Report on
MEDICARE COMPLIANCE

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Weekly News and Compliance Strategies on CMS/OIG Regulations, Enforcement Actions and Audits

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Outlook 2017: Enforcement Probably Won't Let Up, but Expect More Payment Changes

The presence of Sen. Charles Grassley, the human shield of the False Claims Act, and the billions of dollars the Department of Justice recovered in civil fraud cases in 2016 probably ensure enforcement won't wane in 2017, despite other sea changes facing the health care industry, including the likely repeal of the Affordable Care Act. Some regulatory unburdening may be coming — although that may have unintended consequences — and payment and audit surprises are likely around the corner.

Some significant changes will come from CMS as it moves toward site-neutral payments for 10 inpatient procedures, which were mandated in the 21st Century Cures Act, and continues to implement pay-for-performance programs that require compliance oversight. Meanwhile, the recovery audit contractors are poised to start work early this year, but if they are perceived as overzealous, providers may find a friendlier ear for their complaints when Rep. Tom Price (R-Ga.), a physician, is confirmed as HHS secretary (see story, below).

Enforcement is expected to continue unabated, lawyers and compliance officers agree. "Enforcement has been resilient to all kinds of political changes," says Washington, D.C., attorney Andy Ruskin, who is with Morgan Lewis.

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Outlook 2017: Watch for RAC, Medicaid Audits; NCDs, Short Stays Are Targets

After years of living in the shadow of Medicare audits, Medicaid audits may absorb more time and money than usual from health care organizations in 2017. There seems to be an uptick in Medicaid audits in some states and it runs parallel to CMS's moving ahead with its national strategy to meld certain Medicare and Medicaid program-integrity contractors.

"We are seeing much more of it now," says Andrei Costantino, vice president of integrity and compliance for Trinity Health, which has hospitals and other entities in 21 states. "In Michigan we got hit a lot, and in New York, Illinois and Florida, the Medicaid programs are becoming more aggressive." Meanwhile, CMS has dispatched unified program integrity contractors (UPICs), which replace zone program integrity contractors, program safeguard contractors, the Medicare-Medicaid data match program and Medicaid integrity contractors *(RMC 11/21/16, p. 8)*.

The uptick in Medicaid audits serves as a reminder that organizations may not be paying enough attention to Medicaid oversight. "Just because you're doing something accurately for Medicare rules doesn't mean it's accurate for the Medicaid business," Costantino says. Medicaid auditors are into everything, including inpatient admissions, physician services and post-acute care, and they have bite. For example, auditors will review 100 medical records for a five- to six-year time period, extrapolate the overpay-

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ment and demand $2 million, Costantino says. "We have to fight every record," he says. While Trinity Health has been able to drive down the overpayments significantly, it takes a couple of years.

Alarmingly, Medicaid auditors in Connecticut have identified overpayments for evaluation and management (E/M) services based on physician coding that's one level higher than auditors believe is appropriate. "It's very surprising. Billing 99214 when it should have been a 99213? Even the feds don't do that because it's getting into a gray area," Costantino says, unless the one-level difference in physician coding is part of a larger case.

These are not Medicaid recovery audit contractors, which are falling away because they are only allowed to audit fee-for-service claims and most states are converting Medicaid to managed care, says J. Paul Spencer, compliance consultant with DoctorsManagement. "It has a lot to do with states expanding their Medicaid fraud control units and managed care companies [entering audit territory]," he says.

In the Medicare world, recovery audit contractors (RACs) come back online in 2017 and it will be mostly the status quo despite the change in administration, says Emily Evans, managing director of health policy for Hedgeye Risk Management. "I think you will see some tweaking around the margins in how the program is implemented," she says. If Rep. Tom Price (R-Ga.), a physician, is confirmed as HHS secretary, "he will be a whole lot more sympathetic to the provider community, so I suspect there will be some changes to the CMS program integrity department, which will impact how the RAC program is managed," Evans predicts. "But there will still be RAC audits."

