this program on its face appears to be relevant only to physicians, hospitals should understand MIPS and Advanced Alternative Payment Models (Advanced APMs) requirements in order to support their physicians in meeting these standards.[25] Hospitals want to ensure that physicians are eligible for incentives, or are at least able to avoid reductions, but this may be particularly challenging because hospitals must stay in compliance with prohibitions on incentives and referrals.

Hospital reimbursements for drugs purchased under the 340B plan

Beginning January 1, 2018, discounts to hospitals for drugs purchased and administered in outpatient hospitals under the 340B program will be reduced by almost 30%.[26]

Adoption of electronic health records

CMS Administrator Verma introduced the "Patients over Paperwork" Initiative at the end of October in an effort to improve patient care while lowering healthcare costs through the process of reducing unnecessary or overly burdensome regulations.[27] CMS will begin to review provider regulations and make determinations about which rules should be revised, replaced, or taken off the books.

Despite this potential reduction in regulatory requirements on the horizon, continued adoption of EHR by hospitals will be significant in 2018, including the following guidance changes and proposed rules.

- Hospitals must have a certified EHR product in place by the end of 2017 in order to complete 2018 reporting under Meaningful Use requirements, or else face Medicare payment penalties.[28]
- Hospitals participating in the Hospital Inpatient Quality Reporting (IQR) Program must self-select and successfully report on at least four of the 15 available clinical quality measures (eCQMs) using EHR technology certified to the 2014 and/or 2015 standards through QNet.[29]
- In September 2017, CMS issued an addendum to the eCQM annual update specification, updating the eCQM value sets, technical release notes, and the binding parameter specifications for the Fourth Quarter 2017 reporting period for eligible hospitals and critical access hospitals.[30]
- In 2017, CMS issued guidance requiring providers to attest that they are timely sharing information with their patients and other clinicians as necessary.[31] However, in order to properly make such an attestation, a hospital must have the proper technology in place and train their physicians on how to effectively use it.

Conclusion

Given that DOJ and OIG continue to secure large monetary recoveries from hospitals and are successfully holding individuals in the hospital sector to personal responsibility for alleged wrongdoing, momentum is clearly building for vigorous enforcement to continue in 2018. Despite cutting funding to HHS overall, President Trump has increased funding to the HHS Health Care Fraud and Abuse Control Unit by $70 million, with the return on investment a substantial $5 returned for every $1 expended. Regardless of the changes to come, the importance of regularly auditing hospital practices and implementing remedial measures to address deficiencies identified in audits cannot be understated.

