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

Contents

HCCA

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New NYS Compliance-Program Requirements May Be Useful Everywhere as a 'Fresh Look'

On March 28, a sea change in compliance-program requirements takes effect in New York state, and it may be useful to compliance officers everywhere. New York state has now made an effective compliance program a condition of Medicaid payment and the requirements are more expansive, according to a Dec. 28, 2022, regulation from the Office of the Medicaid Inspector General (OMIG).[1] The regulations touch on virtually every aspect of provider compliance programs, require annual effectiveness reviews and extend the provider's compliance program to its contractors, among other things.

Providers in other states may find it useful to mine the requirements for effectiveness purposes, experts say. The regulations and their companion documents "afford providers outside New York an opportunity to look at their compliance programs with fresh eyes," said Laurel Baum, chief compliance and integrity officer for Trinity Health's New York region. They just don't have the same pressure as providers in her state because "compliance is mandatory for New York providers subject to the regulations."

Although there has been a compliance-program requirement in New York state since 2009, it was expanded by the state legislature in 2020, said attorney Robert Hussar, former first deputy Medicaid inspector general. The implementing regulation wasn't released until January, apparently because of the COVID-19 pandemic, and now the effective date is around the corner, said Hussar, with Rivkin Radler in Albany, New York.

"It's a game-changer," he said. "It's probably the most significant change to compliance programs since they originally came out in the late 1990s," including the Federal Sentencing Guidelines and compliance program guidance from the HHS Office of Inspector General (OIG). "Unlike a lot of those standards, these are mandatory." He thinks the OMIG development "raises the bar" and may cause OIG

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DOJ Again Deploys FCA in Cybersecurity Case; Florida Medicaid Contractor Was Hacked

In its third use of the False Claims Act (FCA) against alleged "cybersecurity failures," the Department of Justice (DOJ) said March 14 that a government contractor providing services to Florida Healthy Kids Corporation (FHKC) agreed to pay $293,771 in a settlement after its website was hacked.[1] The contractor, Jelly Bean Communications Design LLC, and Jeremy Spinks, its only employee and 50% owner, was required to comply with HIPAA but dropped the ball, and as a result, the protected health information of about 500,000 children was potentially exposed, DOJ alleged. The effect of Jelly Bean's alleged disregard for cybersecurity in connection with a program funded partly by the federal government provided a bridge to the FCA, an attorney said.

According to the settlement, FHKC, a state-created entity that offers health and dental insurance to Florida kids between ages five and 18, receives federal Medicaid funds and state funds.[2] In July 2012, the Agency for Health Care Administration (AHCA), which is Florida's Medicaid agency, contracted with FHKC to provide services for the state Children's Health Insurance Program. "This included

continued

implementing technical safeguards to protect the confidentiality, integrity, and availability of electronic protected health information received, maintained, or transmitted on behalf of AHCA," the settlement stated. FHKC turned to Jelly Bean for website design and programming. In an Oct. 31, 2013, agreement, Jelly Bean was required to "provide a fully-functional hosting environment that complied with HIPAA" and "adapt, modify, and create the necessary code on the webserver to support the secure communication of data."

DOJ alleged that Jelly Bean created, hosted and maintained the website HealthyKids.org for FHKC, where parents and others entered data on an online application for state Medicaid insurance coverage for their children. The data was collected and sent to FHKC's third-party administrator. Jelly Bean submitted invoices for the services that included a line item for "HIPAA-compliant hosting" and charged a monthly "retainer fee" for hosting and other tasks, according to the settlement.

But contrary to its pledges, Jelly Bean didn't provide secure hosting of applicants' personal information or properly maintain, patch and update the software systems underlying HealthyKids.org and related websites, leaving the site and the data collected by Jelly Bean from applicants "vulnerable to attack," DOJ alleged. By December 2020, apparently more than half a million applications submitted on HealthyKids.org had been hacked. "Independent investigation by FHKC revealed that the hackers altered applications, inserting a specific street address as their 'calling card.' The FHKC investigation also revealed that the website created by Jelly Bean was running multiple outdated and vulnerable applications, including some software that Jelly Bean had not updated or patched since November 2013," DOJ alleged.