NCDs, LCDs May Be RAC Targets

What will RACs focus on? Valerie Rinkle, president of Valorize Consulting, believes that RACs will turn to hospital compliance with national coverage determinations (NCDs) and local coverage determinations (LCDs), with an emphasis on procedures that require documentation that patients have first exhausted conservative treatments before surgery, including joint replacement, spinal cord stimulator implants and treatment for varicose veins. RACs will analyze NCDs and LCDs "and the vulnerability hospitals have is not producing good medical records for the surgery itself and for the conservative treatments in the three to six months before," Rinkle says. "Hospitals will be scrambling to get medical records" from surgeons and primary care physicians. She recommends hospitals put together a pre-service coverage analysis group, where clinical staff asks physicians to assemble records and analyze coverage before the surgery is performed. RACs and the comprehensive error rate testing (CERT) contractor have identified problems in this area and they have been reported in issues of Medicare's quarterly compliance newsletter, Rinkle says.

The RACs may also circle back to the two-midnight rule in the wake of a December report by the HHS Office of Inspector General that found hospitals still billing for potentially improper short inpatient stays, says Ronald Hirsch, vice president of education and regulations at Accretive Physician Advisory Services. Even with limited audits, Medicare spent almost $2.9 billion on inappropriate short inpatient stays since the two-midnight rule took effect, OIG said. "That will produce a lot of waves at CMS and in the auditor business," he predicts.

OIG looked at hospital stays during fiscal year 2014, and found that while some goals of the two-midnight rule were achieved, there are still vulnerabilities. "Hospitals are billing for many short inpatient stays that are potentially inappropriate under the 2-midnight policy, and some of these stays are for similar reasons as short outpatient stays. This raises concerns that Medicare is paying differently for similar care and may reflect hospitals' financial incentives to use inpatient stays," OIG said. Of the short inpatient stays billed to Medicare, "39 percent were potentially inappropriate," according to the report.

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The two-midnight rule was expected to promote consistent use of inpatient and outpatient stays, but hospitals are all over the map. Short inpatient stays increased at 18% of hospitals, while long outpatient stays went up at 51% of hospitals. For certain conditions, such as chest pain, short inpatient stays went down considerably, but 29% of hospitals increased their short inpatient stays for chest pain. In light of the findings, OIG urged CMS to increase routine oversight of the two-midnight rule, and target hospitals "with high or increasing numbers of short inpatient stays that are potentially inappropriate under the two midnight rule."

Hirsch is baffled that almost one-third of hospitals increased their use of inpatient admissions for chest pain. "That's such a common diagnosis that fits perfectly into observation," he says. Continuing down this path is falling right into the hands of auditors, who he assumes will be back in force in light of this report after three years of a light touch. "I don't think the RACs and advocates of auditing are going to sit back and wait a year before hospitals get referred for greater auditing beyond 10 charts every six months" by the QIOs, Hirsch says.

More Consolidation = More Due Diligence

Compliance officers will increasingly cope with the audit and compliance challenges brought on by health reform — consolidation and bundled payments/pay for performance. With rapid consolidation in the industry, compliance officers have to ensure effective due diligence on the front end and continual due diligence as the organization evolves, says Greg Radinsky, vice president and chief corporate compliance officer at Northwell Health in New Hyde Park, N.Y. They may not have oversight over the entire entity after a merger or joint venture, and that complicates compliance, he notes. There may be a new board of directors and differences between the compliance programs at the merging organizations. More training and baseline audits could be necessary. "There's a lot of work this creates," Radinsky notes. "Even if they have a good compliance program, trust and awareness must be built up."

And there are risks to mitigate after consolidations, notes Debi Weatherford, executive director of internal audit for Piedmont Healthcare in Atlanta. "If you are on two different software systems, there can be some different attitudes to estimates and reserves and how information is captured and communicated," she says. It's essential to ensure information reported (e.g., quality measures) is accurate and audited consistently. "Make sure everyone is aware that standardization is occurring." Similarly, with all the new construction underway, Weatherford says health systems should have tight controls. She recently discovered a vendor billed twice for an expensive piece of radiology equipment. There were separate invoices with different information, but the serial number was the same, which was a tip off. "You have to be careful how you're tracking," she adds.