1. Department of Justice (DOJ) Office of the Deputy Attorney General: Yates Memorandum. September 9, 2015. Available at bit.ly/2tSoJh8
2. DOJ, Justice News: "Acting Assistant Attorney General Kenneth A. Blanco of the Criminal Division Speaks at the American Bar Association 27th Annual Institute on Health Care Fraud" May 18, 2017. Available at bit.ly/2jxHHBW
3. DOJ, press release: "Oklahoma Hospital, Former Hospital Administrator, and Physicians Agree to Pay $1,618,750 to Settle Allegations of Submitting False Claims for Medical Services Provided to Medicare Patients" April 11, 2017. Available at bit.ly/2zFptFq
4. DOJ, Justice News: "Assistant Attorney General Leslie R. Caldwell Speaks at Health Care Compliance Association's 20th Annual Compliance Institute" April 18, 2016. Available at bit.ly/2zRRUnW
5. USAO Northern District of Georgia, press release: "ANMED Health agrees to pay $7 million to settle False Claims Act allegations" September 27, 2017. Available at bit.ly/2j4LFTe
6. USAO Northern District of New York, press release: "University of Rochester to Pay More Than $100,000 to Resolve False Claims Act Lawsuit" June 13, 2017. Available at bit.ly/2Bopi1P
7. HHS: Office of Inspector General: OIG Work Plan for Fiscal Year 2017, at page 4. Available at bit.ly/2yFAklM.
8. *U.S. ex. rel. Worthy v. Eastern Maine Health Care Systems et al.*, No. 2:2014-cv-00184 (D. Me. 2017).
9. Negron v. Progressive Casualty Insurance Co., No. 14-577, 2016 U.S. Dist. LEXIS 24994 (D.N.J. Mar. 1, 2016).
10. OIG Work Plan: Fiscal Year 2017, at page 6.
11. Kristen Rasmussen: "Investigations Into Alleged Surgery Double-Booking Highlight Hospitals' Need for Compliance" *National Law Journal*; October 12, 2017. Available at bit.ly/2AmJrGs
12. Senate Finance Committee Staff Report: Concurrent and Overlapping Surgeries: Additional Measures Warranted. December 6, 2016. Available at bit.ly/2nfYqyO
13. American College of Surgeons: Statement on Principles. Revised April 12, 2016. Available at bit.ly/2jyuYPK
14. DOJ, press release: "Los Angeles Hospital Agrees to Pay $42 Million to Settle Alleged False Claims Act Violations Arising from Improper Payments to Physicians" June 28, 2017. Available at bit.ly/2nllP2a
15. DOJ, press release: "Missouri Hospitals Agree to Pay United States $34 Million to Settle Alleged False Claims Act Violations Arising from Improper Payments to Oncologists" May 18, 2017. Available at bit.ly/2zC1k2M
16. Corporate Integrity Agreement between the OIG-HHS, Mercy Hospital Springfield, Mercy Clinic Springfield Communities, MHM Support Services. May 22, 2017. Available at bit.ly/2AMdtpS
17. HHS, Office for Civil Rights: Breach Portal: Notice to the Secretary of HHS Breach of Unsecured Protected Health Information. Available at 1.usa.gov/1yY3CaK
18. USAO Southern District of Texas, press release: "Four Area Hospitals to Pay Millions to Resolve Ambulance Swapping Allegations" October 4, 2017. Available at bit.ly/2ni4dUI
19. USAO Southern District of Texas, press release: "Skilled Nursing Facility Company Agrees to Pay More Than $3 Million to Resolve Kickback Allegations" November 30, 2015. Available at bit.ly/2ni4UgM
20. Heather Landi: "CMS Signals 'New Direction' for Innovation Center, Issues Request for Information" *Healthcare Informatics*, September 20, 2017. Available at bit.ly/2BzmKyQ
21. CMS.gov: "CMS proposes changes to the Comprehensive Care for Joint Replacement Model, cancellation of the mandatory Episode Payment Models and Cardiac Rehabilitation Incentive payment model" August 15, 2017. Available at go.cms.gov/2w5egyR
22. Medicaid.gov: "Medicaid Disproportionate Share Hospital (DSH) Payments" Available at bit.ly/2iqwhnk
23. CMS: Details for title: CMS-1656-FC, 2017. Available at go.cms.gov/2ismLA7
24. CMS.gov: "Details for title: CMS-1677-F; CMS-1677-CN CMS Final Rule and Correction Notice" Available at go.cms.gov/2zSvwLm
25. Jeff Byers: "9 major takeaways from the 2018 MACRA proposed rule" *HealthcareDIVE*; June 26, 2017. Available at bit.ly/2BoQbCK
26. 82 FR 52356, 52362 (Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs) November 13, 2017. Available at bit.ly/2is4Wkm
27. Shannon Firth: "CMS to Ease Physician Burden, Give More Patient Time—New initiative aims to reduce regulatory burdens" *MedPage Today*; October 26, 2017. Available at bit.ly/2jzpbcL
28. Rachel Z. Ardnt: "MACRA proposal would ease EHR burden for docs, but not hospitals" *Modern Healthcare*; June 20, 2017. Available at bit.ly/2j3Hzef
29. CMS.gov: Electronic Health Records (EHR) Incentive Programs. November 14, 2017. Available at go.cms.gov/2zDtD0L
30. QualityNet: CY 2017 eCQM Reporting Updates and Resources for the Hospital IQR and Medicare EHR Incentive Programs Issued Oct. 18, 2017. Available at bit.ly/2ArMK1f.
31. CMS: The Merit-based Incentive Payment System (MIPS) Advancing Care Information Prevention of Information Blocking Attestation: Making Sure EHR Information is Shared. October 2017. Available at go.cms.gov/2As35U0