Although Jelly Bean allegedly didn't have sufficient audit logs indicating who accessed applicants' personal information, "the information potentially exposed by the website's vulnerabilities included an applicant's: 1) full name and date of birth; 2) email address and telephone number; 3) physical and mailing address; 4) social security number; 5) financial information, to include wages, alimony, child support, royalties, other income, and tax deductions; 6) family relationships (such as mother of child, sister/brother of applicant, etc.); and 7) secondary insurance information." Because of the breach and Jelly Bean's alleged cybersecurity failures, FHKC shut down the website's application portal in December 2020.

DOJ alleged that Jelly Bean and Spinks caused the submission of false claims for federal funds through AHCA's contract with FHKC from Jan. 1, 2014, through Dec. 14, 2020.

Jelly Bean and Spinks didn't admit liability in the settlement. Their attorney, Thomas M. Findley, said "we are pleased that the case has been resolved."

'It Wouldn't Have Been Just a Breach'

The FCA settlement stems from DOJ's cyber civil-fraud initiative. To connect the dots between a cybersecurity failure and the FCA, DOJ has to have evidence of a knowing violation, said attorney Colette Matzzie, with Phillips and Cohen in Washington, D.C. "It wouldn't have just been a breach," she noted. "And whether it becomes a False Claims Act case depends on whether there's federal funding behind it. Software manufacturers should assume if their software is being used to protect protected health information and the system is being paid in part by federal or state funds, the federal or state false claims acts will apply. It would be a straightforward application of a contractual or regulatory requirement. It happened to be a contract in this case but if regulations require cybersecurity technology, and there is federal or state money, that also could be enforced."

There have been two other settlements in the cyber civil-fraud initiative. For example, Comprehensive Health Services LLC (CHS) in Cape Canaveral, Florida, agreed to pay $930,000 to settle false claims allegations by falsely representing that it complied with contract requirements relating to the provision of medical services at State Department and Air Force facilities in Iraq and Afghanistan.[3] Under one of its contracts, CHS submitted claims to the State Department for the cost of a secure electronic medical record (EMR) system to store patients' medical records. DOJ alleged that from 2012 to 2019, CHS didn't reveal to the State Department that it hadn't consistently stored medical records on secure EMRs.

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Endnotes

1. U.S. Department of Justice, Office of Public Affairs, "Jelly Bean Communications Design and its Manager Settle False Claims Act Liability for Cybersecurity Failures on Florida Medicaid Enrollment Website," news release, March 14, 2023, http://bit.ly/3mVCV5K.
2. Settlement agreement, United States v. Jelly Bean Communications Design LLC and Jeremy Spinks, last accessed March 16, 2023, https://bit.ly/3lfm1Pc.
3. U.S. Department of Justice, Office of Public Affairs, "Medical Services Contractor Pays $930,000 to Settle False Claims Act Allegations Relating to Medical Services Contracts at State Department and Air Force Facilities in Iraq and Afghanistan," news release, March 8, 2022, https://bit.ly/3rTEsIH.

Modifier 24 May Trip Up Physicians; 'Global Period Is Very Messy'

A surgeon performs a biopsy on a patient's mass and unfortunately determines it's malignant. When the patient returns to the surgeon to discuss treatment options for the cancer, the evaluation and management (E/M) visit is separately billable to Medicare with modifier 24 even though the patient is still in the global surgery period.

Although it seems counterintuitive to bill separately for E/M services provided during the post-op period, Medicare excludes treatment for the underlying condition that's not part of the patient's normal recovery from surgery, said Amanda Buonocore, coding and reimbursement senior manager at Northwell Health Physician Partners in New York.

Modifier 24 and other modifiers are available to allow separate billing for services provided during the global surgery period, but they can be a compliance minefield. "The global period is very messy," she noted. Compliance with modifier 24 is also complicated by the fact that Medicare's application is at odds with the American Medical Association's CPT code book.