A new mindset is also needed for auditing and monitoring the fee-for-value programs that are slowly subsuming fee-for-service Medicare. Whether it's comprehensive care for joint replacement, the Medicare Access and CHIP Reauthorization Act *(RMC 12/19/16, p. 1)* or accountable care organizations *(RMC 10/31/16, p. 1)*, compliance officers will have to adapt their oversight skills to bundled payments and other pay-for-performance programs. "Compliance officers will be challenged by new pricing structures," says attorney Brian Flood, who is with Husch Blackwell in Austin, Texas. "I don't think that will change whether Obamacare is repealed or not because you have to control spending. If I were a CCO, I would keep an extra eye on what type of models we are creating, and do those models appear to enhance revenue or utilization unnaturally vs. merely being a good deal or efficient, because the government is starting to compare which one it is."

MOON Is on the Horizon

Hospitals also have until March 8 to start using the new Medicare Outpatient Observation Notice (MOON). Developed by CMS at the behest of Congress *(RMC 12/12/16, p. 1)*, the MOON informs patients they are outpatients receiving observation services, not inpatients. "I have already seen hospitals modify the MOON in noncompliant ways to try to meet their state requirements and only use one form," Hirsch says. The MOON has been approved by the Office of Management and Budget, which means neither the format nor the substance can be altered.

Cybersecurity and privacy will be high on the audit list this year. "The biggest thing you can do is try to gauge where you stand and ensure management and the board is aware of where you are with controls and devices to detect intruders and to respond quickly when a hacking incident is identified," Weatherford says.

Michael Salvatore, M.D., physician adviser at Beebe Medical Center in Lewes, Del., isn't feeling confident there will be any more clarity about Medicare mandates than there's been in the past. Who should deliver the MOON, for example? And what good was the OIG report on the two-midnight rule when the data relate to 2014 hospital stays "and the whole game field has changed since then"? It seems like CMS doesn't adequately define things, Salvatore says. "In the end, my feeling is, CMS doesn't have to come out with clear policies."

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Mediation With OMHA Has Upside As Appeals Still Move Slowly

Mediators may be a faster way for hospitals and other providers to get their Medicare appeals resolved, even with a federal court ordering the Office of Medicare Hearings and Appeals (OMHA) to clear the backlog by Dec. 31, 2020 *(RMC 5/12/16, p. 6)*, one attorney says.

OMHA is providing mediators to Part A providers through its expanded "settlement conference facilitation," and so far, it's promising, attorney Andrew Wachler said at a recent webinar sponsored by the Health Care Compliance Association. Settlement conference facilitation is one of CMS's and OMHA's strategies for reducing the backlog of Medicare appeals. The process brings CMS and providers or suppliers together voluntarily to try to hammer out a compromise on disputed claims instead of waiting for a hearing before an administrative law judge.

"I am cautiously optimistic it's worth our while," said Wachler, who is with Wachler & Associates in Royal Oak, Mich.

The reason: if providers settle the claim dispute with CMS, they may walk away with a check, end of story. If not, they just walk away — no harm, no foul. "If you can settle it, great. If not, you go back to where you were before, waiting in line for a hearing," he said.

During settlement conference facilitation, appellants (i.e., providers and suppliers) and CMS try to compromise on a percentage of payment for disputed claims with the help of an OMHA-trained facilitator who doesn't make decisions about the merits of a claim or serve as a factfinder. But if CMS and the appellant work out a deal and sign an agreement drafted by the facilitator, the Medicare administrative contractor can write a check and there's no need to continue the appeal.

Wachler thinks CMS may be motivated to make providers an offer they wouldn't want to refuse. "If it comes out that everyone is complaining about facilitation and they're not coming up with fair numbers, CMS won't look good," Wachler said. "I think they will come up with fair numbers because it reduces the backlog."

OMHA launched the pilot with Phase I for Part B appeals in 2014, and has resolved more than 2,600 ALJ appeals that had not yet been assigned to ALJs, Wachler said. This applied to ALJ hearing requests filed in 2013. The pilot was expanded in 2015 to Part B providers and suppliers, including physicians, physical therapists, labs and ambulance providers. Appeals that were pending before ALJs are eligible as long as no hearing had been scheduled, he said. However, a request for hearing had to have been filed by Sept. 30, 2015, and the claims at issue worth $100,000 or less.

