Report on
MEDICARE COMPLIANCE

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

Contents



# COVID-19 Changes Content, Process of Risk Assessments; Expect to Update Them More Often

Updating their risk assessments and internal work plans may be a surreal experience for compliance officers this time around, as they account for the magnitude and complexity of COVID-19. Some of the risks are unique, and work plans will require continual adjustments, a compliance officer said.

"COVID-19 has brought a litany of risks to our organizations," said Betsy Wade, chief compliance and ethics officer at Signature HealthCARE, at a Nov. 12 webinar sponsored by the Health Care Compliance Association.[1] "We have to modify work plans to address emerging risks. Acting quickly can help us mitigate risks going forward because the pandemic is ongoing and the risk assessment should be evaluated frequently."

The HHS Office of Inspector General (OIG) already has 43 COVID-19-related items on its Work Plan, and they're all over the map, a sign of how many risks the pandemic poses to organizations and how urgently they need to adapt their risk assessments to it, Wade said. OIG and the Health Resources and Services Administration[2] are auditing compliance with the attestation and requirements for accepting Provider Relief Fund money.

*continued on p. 7*

# OIG Worksheets From Malnutrition Audit Raise Questions About Reasons for Denials, Experts Say

When the HHS Office of Inspector General (OIG) declared in July that hospitals had overbilled Medicare $1 billion in two years for severe malnutrition,[1] physician James Kennedy and compliance professional Paul Belton decided to look behind the curtain at OIG's conclusions. Kennedy submitted a Freedom of Information Act (FOIA) request to OIG for the audit worksheets and got 200 summaries of the malnutrition reviews, which shed more light on what the audits potentially mean for hospitals.

What they learned: In some cases, the reviewers hired by OIG were satisfied that patients met the American Society for Parenteral and Enteral Nutrition (ASPEN) criteria for severe malnutrition and that it was documented by the physician, which would seem to bode well for the inpatient claims. But some of the diagnosis codes were rejected anyway.

"OIG often stated the complexity of the treatment didn't support their interpretation of the coding guidelines as an additional diagnosis," Belton said. That doesn't square with the definition of an additional (secondary) diagnosis in coding guidelines and the *Coding Clinic*, said Kennedy, president of CDIMD in Nashville, Tennessee. According to the Uniform Hospital Discharge Data Set (UHDDS), secondary diagnoses are defined as "other diagnoses." For reporting purposes, "the definition of 'other diagnoses' is additional conditions that affect patient care in terms of requiring clinical evaluation, or therapeutic treatment, or diagnostic procedures, or extended length of hospital stay, or increased nursing care and/or monitoring." Any one of them would allow the coding of malnutrition on the claim, which affects MS-DRG assignment because it's a major complication and comorbidity (MCC).

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"The fact that the physician documented and addressed it is enough, given that the patient was clinically evaluated as to determine the presence of the documented diagnosis and treated in the safest manner possible," Kennedy said Nov. 4 on a podcast hosted by the Association of Clinical Documentation Integrity Specialists.[2] "It's codable." OIG's conclusions could be "putting uncertainty in the minds of coders," added Belton, former vice president of corporate compliance at Sharp HealthCare in San Diego who is now affiliated with CDIMD (see box, pp. 3-4).[3]

The other tidbit they learned from the FOIA request: The malnutrition cases were reviewed by a licensed physician and coder at a zone program integrity contractor.

The OIG audit[4] has landed hard in the compliance world. OIG selected a random sample of 200 inpatient claims worth $2.9 million with discharge dates between Oct. 1, 2015, and Sept. 30, 2017. They had severe malnutrition diagnosis codes—nutritional marasmus (E41) or unspecified severe protein-calorie malnutrition (E43)—as the sole MCC. OIG's findings: Hospitals incorrectly billed 173 claims. For nine of them, documentation supported a secondary diagnosis besides severe malnutrition, and for 164 of the claims, the billing errors caused net overpayments of $914,128. OIG said hospitals should have used codes for other forms of malnutrition or no malnutrition diagnosis codes. "On the basis of our sample results, we estimated that hospitals received overpayments of $1 billion for FYs 2016 and 2017," according to the report.