Medicare generally doesn't want to pay surgeons for E/M services or procedures performed within the 10-day or 90-day global surgery period because it's supposed to be all-inclusive, but CMS has carved out exceptions, Buonocore said. Modifier 24 is used when a physician provides unrelated E/M services and is entitled to a separate payment. The modifier is applied to two code sets: (E/M) services (99202-99499) and ophthalmology services (92002-92014). "When this modifier is submitted, supporting documentation in the form of a clearly unrelated diagnosis code and/or additional documentation must be submitted with the claim," according to a fact sheet from Palmetto GBA, a Medicare administrative contractor.[1]

Buonocore said CMS is specific about the circumstances when the modifier use is appropriate. They are described in chapter 12 of the *Medicare Claims Processing Manual*: (1) "visits unrelated to the diagnosis for which the surgical procedure is performed unless the visits occur due to complications of the surgery;" (2) "treatment for the underlying condition or an added course of treatment which is not part of normal recovery from surgery;" and (3) "critical care services (codes 99291 and 99292) unrelated to the surgery, for example where a seriously injured or burned patient is critically ill and requires constant attendance of the physician" although the critical care services are billed with a different modifier (FT).[2]

Sometimes surgeons struggle with applying the manual to real-life situations, especially when the global surgery period is 90 days, Buonocore said. They also get frustrated with billing rules around pain management in connection with the procedure. "E/M services for prescriptions for narcotic and anti-inflammatory medications or ablation of nerves are included in the global surgery period if they're directly related to the procedure," she said. "But some people might argue they're above and beyond."

The global surgery period has been hit in Targeted Probe and Educate reviews. They focused on critical care services provided during the global period, including the highest-paid E/M. If the critical care physician is in the same specialty as the surgeon, the E/M visit must be "for something other than the surgery itself," Buonocore noted.

Another challenge with modifier 24 is that Medicare and the CPT coding book treat it differently, said Richelle Marting, an attorney and certified coder in Olathe, Kansas. The CPT book allows providers to bill E/Ms separately with modifier 24 when visits are for a new problem unrelated to the procedure, for treatment of the underlying condition that prompted the procedure and for treatment of complications, exacerbation or recurrence, while Medicare won't pay for post-op visits to treat complications during the global period. That departure can lead to overbilling in circumstances where providers add modifier 24 to a claim in circumstances CPT would permit to be reported separately, "not realizing that Medicare has a different policy," she explained. But providers shouldn't assume that every private payer follows the CPT rule. To ensure compliance, they have to know whether the payer has a Medicare-like rule on modifier 24 or sticks with CPT.

Contact Buonocore at abuonocore@northwell.edu and Marting at rmarting@richellemarting.com. ✧

Endnotes

1. Palmetto GBA, "CPT Modifier 24," July 16, 2022, http://bit.ly/3JKXsmB.
2. Centers for Medicare & Medicaid Services, "Chapter 12 - Physicians/Nonphysician Practitioners," *Medicare Claims Processing Manual*, Pub. 100-04, revised February 2, 2023, https://bit.ly/3ToAipp.

CMS Adds NPP Supervision of Diagnostic Tests to Medicare Manual

In a new Medicare transmittal, CMS acknowledged the ability of nonphysician practitioners, including physician assistants and nurse practitioners, to supervise the performance of diagnostic tests.[1] It represents the morphing of a COVID-19 waiver into a permanent Medicare policy, although the manual provision comes two years after the regulatory change.

"I call it the time-traveling manual because it was issued March 16, 2023, but was effective Jan. 1, 2021,"

said attorney David Glaser, with Fredrikson & Byron in Minneapolis. "It memorializes a change that already happened. This should have been changed two years ago." Delays like this are one reason why Glaser tells providers that Medicare manuals are not binding and shouldn't be the sole basis for overpayment returns.

According to the transmittal (11,901), diagnostic tests covered by Sec. 1861(s)(3) of the Social Security Act and payable under the Medicare Physician Fee Schedule (MPFS) generally must be performed under the supervision of a physician, although the 2021 MPFS rule tinkered with this requirement. "This basic rule regarding individuals supervising the performance of diagnostic tests also includes nurse practitioners, clinical nurse specialists, certified nurse-midwives, certified registered nurse anesthetists and physician assistants," the transmittal explained. "When nurse practitioners, clinical nurse specialists, and physician assistants personally perform diagnostic tests as provided under §1861(s)(2)(K) of the Act, the supervision requirements under §1861(s)(3) of the Act and under 42 CFR 410.32 do not apply. Rather, these practitioners are authorized to personally perform diagnostic tests under the supervision requirements applicable to their practitioner benefit category pursuant to State scope of practice laws and under the applicable State requirements."