In February 2016, OMHA invited all Part A providers into settlement conference facilitation, as long as no ALJ hearing had been scheduled yet but they requested one by Dec. 31, 2015. "At least 50 claims must be at issue and at least $20,000 must be in controversy," Wachler said.

In theory, there's little downside to settlement conference facilitation, Wachler says. If the provider and CMS can't agree on a settlement, the negotiation dissolves, but the provider just goes back in the queue, where it was before, and will have its turn before the ALJ as if the settlement conference facilitation never happened. This is the first time there's an option to settle a claims disagreement in the HHS administrative appeals process, Wachler says, and until he sees evidence to the contrary, it's worth a shot.

This assumes, of course, that the CMS mediator operates in good faith, coming up with a reasonable dollar figure for disputed claims. The pressure is on now that HHS and OMHA are under a court-ordered deadline to clear out the Medicare appeals backlog *(RMC 12/12/16, p. 6)*. According to a Dec. 5, 2016, decision from the U.S. District Court for the District of Columbia in a court battle between HHS and the American Hospital Association over the Medicare appeals backlog, OMHA has to clear the decks according to these deadlines:

- By Dec. 31, 2017, there must be a 30% reduction in the backlog of cases pending before ALJs;
- By Dec. 31, 2018, the backlog must be cut by 60%;
- By Dec. 31, 2019, there must be a 90% reduction; and
- The following year, it must be gone.

"I think they will come up with good numbers," Wachler said. In addition to clearing the backlog, "CMS is at risk their auditing will be hamstrung."

As for providers, Wachler suggested approaching settlement conference facilitation strategically. "Look at specific trends," he said. If ALJs denied a small percent of a certain kind of claim three years ago and now are denying 25% of the same kinds of cases (e.g., home health claims for purported lack of face-to-face narratives), consider these cases for settlement conference facilitation. He said providers should try to show the strength of the cases as a whole rather than argue each case as if it were in an ALJ hearing.

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Enforcement Won't Lose Steam

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That's why former federal prosecutor Robert Trusiak advises health care organizations to stick to their compliance programs and move forward with pay-for-performance initiatives. "It would be reckless for individuals to want to wait and see because they don't know what will happen with the Affordable Care Act or how aggressive Jeff Sessions will be with the False Claims Act," he says, referring to the nominee for attorney general. "The bottom line is, we have laws on the books, directives and policies issued by CMS, and most can't be undone. We are advancing toward a value-based format and let's proceed until we get the stoplight that says no more."

There also will be a lot of action from the HHS Office of Inspector General. In addition to audits, OIG imposes exclusions and civil monetary penalties (CMPs) on organizations, says San Francisco attorney Judy Waltz, who is with Foley & Lardner LLP. In December, OIG added to its arsenal when it finalized regulations that implemented additional CMPs authorized by the ACA including one for failure to comply with the 60-day rule.

And now OIG has been empowered by the 21st Century Cures Act to levy CMPs on institutions and others that engage in contract fraud, says Lisa Re, who is assistant inspector general for legal affairs. That includes any kind of HHS contract fraud, including research grants from the National Institutes of Health and the Centers for Disease Control and Prevention, Re tells *RMC*. "This is a way for us to have an additional tool to protect those funds that have been misspent," she says.

Amount of CMP Fines Was Raised

In the December regulation OIG also raised the amount of CMP fines, and providers should pay close attention to the increase (from $100,000 to $159,089) for violating the CMP law against Stark circumvention schemes, says Trusiak, who is a principal in Health Care Compliance Support in Buffalo, N.Y. Physicians may be tempted by investment opportunities that offer a clever way to "circumvent the express prohibitions" of the Stark regulations, he says. "As reimbursement rates continue to decline, such passive investment opportunities may seem attractive — until measured against the increased financial exposure." In light of this CMP and its higher fines, Trusiak suggests compliance officers put more explicit questions in their conflict of interest disclosure forms. "I would want to identify Stark-risky schemes and make sure physicians say, 'no, I am not involved in that,'" or have answers that lead to more meaningful conversations about their financial relationships, he says. "People should be spending more time on conflicts of interest to ensure protection against downstream risk."