OIG recommended CMS collect the part of the $914,128 in overpayments for severe protein-calorie malnutrition and nutritional marasmus that are within Medicare's reopening period. Also, CMS should inform providers that if the audit amounts to "credible information" of potential overpayments under the 60-day rule, they should "exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule." CMS agreed.

Because of the challenges with malnutrition coding and documentation and the big dollars at stake, "compliance needs to spearhead this and walk through some traditional organizational silos," Belton said. It requires a "multidisciplinary approach" with nursing, the medical staff, nutrition, dietary, compliance and clinical documentation integrity (CDI) to establish guidelines and "champion the effort to mitigate risk."

CDI departments in particular need collaboration and coordination from compliance officers. "CDI has to be tied to the hip with the compliance officer because there is a power differential many of us in CDI have where medical staff has more power than we do," Kennedy said. "Compliance officers bring leverage to discussions and can actually call balls and strikes in setting up the structure in how this is done, because it is the role of the compliance officer to anticipate reports like this."

Kennedy and Belton encouraged hospitals to establish policies and procedures for malnutrition, which is addressed in the first quarter 2020 edition of *Coding Clinic* (pages four to seven). Otherwise, "we are rudderless in our approach," Kennedy said. Hospitals also need a "well-defined, consistent assessment tool that demonstrates that the patient meets ASPEN criteria" and that it's crystal clear the patient has malnutrition consistent with its internal policy, Kennedy said. The diagnosis should be "based on evidence the physician is monitoring the impact of dietary therapy." Also, there should be an assessment for refeeding syndrome in patients, which validates they were starving, he said. Finally, hospitals would benefit from a prebill review process for malnutrition when it's the only major complication or comorbidity, Belton said.

## One 'Surprising' Denial for Patient With G-Tube

More insights about the OIG worksheets came from physician Beth Wolf, medical director for the health information management department at Roper St. Francis Healthcare in Charleston, South Carolina, after Kennedy shared 11 samples with her. "What struck home is the reviews were comprehensive, from the emergency room to discharge," Wolf said at a webinar sponsored by RACmonitor.com on Sept. 30.[5]

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For seven of the 11 samples, the ASPEN criteria for severe malnutrition was not documented. In three of the other cases, "oral supplements and registered dietician monitoring were not considered highly complex interventions," Wolf said.

OIG's conclusion in the fourth case was surprising. A patient was admitted for aspiration pneumonia and stayed for nine days. The documentation showed a BMI of 21, severe orbital wasting, a 13% weight loss over one year and G-tube placement. The patient

continued on p. 4

## Deconstructing OIG Malnutrition Denials

Here's an analysis by James Kennedy, M.D., president of CDIMD in Nashville, and compliance professional Paul Belton, of two malnutrition cases from the HHS Office of Inspector General's $1 billion audit report on malnutrition (see story, p. 1).[1] Contact Kennedy at jkennedy@cdimd.com and Belton at 1paulbelton@gmail.com.

### Case 1 - Facts

- A review of the record indicates that the patient is a female Medicare enrollee with a medical history including *chronic obstructive pulmonary disease (COPD) and oxygen-dependence, hypertension, and non-Hodgkin's lymphoma*. The patient presented to the hospital on 12/18/2016 for increasing shortness of breath and brown phlegm. The patient was treated as an inpatient over the period 12/18/2016–1/3/2017.
- The patient's History and Physical (H&P) by the *emergency physician documented the patient's appearance as well-developed and well-nourished*, with moist oropharynx. The patient was in respiratory distress with diffuse wheezes but was afebrile and alert and oriented. Her abdomen was soft.
- A chest X-ray showed no acute findings. The patient's lab results showed elevated white blood cells (WBC), glucose level, and blood urea nitrogen (BUN) and low hemoglobin and hematocrit. The patient was admitted for medical management and was started on a cardiac diet.
- *Active problems included obesity, with BMI 30-34.9kg/m$^2$.*
- A nutrition assessment on 12/23/2016 documented that the patient's weight was 82.4kg and body mass index (BMI) was 35.5kg/m$^2$.
- *The assessment noted that, per chart review, the patient had not had recent weight loss*. Inadequate oral intake related to decreased appetite, and illness as evidenced by patient eating 25%-75% of meals, was documented.
- *The intervention was to trial Carnation Instant Breakfast (CIB) with lunch and monitor meal and supplement intakes*; follow-up was planned in 3-4 days due to the holiday. The goal was for oral intake >/= 50% of meals and consumption of nutrition supplement.
- On 12/24/2016, the nurse documented encouraging adequate intake. *Albumin level was low (2.9) on 12/27/2016*. Ensure pudding was added with lunch and dinner in place of CIB due to fluid restriction, per dietitian note on 12/27/2016; the patient was eating 75% of meals. By 1/2/2017, the patient was consuming 50-75% of meals and 100% of CIB at breakfast.