An 'Important, Positive Change'

The relaxed supervision requirement originated with one of a series of regulations CMS implemented to reduce the burdens on providers during the PHE. In the May 8, 2020, version, CMS specified that "diagnostic tests covered under section 1861(s)(3) of the Act and payable under the PFS must be furnished under the appropriate level of supervision by a physician as defined under section 1861(r) of the Act or, during the PHE, by a NP, CNS, PA, and CNM."[2]

Historically only physicians could supervise diagnostic tests, Glaser noted. "Before the pandemic the rule was pretty counterintuitive. Nonphysician practitioners could do the test, but could not supervise someone else, like a tech, doing the test," he explained. "I'm glad the manual caught up with this important, positive change."

One caveat: as the transmittal noted, diagnostic tests can't be performed incident to the physician's services.

Contact Glaser at dglaser@fredlaw.com. ✧

Endnotes

1. Update to the Manual to Clarify Supervision Requirements for Diagnostic Tests, Trans. 11,901 (March 16, 2023), https://bit.ly/4066rUK.
2. Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program, 85 Fed. Reg. 27,550 (May 8, 2020), https://bit.ly/2zpIMr2.

Consider Letters at Registration as Medicaid Redetermination Looms

On April 1, states are required to begin determining whether Medicaid enrollees are still eligible for the program, ending the uninterrupted coverage they've had for three years because of the COVID-19 public health emergency (PHE). Hospitals also have a part to play in communicating to patients the possibility they will lose Medicaid coverage, which may become a probability if they don't respond when the state reaches out, an expert said.

If large numbers of Medicaid patients are again without insurance, they will suffer and hospitals will take a financial hit, said Day Egusquiza, president of AR Systems Inc.

"Think back to 2020," Egusquiza said at a Finally Friday webinar sponsored by the Appeal Academy Feb. 17. "We were checking each eligibility with registration." It's now time to use the wayback machine because pre-PHE Medicaid enrollment rules will apply, although CMS is giving states a year to reenroll people, she explained. Hospitals and other providers should be prepared to help panicky patients who receive a letter saying the state is reviewing their eligibility for Medicaid, although they're safe for now. The states are also required to redetermine eligibility for the Children's Health Insurance Program.

Advice: Draft a Redetermination Letter

States used to screen Medicaid patients for eligibility every 30 days, but that hasn't happened for three years, she said. Now, a little more than a month before the end of the PHE May 11, states are required to start the process of redetermining eligibility for 18 million Medicaid enrollees. Egusquiza said the people who may lose Medicaid fall into two groups: enrollees who aren't eligible anymore because of improved circumstances (e.g., they got a job with insurance or can afford the marketplace) and enrollees who could still qualify but are dropped because they don't know about the redeterminations and/or the state is unable to locate them and confirm their eligibility. "Every Medicaid patient will have to make sure health and welfare has their most current address. That's step one," Egusquiza said. Otherwise, they will be automatically excluded.

She recommends hospitals draft a letter about the redeterminations and give it to all Medicaid patients at registration. The letter would direct them to the state health and welfare contact and the hospital's patient financial navigator. The patient financial navigator "is the point person within the organization for these types of issues that are dramatically impacting your patients," she explained.

It's in the interest of hospitals to help patients remain covered by insurance, although she cautions that the marketplace, with its subsidies, will be a brand-new concept for some Medicaid recipients.

"We don't want them self-pay and in the emergency department all the time, but they have to apply for subsidies," Egusquiza said. "Even if they get help with their premiums, they don't have help with copays and deductibles."

Expect some glitches with redeterminations. State health and welfare departments may call enrollees, mail them letters or tell them face to face depending on the population (e.g., nursing homes). "The letter has to have a good address," she noted. What if the agency's letter is returned? Or the enrollee doesn't return the state's message that was left on the most recent phone number the state had for that recipient? "My state said they would automatically deny coverage [to enrollees] because there's no way to get in touch with them. There's only so much caseworkers will do to get in touch with 18 million patients."