The new CMPs could conceivably disappear, however. Under the Congressional Review Act (5 USC Sections 801-808), the Trump administration could nullify the new CMP regulations because they were finalized in the past six months, Waltz says. "There is great uncertainty about what will happen in the next four years, if not the next eight hours," she says.

DOJ's 2016 Recoveries Will Fuel Enforcement

If past is prologue, then the colossal recoveries reported by the Department of Justice for fiscal 2016 — more than $4.7 billion in civil fraud and false claims cases — will keep the enforcement machinery churning. "That will give them fuel for the fire," says attorney Brian Flood, who is with Husch Blackwell in Austin, Texas. With recent headlines of big-dollar fraud cases, including Tenet Healthcare Corp.'s $513 million settlement *(RMC 10/17/16, p. 1)*, and higher costs of care, such as drug price increases, "I anticipate CMS, OIG and DOJ will go to Congress and say, 'look how much we're losing. More needs to be done.' And they have the data to support that argument."

Flood also predicts enforcers will take little for granted in their investigations. "One thing to watch for this year is the business relationships that may appear legal on the surface but were put together for illegal purposes. Even though the deal is legal on its face, if it pushes exaggerated billing to the government, it could be subject to challenge," Flood says. That's the kind of allegation that surfaced in the criminal case against 21 physicians and others involved in Forest Park Medical Center in Dallas, he says *(RMC 12/12/16, p. 5)*.

Although whistleblowers will continue to be a potent force, there may be a turn toward more enforcement actions initiated by DOJ, "if all things remain equal under the Trump administration," says Denver attorney Tom Donohoe, who is with Hall Render. In fiscal year 2016, more civil fraud cases were initiated by the government than by whistleblowers for the first time in a long time, "and you may see that again in coming years" if the trend continues, he says. The implication is that the government would set its own agenda rather than just react to whistleblower cases, Donohoe notes. And providers may face more false claims lawsuits based on regulatory violations because of the June 2016 Supreme Court decision in *United States ex rel. Escobar v. United Health Services (RMC 6/20/16, p. 1)*.

Shifting over to the payment world, hospitals got a big surprise in the 21st Century Cures Act when Congress ordered CMS to identify the 10 most common one-day inpatient surgeries and develop an inpatient-outpatient coding crosswalk with the probable goal of equalizing payment for these services between settings,

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says Washington, D.C., attorney Christopher Kenny, who is with King & Spalding. "You are potentially looking at reduced revenues down the road for the 10 most common kinds of one-day inpatient surgical cases," Kenny says. CMS has one year to develop the outpatient code set for those surgeries.

Site neutrality has caught fire with lawmakers and regulators, between this development and Sec. 603 of the 2015 Bipartisan Budget Act, which ended outpatient prospective payment system (OPPS) billing for off-campus provider-based departments established after Nov. 2, 2015 — although the 21st Century Cures Act carved out an exception to Sec. 603 *(RMC 12/5/16, p. 3)*. "Long-term, regardless of what happens in the new administration and to the Affordable Care Act, site neutrality and the push to reduce hospital expenditures is going to continue," Kenny says. Even if Congress kills the Center for Medicare and Medicaid Innovation, it will search for other ways to equalize payment across care settings, he

CMS Transmittals and *Federal Register* Regulations
Dec. 16, 2016 — Jan. 5, 2017

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Transmittals

(R) indicates a replacement transmittal.

Pub. 100-02, Medicare Benefit Policy Manual

- January 2017 Update of the Hospital Outpatient Prospective Payment System, Trans. 232BP, CR 9930 (Dec. 22, 2016; eff. Jan. 1; impl. Jan. 3)
- Implementation of Changes in the End-Stage Renal Disease Prospective Payment System and Payment for Dialysis Furnished for Acute Kidney Injury in ESRD Facilities for Calendar Year 2017 (R), Trans. 231BP, CR 9807 (Dec. 15, 2016; eff. Jan. 1; impl. Jan. 3)