| Clinical Factors for Review | Support in Record |
|---|---|
| **Nutritional Marasmus or Other Severe Protein-Calorie Malnutrition Hospital Claims** | |
| **Did the patient medically have Nutritional Marasmus or suffer from severe malnutrition of any type?**<br>SSA § 1862, 42 C.F.R. § 424.5(a)(6) | No |
| **Was the assignment of diagnosis code E41 (Nutritional Marasmus) and/or E43 (Unspecified Severe Protein-Calorie Malnutrition) adequately supported by the documentation contained in the medical record? If not, what malnutrition diagnosis code, if any, was supported by the medical records?**<br>CMS Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 1, § 10 Covered Inpatient Hospital Services; *Journal of the Academy of Nutrition and Dietetics.* May 2012; Volume 112, Issue 5: Pages 730-738. Consensus Statement of the Academy of Nutrition and Dietetics/American Society for Parenteral and Enteral Nutrition: Characteristics Recommended for the Identification and Documentation of Adult Malnutrition (Undernutrition). | No<br>None |
| **Is the DRG assignment substantiated by the patient's diagnoses and procedures?**<br>CMS Publication 100-08, *Medicare Program Integrity Manual*, Chapter 6, § 6.5.3 DRG Validation Review. CMS Publication 100-04, *Medicare Claims Processing Manual*, Chapter 1, § 80.3.2.2. | No |

### Rationale

- Review of the medical records found that there was no weight loss documented.
- The patient was obese. It is difficult to establish malnutrition with modest weight loss in an obese person. Patients whose BMIs are in the obese or very obese range can be deficient in micronutrients. However, no documentation of micronutrient deficiency was provided in this patient's record.
- The patient was eating; there is no evidence of inadequate intake.
- This patient's serum albumin was noted to be 2.9, below the normal range. However, this patient was given prednisone to treat an acute COPD exacerbation. Prednisone is known to depress serum albumin levels in proportion to dosage level. In the setting of steroid dosing, serum albumin is not a reliable measure for determining malnutrition risk.
- The dietary interventions were more consistent with prevention of malnutrition. There was no specific medical management of malnutrition; the dietary interventions were nonspecific; there were no complications from malnutrition, and malnutrition did not complicate the clinical course. No specific malnutrition diagnosis is evident.

## Case 3 - Facts

- The patient's History and Physical (H&P) documented that the patient was alert, but not oriented on examination. A complete review of systems was unobtainable secondary to the patient's mental condition. The patient had dry mucous membranes, and the abdomen was noted to be soft and nontender, with normal bowel sounds.
- **The record indicated that the patient had little oral intake and had severe protein-calorie malnutrition present on admission**.
- Functionally, the patient required assistance and had very limited mobility.
- **There was no obvious comprehensive nutritional assessment found in the record provided, and none was provided on request.**
- The record contained an admission high-risk nutrition score completed on 10/2/2016, which the patient was rated a two and a daily nutritional risk score was documented as three (eight or higher prompted a registered dietitian assessment within 48 hours).

| Clinical Factors for Review | Support in Record |
|---|---|
| **Nutritional Marasmus or Other Severe Protein-Calorie Malnutrition Hospital Claims** | |
| **Did the patient medically have Nutritional Marasmus or suffer from severe malnutrition of any type?**<br>SSA § 1862, 42 C.F.R. § 424.5(a)(6) | Yes |
| **Was the assignment of diagnosis code E41 (Nutritional Marasmus) and/or E43 (Unspecified Severe Protein-Calorie Malnutrition) adequately supported by the documentation contained in the medical record? If not, what malnutrition diagnosis code, if any, was supported by the medical records?**<br>CMS Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 1, § 10 Covered Inpatient Hospital Services; *Journal of the Academy of Nutrition and Dietetics.* May 2012; Volume 112, Issue 5: Pages 730-738. Consensus Statement of the Academy of Nutrition and Dietetics/American Society for Parenteral and Enteral Nutrition: Characteristics Recommended for the Identification and Documentation of Adult Malnutrition (Undernutrition). | No<br>None |
| **Is the DRG assignment substantiated by the patient's diagnoses and procedures?**<br>CMS Publication 100-08, *Medicare Program Integrity Manual*, Chapter 6, § 6.5.3 DRG Validation Review. CMS Publication 100-04, *Medicare Claims Processing Manual*, Chapter 1, § 80.3.2.2. | No |