Contact Egusquiza at daylee1@mindspring.com. ✧

Compliance Checklist for the End of the COVID-19 Public Health Emergency (PHE)

Here's an excerpt of an 11-page checklist developed by PYA. View the entire checklist at https://bit.ly/3li7rpW. Contact Martie Ross, a consulting principal with PYA, at mross@pyapc.com and Kathy Reep, a senior manager with PYA, at kreep@pyapc.com.

READ ME: The end of the COVID-19 public health emergency (PHE) means the end of federal regulatory waivers and flexibilities. Providers must now roll back policies and practices implemented in reliance on those waivers and flexibilities. Unless stated otherwise, return to normal operations must be completed before May 12, 2023.

PYA has prepared this checklist to help providers identify the work to be done by that date. Rather than summarizing each waiver and flexibility (e.g., "CMS changed the timeline from 5 to 21 days"), the checklist states the rule that will be in effect following the end of the PHE (e.g., "The timeline is 5 days"). For each item, we cite the relevant regulation, as applicable.

This checklist focuses primarily on waivers and flexibilities relating to the Medicare program. It does not address the following:

- Waivers and flexibilities made permanent or terminated prior to 1/1/2022
- Reimbursement for COVID-19 vaccinations, testing, and treatment
- Modifications to Medicare value-based purchasing programs
- CMS-approved state Medicaid program waivers and flexibilities
- State and local waivers and flexibilities

Note the following are not impacted by the end of the PHE. Any changes to or discontinuation of these requirements will be the subject of separate regulatory action:

- Food and Drug Administration (FDA) emergency use authorization for COVID-19 vaccines, tests, and treatments
- Hospital and long-term care facility COVID-19-related reporting requirements
- Health care provider vaccine mandates
- Occupational Safety and Health Administration's (OSHA)'s Healthcare Emergency Temporary Standard
- Duties and obligations relating to Provider Relief Fund payments

We have categorized the waivers and flexibilities by the type of provider most directly impacted. Because a waiver or flexibility may impact more than one provider type, one should review each section to identify all relevant post-PHE changes.

This checklist is current as of the date of publication noted below. PYA will update the checklist as additional guidance becomes available. This checklist does not constitute and cannot be relied upon as legal, tax, accounting, banking, financial, or any other form of professional or other advice. We have made a reasonable effort to address all waivers and flexibilities, but we do not and cannot warrant the completeness of this checklist.

1. Applicable to Multiple Provider Types
A. Medicare Provider Enrollment 1. CMS will resume normal application processing timelines 2. Practitioners who have opted out of the Medicare program will no longer be permitted to cancel their opt-out status earlier than allowed by regulation (42 C.F.R. 405.445) 3. Effective Jan. 1, 2024, practitioners who render telehealth services from their home will be required to report their home address on their Medicare enrollment
B. Medicare Appeals All regulatory flexibilities relating to Medicare appeals (e.g., extended timeframes) will terminate
C. COVID-19 Diagnostic Testing and Reporting Providers of COVID-19 diagnostic tests will no longer be required to post cash prices for those tests; however, all hospital price transparency rules will remain in effect
D. State licensure requirements CMS will defer to state law on issues regarding licensure requirements
E. Fraud and abuse 1. Any financial arrangement with a physician entered into in reliance on the Stark Law blanket waivers must be brought into compliance with a Stark Law exception (including fair market value) or be terminated, except appropriate repayment terms agreed to prior to the end of the PHE may continue beyond that date 2. Any financial arrangements entered into in reliance on HHS Office of Inspector General's (OIG)'s FAQs regarding the application of its administrative enforcement authorities to arrangements directly connected to the PHE must be brought into compliance with the fraud and abuse laws or terminated (https://oig.hhs.gov/coronavirus/authorities-faq.asp)

Example of Item from OMIG Compliance Program Review Module

On the heels of new compliance-program requirements taking effect in New York State (see story, p. 1), the Office of Medicaid Inspector General (OMIG) will start reviewing the effectiveness of provider compliance programs in July. If providers are selected for a review, they will complete a compliance program review module posted by OMIG March 8.[1] The module also doubles as a roadmap for internal review of the requirements, which may be useful to compliance officers everywhere as they perform their own effectiveness reviews.