Pub. 100-04, Medicare Claims Processing Manual

- Update to the Federally Qualified Health Centers (FQHC) Prospective Payment System (PPS) - Recurring File Updates (Jan. 4, 2017; eff. date Jan. 1; impl Jan. 3)
- Calendar Year (CY) 2017 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment Trans. (Dec. 29, 2017; eff. Jan. 1; impl. Jan. 3)
- 2017 Durable Medical Equipment Prosthetics, Orthotics, and Supplies Healthcare Common Procedure Coding System Code Jurisdiction List, Trans. 3684CP, CR 9903 (Dec. 22, 2016; eff. Jan. 1; impl. Jan. 24)
- January 2017 Update of the Ambulatory Surgical Center (ASC) Payment System, Trans. 3683CP, CR 9923 (Dec. 22, 2016; eff. Jan. 1; impl. Jan. 3)
- Calendar Year (CY) 2017 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment, Trans. 3682CP, CR 9909 (Dec. 22, 2016; eff. Jan. 1; impl. Jan. 3)
- January 2017 Update of the Hospital Outpatient Prospective Payment System, Trans. 3685CP, CR 9930 (Dec. 22, 2016; eff. Jan. 1; impl. Jan. 3)
- Summary of Policies in the Calendar Year 2017 Medicare Physician Fee Schedule Final Rule, Telehealth Originating Site Facility Fee Payment Amount and Telehealth Services List, and CT Modifier Reduction List, Trans. 3676CP, CR 9844 (Dec. 16, 2016; eff. Jan. 1; impl. Jan. 3)
- Prolonged Services Without Direct Face-to-Face Patient Contact Separately Payable Under the Physician Fee Schedule (Manual Update), Trans. 3678CP, CR 9905 (Dec. 16, 2016; eff. Jan. 1; impl. Jan. 3)
- Payment for Oxygen Volume Adjustments and Portable Oxygen Equipment (R), Trans. 3679CP, CR 9848 (Dec. 16, 2016; eff. April 1; impl. April 3)

Pub. 100-06, Medicare Financial Management

- Instructions to Hospitals on the Election of a Medicare-Supplemental Security Income Component of the Disproportionate Share Payment Adjustment for Cost Reports that Involve SSI Ratios for Fiscal Year 2004 and Earlier, or SSI Ratios for Hospital Cost-Reporting Periods for Patient Discharges Occurring Before October 1, 2004, Trans. 279FM, CR 9896 (Dec. 16, 2016; eff. /impl. Jan. 19)

Pub. 100-20, One-Time Notification

- Shared Savings Program (SSP) Accountable Care Organization (ACO) Qualifying Stay Edits (R), Trans. 17630TN, CR 9568 (Dec. 16, 2016; eff. Jan. 1; impl. Jan. 3)

Federal Register Regulations

- Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability; Corrections 82 Fed. Reg. 37 (Jan. 3, 2017)
- Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (EHR) Incentive Programs; Payment to Nonexcepted Off-Campus Provider-Based Department of a Hospital; Hospital Value-Based Purchasing (VBP) Program; Establishment of Payment Rates Under the Medicare Physician Fee Schedule for Nonexcepted Items and Services Furnished by an Off-Campus Provider-Based Department of a Hospital; Correction and Extension of Comment Period 82 Fed. Reg. 24 (Jan. 3, 2017)
- Medicare Program; Advancing Care Coordination Through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model (CJR) 82 Fed. Reg. 180 (Jan. 3, 2017)
- Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements; Corrections 81 Fed. Reg. 95890 (Dec. 29, 2016)
- End-Stage Renal Disease Quality Incentive Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program Bid Surety Bonds, State Licensure, and Appeals Process for Breach of Contract Actions; Correction, 81 Fed. Reg. 94268 (Dec. 23, 2016)

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says. "The hospital community needs to be very aware of what is going on and prepare accordingly."

Clock Is Ticking on 'Cures' Exception

Meanwhile, the clock is ticking for hospitals that are dependent on the Sec. 603 "mid-build" exception in the 21st Century Cures Act, Kenny says. It allows OPPS billing if the off-campus provider-based departments had a binding written agreement for construction on or before Nov. 2, 2015, and the hospital's CEO or COO submit to CMS a letter stating that the provider-based department meets the definition of "mid-build." Hospitals also must submit an attestation of compliance with provider-based status within 60 days of the bill becoming law, Kenny says. President Obama signed the law on Dec. 13.