## Rationale

- Review of the medical records found that documentation does not support the diagnosis of severe protein-calorie malnutrition.
- The patient medically had severe protein-calorie malnutrition, with a BMI of 15 kg/m$^2$, in association with being a debilitated patient with limited mobility and advanced dementia, although there is no documentation of other criteria present in the record.
- **However, while the patient was severely malnourished, the nutritional condition did not affect the length of stay or treatment plan; the nutritional interventions were not complex and consisted of offering an oral diet.**
- The Medicare criteria were not met to support the secondary diagnosis of severe protein-calorie malnutrition.

### Endnotes

1. Nina Youngstrom, "OIG Worksheets From Malnutrition Audit Raise Questions About Reasons for Denials, Experts Say," *Report on Medicare Compliance* 29, no. 41 (November 16, 2020).

*continued from p. 3*

met ASPEN criteria for severe malnutrition. "Despite that description, the reviewer did not consider this a highly complex intervention and felt the treatment plan and length of stay were not affected," Wolf said. "I was a little surprised by that. It's helpful to peek behind the curtain and see how they are interpreting some of the rules they are citing related to the coding and reporting of diagnoses."

### Tension Between Prevalence and Denials

Hospitals are in a quandary because severe malnutrition should be identified to improve patient outcomes, but it's a "significant audit risk," Wolf said. According to the Agency for Healthcare Research and Quality's 2016 Healthcare Cost and Utilization Project (HCUP),[6] 2.2 million adult hospitalizations were related to malnutrition, which was about 8% of the hospital stays. But the *Journal of Hospital Medicine* reported in 2013 that between 20% and 50% of adult hospitalized patients are malnourished.[7]

"It is fair to say we are underdiagnosing and undercoding it in adult patients," Wolf said. The gap between the prevalence and coding of malnutrition can be closed with nutritionist-led programs in the hospital setting.

She noted malnutrition's other side effects. According to the HCUP, length of stay is twice as long than in patients without malnutrition; 30-day readmissions are 1.6 times higher in patients with malnutrition; hospital costs are twice as much as the average cost of all hospital stays; and the death rate is three times more than the average death rate.

To help support a malnutrition diagnosis, hospitals should identify and address documentation gaps, Wolf said. One aspect is writing queries to get clarification

from the physician about the diagnosis. "We want to be clear and concise," she said. "It's all about the communication. If you wouldn't stand in front of physicians and read your query out loud to them, you probably need to rethink how you're writing them."

Queries should include clinical indicators from the health record, present the facts identifying why a clarification is required and comply with the practices in the query practice brief published by the American Health Information Management Association. But steer clear of information on how the diagnosis will affect reimbursement or quality measures.

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**Endnotes**

1. Nina Youngstrom, "OIG: Hospitals Overbilled $1B for Malnutrition, CMS Will Recoup; Other Audits to Resume," *Report on Medicare Compliance* 29, no. 26 (July 20, 2020), https://bit.ly/33IYlHo.
2. James Kennedy, Paul Belton, Laurie Prescott, "Severe malnutrition: Review of OIG worksheets," *ACDIS Podcast*, November 4, 2020, https://bit.ly/2IuQLrV.
3. Nina Youngstrom, "Deconstructing OIG Malnutrition Denials," *Report on Medicare Compliance* 29, no. 41 (November 16, 2020).
4. Christi A. Grimm, "Hospitals Overbilled Medicare $1 Billion By Incorrectly Assigning Severe Malnutrition Diagnosis Codes to Inpatient Hospital Claims," OIG, July 2020, https://go.usa.gov/xfbJE.
5. Beth Wolf, "Severe Malnutrition: Keys to Validating Documentation and ICD-10-CM Coding," webcast, September 30, 2020, https://bit.ly/38FwACc.
6. Agency for Healthcare Research and Quality, Healthcare Cost and Utilization Project, *Non-Material and Non-Neonatal Inpatient Stays in the United States Involving Malnutrition 2016*, August 30, 2018, https://bit.ly/3nh6oC2.
7. Lisa L. Kirkland et al., "Nutrition in hospitalized patient," *Journal of Hospital Medicine* 8, no. 1 (January 2013), 52-58, https://doi.org/10.1002/jhm.1969.