Element 2: Compliance Officer and Compliance Committee

18 NYCRR § 521-1.4(c)

(c) Compliance committee. The required provider shall designate a compliance committee which shall be responsible for coordinating with the compliance officer to ensure that the required provider is conducting its business in an ethical and responsible manner, consistent with its compliance program. The required provider shall outline the duties and responsibilities, membership, designation of a chair and frequency of meetings in a compliance committee charter. The required provider's designation of a compliance committee shall meet the following requirements:

(1) The compliance committee's responsibilities shall include:

(i) coordinating with the compliance officer to ensure that the written policies and procedures, and standards of conduct required by subdivision (a) of this section are current, accurate and complete, and that the training topics required by subdivision (d) of this section are timely completed;

(ii) coordinating with the compliance officer to ensure communication and cooperation by affected individuals on compliance related issues, internal or external audits, or any other function or activity required by this SubPart;

(iii) advocating for the allocation of sufficient funding, resources and staff for the compliance officer to fully perform their responsibilities;

(iv) ensuring that the required provider has effective systems and processes in place to identify compliance program risks, overpayments and other issues, and effective policies and procedures for correcting and reporting such issues; and

(v) advocating for adoption and implementation of required modifications to the compliance program.

(2) Membership in the committee shall, at a minimum, be comprised of senior managers. The compliance committee shall meet no less frequently than quarterly and shall, no less frequently than annually, review and update the compliance committee charter.

(3) The compliance committee shall report directly and be accountable to the required provider's chief executive and governing body.

2-6	**18 NYCRR § 521-1.4(c)** Did the provider have a designated compliance committee for the entire Review Period that meets the requirements of 18 NYCRR § 521-1.4(c)? Yes _____ No _____	If yes provide, as "Attachment 2-6a," documentation evidencing the provider had a designed compliance committee which may include, but is not limited to: a. a summary identifying compliance committee members and designated chair during the Review Period, including their names, titles, and from/to service dates, and b. any other dated documentation evidencing the provider had a designated compliance committee comprised of senior managers for the entire Review Period.
		If yes provide, as "Attachment 2-6b," a copy of a dated compliance committee charter along with copies of dated annual compliance committee charter reviews, or any other documentation evidencing annual compliance committee charter reviews.
		If yes provide, as "Attachment 2-6c," documentation evidencing: a. the reporting structure between the compliance committee and the organization's chief executive and governing body, and b. the compliance committee met at least quarterly during the Review Period. Such evidence may include, but is not limited to: a. organizational chart showing the reporting structure between the compliance committee and the organization's chief executive and governing body, b. quarterly reports from the compliance committee to the organization's chief executive and governing body; and c. copies of minutes from all compliance committee meetings during the Review Period.
	Please mark which months during the Review Period that the provider had a designated compliance committee that met all the requirements of 18 NYCRR § 521-1.4(c): ☐ None ☐ Jan ☐ Feb ☐ Mar ☐ Apr ☐ May ☐ Jun ☐ Jul ☐ Aug ☐ Sep ☐ Oct ☐ Nov ☐ Dec	

Endnotes

1. New York State, Office of the Medicaid Inspector General, "Compliance Library," last accessed March 16, 2023, http://bit.ly/3JFUwHF.

NYS Expands Compliance-Program Requirements

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to reconsider its compliance guidance. OIG already has a process underway to modernize program integrity and compliance information and communications.

New York's compliance-program mandate applies to all hospitals and certain other types of facilities that participate in Medicaid as well as other providers that receive more than $1 million from Medicaid per year. That threshold is new; until now it was half a million dollars.

OMIG requires provider compliance programs to satisfy the seven elements of an effective compliance program as spelled out in the regulation. What had previously been an eighth element, nonretaliation policies, has been added to the first element, which is adopting written policies, procedures and standards of conduct.

In terms of the regulatory changes, the biggest is that "having an effective compliance program in New York is a condition of payment, so there's no question OMIG has the ability to claw back payments" from providers in addition to imposing fines and penalties for failure to implement the state's compliance-program requirements, Hussar said. Until now, the consequences for not having an effective compliance program included a $5,000 penalty for every month that's been the case. "Clawing back claims could dwarf the amount in a heartbeat," he noted.