The path ahead for some regulations is unclear. There's interest in "repealing some of the esoteric, outdated Stark requirements," Donohoe says, on the heels of changes CMS made to Stark requirements in the 2016 Medicare physician fee schedule regulation, which reduced some of the burdens and created two exceptions *(RMC 11/9/15, p. 1)*.

Ruskin agrees, although he says it could be a mixed bag. "You may see a movement away from detailed and senseless regulations. Obama tried to do some of that already," he notes. How it shakes out will determine whether providers actually come out on top. "People have to understand that a lot of the reason why regulations are so complex is that, when you add exceptions for providers, you add complexity," Ruskin says. "How much simplicity do you want? Just be careful what you wish for."

There had been certainty that the omnibus guidance on the 340B drug-discount program *(RMC 10/24/16, p. 1)* — the so-called mega guidance — would be issued in December 2016, but Ruskin says the closer we get to Inauguration Day, the less likely it is that it will happen at all. The Health Resources and Services Administration on Jan. 4 finalized one rule that sets penalties on drug manufacturers that overcharge hospitals for 340B drugs, but Ruskin says it's doubtful the comprehensive mega guidance will materialize because there were some portions of the proposed guidance that were very controversial and a new administration wouldn't want to be mired in the fallout from the final guidance. "At a minimum, the Trump administration would put a hold on its enforcement," he says.

The year 2017 also will bring more heated discussion of the effectiveness of compliance programs, says Atlanta attorney Sara Kay Wheeler, who is with King & Spalding. Some compliance officers are tracking conventional metrics, such as how many complaints come into hotlines vs. in person, "but when you look at the government side, they tend to focus on voluntary disclosures and repayments. It has become a bit more myopic in that direction," she says. The update to the DOJ principles of Federal Prosecution of Business Organizations "seems to have a lot more focus on that one element." The magnitude of compliance programs also was conveyed in OIG's 2016 updated guidance on its permissive exclusion authority, Wheeler notes. OIG stated that having a compliance program won't help avoid exclusion because it's expected, but when providers participate in voluntary disclosures, it makes a big impression *(RMC 4/25/16, p. 1)*. "You have a heightened expectation for compliance programs," Wheeler says, and an increased focus on individual accountability of leaders and governing boards because of the Yates memo, which is DOJ's blueprint for nailing culpable individuals as part of corporate civil and criminal fraud settlements. "It is an almost perfect opportunity to step back and rethink some of our strategies."

One strategy: health systems can develop a "framework" to comply with the 60-day Medicare overpayment refund rule, which requires them to report overpayments and return them within 60 days of identifying them, Wheeler says *(RMC 2/15/16, p. 1; 9/5/16, p. 1)*. "It's not as if overpayments are just served up to finance or compliance on a silver platter," she says. "What ends up occurring is the organization receives information from multiple sources, from external or internal inputs, and you try to make sure they are triaged in a thoughtful and consistent manner. Are they really overpayments? Was there potential patient harm?" She suggests health systems consider investing in a systematic process for evaluating reports of possible overpayments this year, during the political transition, when there is unpredictability elsewhere.

'Try to Be Proactive'

"Instead of being distraught in terms of all these converging dynamics, you can put your best foot forward and try to be proactive, almost as an antidote," Wheeler says.

2017 also will bring some new activities from OIG. "We are going to have more outreach with tribes. OIG audits, evaluations and investigations have revealed that the Indian Health Service and tribes would benefit from stronger internal controls and compliance programs," Re says. OIG recently settled a civil monetary penalty case with an Indian tribe after a self-disclosure and anticipates entering into a "Voluntary Tribal Compliance Agreement" with an Indian nation, she says. In 2014, OIG released a Tribal Alert warning Indian tribes that receive Medicare and Medicaid reimbursement to ensure they use them consistently with federal laws, including the Indian Health Care Improvement Act. "It's a priority for OIG," she notes.

continued

OIG hopes to add attorneys to the litigation team, which works exclusively on CMP cases and exclusions *(RMC 7/27/15, p. 1)*. "You will continue to see a robust portfolio of work," Re says. This includes spinning off cases against individuals identified in false claims lawsuits and identifying targets through OIG's other components, including the data center and the Office of Audit Services. "We're not just waiting for a tip from the hotline or DOJ," she says.