## In Mid-Contract Change, Payers Deny Certain Specialty Drug Payments

With the stroke of a pen, some commercial payers are now denying payments for specialty drugs unless hospitals buy them from certain pharmacies, a development that's not sitting well with hospitals for financial and patient-care reasons, attorneys say. The so-called white-bagging policies are positioned as "amendments" or "expansions" to contracts, but attorneys said they are unilateral changes to terms in the middle of a contract, and hospitals have grounds to fight them.

Commercial payers are carving out high-cost drugs midway through negotiated contracts and requiring hospitals to buy them from nonhospital suppliers on lists approved by the payers, said attorney Jim Boswell, with King & Spalding in Atlanta, Georgia, at a Nov. 11 webinar sponsored by the firm. "For some providers, it's millions of dollars a year because it's taking a category of items that had been under the contract and that were going to be paid at the negotiated price above cost and moving it out of the contract entirely," he said.

A few examples:

- In August, Cigna announced[1] that "Per our Specialty Medical Injectables with Reimbursement Restriction guidelines, certain specialty medical injectables administered in the outpatient setting must be dispensed and their claims must be submitted by a specialty pharmacy with which Cigna has a reimbursement arrangement. We will not reimburse facilities that purchase these injectables directly from specialty pharmacies, manufacturers, or wholesalers. The Specialty Medical Injectables with Reimbursement Restriction list only applies to providers who bill Cigna using a hospital fee schedule; it does not apply to those who bill Cigna using their own physician fee schedules."
- Effective Oct. 1 (delayed from April 1), UnitedHealthcare[2] said, "We are expanding our existing specialty pharmacy requirements such that hospitals will be required to obtain certain specialty medications from the specialty pharmacies listed in the table below, unless otherwise authorized by us....In the event a hospital does not obtain the specialty medication through the specialty pharmacy listed below, UnitedHealthcare will issue a denial of payment for the medication for failure to follow the protocol. Hospitals may not bill members for medication that is denied for failure to follow the protocol."
- Anthem Blue Cross in California said, "Providers will be required to obtain specialty pharmacy medications administered in the office or outpatient hospital setting through CVS Specialty effective July 1, 2020."[3]

### 'This Is a Widespread Problem'

Although specialty drugs are the latest focus, some payers also have amended contracts unilaterally to deny payment unless hospitals use certain facilities for imaging or outpatient surgery, Boswell said. "This is a widespread problem that memos are being issued in the middle of a contract term that are basically moving whole areas of the contract out," he contended.

Specialty drugs and biologicals are used to manage highly complex, often chronic diseases, such as cancer, rheumatoid arthritis and multiple sclerosis. The expensive drugs typically aren't stocked at retail pharmacies and

come from hospital pharmacies, or at least they did before the policies were implemented, Boswell noted.

In addition to the effect of white-bagging policies on their finances, hospitals are concerned about the ramifications for patient care and the supply chain, said attorney Jennifer Lewin, with King & Spalding in Atlanta. Hospitals want to be sure specialty pharmacies maintain the same patient safety standards and quality control as their in-house pharmacies, Lewin explained. There are other concerns around getting the drugs in time for the patient's appointment "and the potential to increase medical waste" if delivery is delayed.

Lewin said payers explain white-bagging policies in a few ways. Payers are still covering the drugs and don't interfere with how physicians administer them. "Payers say the policies save money, and employers want to find a way to control specialty pharmacy costs," Lewin explained. The policies aren't new, payers contend; they're just being expanded.

### Keep an Eye Out for Protocols, Amendments

Provisions in some health plan contracts can open the door to white-bagging policies, said attorney Daron Tooch, with King & Spalding in Los Angeles. Hospitals may agree to be bound by protocols, manuals and policies. He recommends hospitals resist these terms. Instead, contracts could say that "hospitals will use reasonable efforts to comply with protocols" or that protocols are for administrative purposes (e.g., utilization review, peer review), not for reimbursement or clinical issues, Tooch said. "There are ways to mitigate language so hospitals are not bound by every new protocol or manual change."