OMIG will start reviewing the effectiveness of provider compliance programs in July. If providers are selected for a review, they will complete a compliance program review module posted by OMIG March 8.[2] The module also doubles as a roadmap for internal review of the requirements (see box, p. 6). "Having the module available now is a gift," Baum said. "Providers can use it to figure out where they stand in terms of compliance with the regulations." Even if a provider believes it has a "robust compliance program, it's always a good idea to review what's in place to ensure we are doing things consistent with regulatory expectations." She emphasized providers shouldn't submit the documentation in the module to OMIG unless they're selected for a review. But it behooves providers to do internal reviews now in the event they're chosen for an OMIG review "so you're not gathering the necessary documentation at the last minute" and wondering if something in the compliance program should be enhanced, Baum said.

In another major change, OMIG has expanded its definition of "affected individuals"—i.e., the people and entities to whom the compliance program applies. In addition to employees, executives and board members, OMIG has added contractors, agents and subcontractors. "That has far-reaching implications when it comes to training," Hussar said. "People are scrambling right now. They will have to use a combination of approaches including options that don't require in-person learning" (e.g., self-learning modules, videos). Policies also will have to be distributed to contractors. But OMIG's requirement is limited in scope. "Contractors are only subject to the provider's compliance program to the extent it is related to their contracted role and responsibilities within the provider's identified risk area," OMIG said in guidance posted on its website.[3]

CMS Transmittals and *Federal Register* Regulations, March 10-March 16

Transmittals

Pub. 100-04, Medicare Claims Processing

- April 2023 Update of the Ambulatory Surgical Center [ASC] Payment System, Trans. 11,903 (March 16, 2023)
- Update to the Internet Only Manual (IOM) Publication (Pub.) 100-04, Chapter 18 Sections 50.3-50.4, and Chapter 32 Sections 130.1, 170.2 for Coding Revisions to National Coverage Determinations (NCDs)--July 2023 Change Request (CR) 13,070, Trans. 11,902 (March 16, 2023)
- April Quarterly Update for 2023 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule, Trans. 11,910 (March 16, 2023)
- Quarterly Update to the National Correct Coding Initiative (NCCI) Procedure-to-Procedure (PTP) Edits, Version 29.2, Effective July 1, 2023, Trans. 11,909 (March 16, 2023)
- Implementation of Rural Emergency Hospital (REH) Provider Type, Trans. 11,900 (March 13, 2023)
- April 2023 Update of the Hospital Outpatient Prospective Payment System (OPPS), Trans. 11,897 (March 10, 2023)
- April 2023 Integrated Outpatient Code Editor (I/OCE) Specifications Version 24.1, Trans. 11,896 (March 10, 2023)

Pub. 100-20, One-Time Notification

- Instructions Relating to the Evaluation of Section 1115 Waiver Days in the Calculation of Disproportionate Share Hospital Reimbursement, Trans. 11,912 (March 16, 2023)
- Implementation of Consolidated Appropriations Act (CAA) of 2023, Section 4143: Waiver of Cap on Annual Payments for Nursing and Allied Health Education Payments, Trans. 11,904 (March 16, 2023)

Pub. 100-02, Medicare Benefit Policy

- Revisions to Medicare Part B Coverage of Pneumococcal Vaccinations for the Medicare Policy Manual Chapter 15, Section 50.4.4.2, Trans. 11,905 (March 15, 2023)
- Update to the Manual to Clarify Supervision Requirements for Diagnostic Tests, Trans. 11,901 (March 16, 2023)

Federal Register

Final rule, correction and correcting amendment

- Medicare and Medicaid Programs, CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Implementing Requirements for Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect to Discarded Amounts; and COVID-19 Interim Final Rules; Corrections, 88 Fed. Reg. 15,918 (March 15, 2023)

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Effectiveness Reviews Are Required

OMIG requires providers to do annual reviews to determine the effectiveness of their compliance programs. The reviews must include on-site visits, reviews of records and surveys and interviews with affected individuals. Although compliance officers and other people with knowledge may conduct the reviews, they should be "independent from the functions being reviewed."

