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Report on Medicare Compliance

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

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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

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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.