Payers also may drop notice amendments on hospitals. They send letters informing hospitals of an amendment to the contract that will take effect unless they object. "I know of no industry where this is accepted—where one party can amend the contract with notice," Tooch said. "It's language we have been fighting. It's not easy to get rid of the language, but there are ways to soften it."

Hospitals also may be successful in arbitration in "attacking changes to policies and manuals," he said. For example, amendments must be agreed to in writing by both sides.

Extracting specialty drug payments from contracts with hospitals also upsets the delicate balance of pricing they agree to during negotiations with payers, Boswell said. Specialty drugs were included at the time hospitals negotiated the contracts and figure into the prices they accepted for a variety of services based on historical utilization and rates, he said. "Ultimately dollars were moved around in the contract so the hospital agreed to lower emergency department rates because of what it would receive for outpatient high-cost drugs," for example, he explained. "If the hospital had known the plan would enact a new policy of carving out high-cost drugs, it would have negotiated differently. It changes basic negotiation assumptions." He alleged this could be the basis for a breach of contract argument that the hospital has been deprived the value of the contract it negotiated. "If someone merely sends a letter and objects, it's not likely to produce any change," Boswell said.

There are other possible responses to white-bagging policies. The first step is for hospitals to object. "That's

## CMS Transmittals and *Federal Register* Regulations, Nov. 6-12

### Transmittals

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

- Internet Only Manual Update, Pub. 100-04, Chapter 11 - This Change Request (CR) Rescinds and Fully Replaces CR 11807, Trans. 10453 (Nov. 9, 2020)
- Home Health Prospective Payment System (HH PPS) Rate Update for Calendar Year (CY) 2021, Trans. 10439 (Nov. 6, 2020)
- Updates to Skilled Nursing Facility (SNF) Patient Driven Payment Model (PDPM) Claims, Trans. 10448 (Nov. 6, 2020)
- Instructions for Retrieving the 2021 Pricing and Healthcare Common Procedure Coding System (HCPCS) Data Files through CMS' Mainframe Telecommunications Systems, Trans. 10440 (Nov. 6, 2020)

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

- Implementation of the Award for the Jurisdiction 6 Part A and Part B Medicare Administrative Contractor (J-6 A/B MAC), Trans. 10452 (Nov. 6, 2020)

**Pub. 100-02, Medicare Benefit Policy Manual**

- Implementation of Changes in the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Payment for Dialysis Furnished for Acute Kidney Injury (AKI) in ESRD Facilities for Calendar Year (CY) 2021, Trans. 10451 (Nov. 6, 2020)
- Home Health Manual Update to Incorporate Allowed Practitioners into Home Health Policy, Trans. 10438 (Nov. 6, 2020)

### *Federal Register*

**Final Rules**

- Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program, 85 Fed. Reg. 71,398 (Nov. 9, 2020)

**Interim Final Rule With Request for Comments**

- Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, 85 Fed. Reg. 71,142 (Nov. 6, 2020)

**Notices**

- Medicare Program; CY 2021 Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts, 85 Fed. Reg. 71,916 (Nov. 12, 2020)
- Medicare Program; Medicare Part B Monthly Actuarial Rates, Premium Rates, and Annual Deductible Beginning January 1, 2021, 85 Fed. Reg. 71,904 (Nov. 12, 2020)
- Medicare Program; CY 2021 Part A Premiums for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement, 85 Fed. Reg. 71,913 (Nov. 12, 2020)

a given. Is it enough? Often it's not," Boswell noted. Another option is for hospitals to terminate their agreement due to a material change if the agreement allows that, although providers often are loathe to do that. They also could decline to service patients from payers with white-bagging policies, but it's not a great idea in terms of continuity of care and liability. Litigation also is an option to reverse white-bagging policies.

"The best solution is to address it in contracting," he said. Contracting language can "prospectively and preemptively address them."