Separately, providers must review their policies and procedures to ensure they've been implemented and assess whether affected individuals are following them and whether they need to be updated, Hussar said. "They don't say how to do that and therein lies the problem," he said. "What's an objective standard to determine whether affected individuals are following policies and procedures? Providers need to be creative on how to measure that." One possibility: They could look at compliance issues and see if there's a link to people not following policies and procedures or to see if the issue is related to weak policies and procedures, Hussar said.

The regulation also requires providers to have a compliance committee and is specific about its composition and functions. "There is an expectation it will be comprised of senior managers, which may be different from some organizations that have used middle managers," Hussar said. The committee will advocate for funding for compliance officers to accomplish their goals, meet at least quarterly and report directly to the CEO and board. Baum already has a management-level compliance committee, but "we updated our charter," she said. "Providers will need to ensure their compliance committee charter is reviewed and updated at least annually."

Even when an organization appears to operate consistently with OMIG's expectations, "it's a rare bird that doesn't need improvement. That's what this is providing everybody with. Take a fresh look at your compliance program and make it fun and engaging," Baum said.

A Little Bit of Uneasiness

There are a few things about OMIG's changes, however, that give her pause. One is the requirement for providers to make lines of communication (e.g., the hotline) available to Medicaid recipients. While it's appropriate for patients to call the compliance hotline for various concerns, the hotline isn't the best place for urgent patient care concerns, Baum said. A patient or family member might mistakenly think the compliance hotline should be used for urgent medical care needs, she explained. "I have had people leave a message with the compliance hotline for potentially immediate care issues and thankfully in those instances we were able to promptly contact the correct clinical staff or department," Baum said. "That's not to say we don't address quality of care issues" but patient calls for medical issues generally aren't the stuff of compliance hotlines.

Baum also mentioned the existing annual certification process required for Medicaid providers. One way to help ensure the accuracy is to look at OMIG's compliance program review module and other resources on its website and make sure as a compliance officer you're confident about the elements your organization is certifying to and how you provide evidence that your compliance program is effective. "It will help ensure the annual certifications by the entity are accurate," Baum said.

Contact Baum at laurel.e.baum@trinity-health.org and Hussar at robert.hussar@rivkin.com. ✧

Endnotes

1. Medicaid Program Fraud, Waste and Abuse Prevention, 44 N.Y. Reg. 59 (December 28, 2022), https://on.ny.gov/3JHeFxi.
2. New York State, Office of the Medicaid Inspector General, "Compliance Library," last accessed March 16, 2023, http://bit.ly/3JFUwHF.
3. New York State, Office of the Medicaid Inspector General, *Compliance Program Guidance*, January 2023, http://bit.ly/40eNaAG.

NEWS BRIEFS

◆ **Although the waiver of the three-day qualifying hospital stay for skilled nursing facility (SNF) admissions will end May 11 when the COVID-19 public health emergency stops, and therefore SNF admissions on or after May 12 must comply with the qualifying stay requirement**, CMS has clarified its payment policy for SNF stays that straddle the end of the PHE. At a recent long-term care open-door forum, CMS said SNF stays will be covered if patients were admitted before May 11 without a three-day qualifying stay even when they're still there after May 11.

◆ **HHS Office of Inspector General has updated its work plan**, adding one item on state survey agency processes for overseeing nursing home preparedness.[1]

◆ **In a March 16 MLN Connects, CMS reminded providers to stop using the CR modifier and DR condition code when the COVID-19 public health emergency (PHE) ends at the end of the day May 11.**[2] "Since the CR modifier and DR condition code should only be reported during a PHE when a formal waiver is in place, plan to discontinue using them for claims with dates of service on or after May 12, 2023."

Endnotes

1. U.S. Department of Health & Human Services, Office of Inspector General, "Recently Added Work Plan Items," last accessed March 17, 2023, https://bit.ly/2AxFtyP.
2. Centers for Medicare & Medicaid Servies, "COVID-19: Don't Report CR Modifier & DR Condition Code After Public Health Emergency," MLN Connects, March 16, 2023, http://bit.ly/3mYKxV5.