Although there's consensus that enforcement will still be hot and heavy, attorney Gabriel Imperato says providers should keep tabs on the Yates memo. The same goes for how DOJ uses its compliance counsel, Hui Chen, who advises line prosecutors on the scope and effectiveness of an organization's compliance program as part of giving it credit during the settlement process. "Is that going to change? It probably won't, but we should keep an eye on it," says Imperato, who is with Broad and Cassel in Fort Lauderdale, Fla.

At this time, he says, it's pretty much status quo for how compliance officers approach their jobs in 2017. "The developments in 2016" — the final regulation on the 60-day rule, the *Escobar* decision, the use of the Yates memo with the former Tuomey Healthcare System CEO who personally settled for $1 million *(RMC 10/3/16, p. 1)*, big-dollar settlements and more — "give them plenty to do for quite a while."

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NEWS BRIEFS

◆ **Abbott Northwestern Hospital was overpaid more than $8 million, according to a Medicare compliance review posted on Jan. 5.** The HHS Office of Inspector General reviewed a stratified random sample of 162 claims submitted by the 952-bed Minneapolis hospital, which is part of Allina Health, and identified 74 billing errors. That resulted in overpayments of $933,991. "On the basis of our sample results, we estimated that the Hospital received overpayments of at least $8,038,356 for the audit period," OIG said. A big chunk of the overpayment stemmed from Part A claims for acute inpatient rehabilitation services. OIG said 30 claims didn't meet Medicare criteria. In its written response, Katherine Tarvestad, Allina's senior vice president and chief compliance officer, disagreed that 25 of the 30 claims were unsupported in the medical record and contends that OIG "turned a blind eye to evidence supporting the validity of those claims." Tarvestad said that OIG's draft report has "numerous factual and legal errors that combine to overstate significantly the amount of overpayments." For example, OIG "extrapolated an inflated overpayment amount from a flawed sample of claims using an equally flawed methodology." Visit http://go.usa.gov/x92vp.

◆ **South Miami Hospital agreed to pay $12 million to settle false claims allegations over medically unnecessary electrophysiology studies and other procedures** allegedly performed by John R. Dylewski, M.D., the U.S. Attorney's Office for the Southern District of Florida said on Dec. 7. The lawsuit was originally filed by a vascular surgeon and a cardiologist at the hospital. "According to court documents, plaintiffs claimed to have personal knowledge of Dr. Dylewski and South Miami Hospital engaging in a number of unnecessary cardiac procedures, including echocardiograms, electrophysiology studies, head upright tilt tests, and other treatments of arrhythmia by ablation, cryoablation, or implantation of an electronic device, for the sole purpose of increasing the amount of physician and hospital reimbursements paid by Medicare and other federally-funded programs," the U.S. attorney's office said. In a statement, the South Miami Hospital said there was no determination of liability and that "Dr. John Dylewski is not practicing at our hospital." Visit http://tinyurl.com/gtnzb24.

◆ **Bay Sleep Clinic and its related businesses and owners, Anooshiravan Mostowfipour and Tara Nader, have agreed to pay $2.6 million to settle false claims allegations over diagnostic sleep tests and medical devices,** the U.S. Attorney's Office for the Northern District of California said on Dec. 28. Mostowfipour, Nader, and their businesses allegedly charged Medicare for sleep tests that were performed by technicians who didn't have licenses or certifications required by Medicare, according to the U.S. attorney's office. The defendants also allegedly dummied documents to make it seem like sleep tests were performed at Medicare-approved locations, when the tests were actually performed at unapproved facilities. Visit http://tinyurl.com/hrfulaf.

Call Justin Allbee at 888.580.8373 x 7938 or Justin.allbee@corporatecompliance.org for rates on bulk subscriptions or site licenses, electronic delivery to multiple readers, and customized feeds of selective news and data…daily, weekly or whenever you need it.