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**Endnotes**

1. Cigna, "List of Specialty Medical Injectables with Reimbursement Restriction," updated August 2020, https://bit.ly/3eUysIv.
2. UnitedHealthcare, "Expansion of the Requirement to Use a Participating Specialty Pharmacy Provider for Certain Medications — UnitedHealthcare Commercial Plan Members, Effective April 1, 2020," *UnitedHealthcare Network Bulletin*, January 2020, 31, https://bit.ly/38AirX5.
3. Anthem, "CVS Specialty: Our designated specialty pharmacy," *California Provider Communications*, June 1, 2020, https://bit.ly/32DXhDB.

## COVID-19 Has Changed Risk Assessments

*continued from page 1*

"Since the beginning of March, I have worked every day and every weekend," Wade remarked. "My focus solely has been on changes in local, state and federal laws and regulations and how they are affecting us. We are in 10 states, and it's a lot to keep up with." Complicating matters, the waivers and flexibilities aren't always consistent between CMS and the states or among the states. In that circumstance, Signature, which has long-term care facilities, home health agencies, telehealth and other services, has different policies. "We would go with the state that issued the guidance or with CMS, whichever was stricter," she explained. "It does create challenges for us because we end up having policies that are different." For example, CMS and states have put out various visitation requirements at skilled nursing facilities, and they have been modified over time. "It's a perfect example of how stuff has changed every day," she noted. Signature has grids and software to try to keep track of everything.

And CMS and OIG are far from the only source of regulatory tinkering. For example, there have been changes from the Occupational Safety and Health Administration (OSHA), which implemented new requirements for respiratory care. "Almost every week we are doing education with all stakeholders to make sure they understand the latest laws and regulations," Wade said.

Although she said it should be widely known, risk assessments are "foundational" to compliance programs. They're highlighted in the Department of Justice compliance program effectiveness guidance, *Evaluation of Corporate Compliance Programs*,[3] and in OIG's guidance, *Measuring Compliance Program Effectiveness: A Resource Guide*.[4] Risk assessments also are required in corporate integrity agreements.

The list of areas that COVID-19 has affected is astoundingly long. In addition to the regulatory risks, here are a few examples of some challenges organizations are facing, Wade said:

- **Clinical**: Organizations have had to change the way they test, treat and isolate patients and screen staff in compliance with Centers for Disease Control and Prevention (CDC) requirements. They also are dealing with visitor restrictions, which in some cases were relaxed, "but now we're facing another surge," she noted. And there are staffing challenges because some clinicians are sick, exhausted and/or unwilling to work.
- **Environmental**: There are new infection control standards and changes in personal protective equipment (PPE) and virus prevention technology (e.g., temperature check stations). Also, "we had to change the air handling in facilities to make sure the virus is not spread from one room to another."
- **Financial**: The losses have mounted as anxious patients stayed away from in-person visits and hospitals delayed elective procedures, and after a rebound, this may be recurring as the number of coronavirus infections climb. At the same time, organizations shelled out more money in overtime and "hero pay," as well as for PPE.
- **Operational**: Employees started working remotely, sometimes with a lack of controls, and there's greater use of technology, which brings cybersecurity threats. She also mentioned supply chain disruptions.
- **Reputational**: This includes more government scrutiny and critical media coverage of COVID-19 infections and deaths, and poor performance on infection control surveys.

### Key Steps of a Risk Assessment

In light of COVID-19's immense impact, compliance officers have their work cut out for them with risk assessments, Wade said. She recommended an expanded team because of the pandemic. In addition to the usual suspects (e.g., compliance, risk management, legal, operations), consider adding clinicians and infection control experts.

The team will identify risks, with an emphasis on document review. That includes emergency orders

from the state and federal government; waivers and regulations from CMS, OSHA and other agencies; and CDC guidance. It should also include the OIG Work Plan, which includes audits of the 20% Medicare bonus payments for COVID-19 MS-DRGs, Provider Relief Fund distributions to hospitals, and Medicare telehealth services, to name just a few. Another source is information from infection control and other surveys at your facility.

Next, compliance officers should interview senior leadership and board members about their perceptions of the impact of COVID-19 on the organization and their concerns about 2021.

Data mining also should be center stage in risk assessments. "It can help you pinpoint where you have potential problems," she noted. They could include coding and billing patterns, reporting of COVID-19 positive cases in compliance with CDC guidance and telemedicine usage. It's also a good idea to look closely at new suppliers to make sure they passed exclusion screening and criminal background checks.

After compliance officers have gathered all the information, they can prioritize the risks, manually or with software. Signature uses a software program that generates a heat map, which ranks the risks by how likely they are to materialize and how much damage they potentially could cause. There are other ways to prioritize risks. For example, they can be given red, yellow or green lights to indicate a low, medium or high risk, or be ranked numerically.

With its risk ranking in hand, Signature does a compliance plan, a compliance monitoring plan and an internal audit plan, Wade said. The compliance plan is a list of actions (e.g., revise a policy) in response to changes in regulations. The compliance monitoring plan involves looking at probe samples to identify trends that require an expanded review. And the internal audit plan focuses on a statistically valid audit of items by the internal audit department. Work plans are approved by the compliance committee and board.

After the work is completed, departments that were audited develop corrective action plans where necessary and follow up to test the effectiveness of the corrective action plans. All this activity should be documented ad nauseam, Wade said. "It's important to be very organized so it's easy to pull the information when you're being reviewed."

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### Endnotes

1. Betsy Wade, "Re-evaluating Your Risk Assessment Process Post-Pandemic and Pivoting Your Action Plans," Health Care Compliance Association (webinar), November 12, 2020, https://bit.ly/32Gp0ne.
2. Nina Youngstrom, "HRSA Plans Several Audits of Provider Relief Fund; Reporting Requirements Raise Alarm," *Report on Medicare Compliance* 29, no. 36 (October 12, 2020), https://bit.ly/3psPG4H.
3. U.S. Dep't of Justice, Criminal Div., *Evaluation of Corporate Compliance Programs* (Updated June 2020), http://bit.ly/2Z2Dp8R.
4. HCCA-OIG Compliance Effectiveness Roundtable, *Measuring Compliance Program Effectiveness: A Resource Guide*, March 27, 2017, http://bit.ly/2V8dajN.

## NEWS BRIEFS

◆ **Virginia obstetrician-gynecologist Javaid Perwaiz was convicted by a jury Nov. 9 on 52 counts in connection with a scheme to bill insurers millions of dollars for hysterectomies and other surgeries and procedures that weren't medically necessary**, the U.S. Attorney's Office for the Eastern District of Virginia said.[1] In many cases, Perwaiz told his patients they needed surgeries to avoid cancer. "The evidence at trial also demonstrated that Perwaiz falsified records for his obstetric patients so that he could induce their labor early, prior to the recommended gestational age that minimizes risk to the mother and baby, to ensure he would be able to conduct and be reimbursed for the deliveries," the U.S. attorney's office said. He faces a maximum penalty of 465 years in prison and is scheduled for sentencing on March 31, 2021.

◆ **Eranga Cardiology P.A. and physician Eranga Haththotuwa have agreed to pay $500,000 to settle false claims allegations**, the U.S. Attorney's Office for the District of Delaware said Nov. 12.[2] Eranga Cardiology, which has locations in Milford and Dover, submitted Medicare and Medicaid claims for cardiology procedures that also require interpretive reports. According to the U.S. attorney's office, the practice didn't generate the interpretive reports from April 2014 to March 2020. They didn't admit liability in the settlement.

◆ **In the 11th case under its Right of Access Initiative, the HHS Office for Civil Rights (OCR) said Rajendra Bhayani, an otolaryngologist in Regal Park, New York, has agreed to pay $15,000 and take corrective actions to settle a potential violation of the HIPAA Privacy Rule**.[3] OCR said it got a complaint in September 2018 that the physician didn't grant a patient's request for access to her medical records in July 2018. "OCR responded by providing Dr. Bhayani with technical assistance on complying with HIPAA's Right of Access requirements and closed the complaint," according to its news release. A year later, however, the patient told OCR the physician still hadn't given her access. OCR determined the failure potentially violated HIPAA's right of access standard. "As a result of OCR's investigation, the complainant received a complete copy of her medical records in September 2020," OCR said. Bhayani didn't admit liability in the resolution agreement.

### Endnotes

1. Department of Justice, "Jury Convicts Doctor of Scheme to Perform Unnecessary Surgeries on Women," news release, November 9, 2020, https://bit.ly/35btPGO.
2. Department of Justice, "Eranga Cardiology To Pay $500,000 To Resolve Health Care Fraud Allegations," news release, November 12, 2020, https://bit.ly/35taf91.
3. HHS, "Bhayani HIPAA Resolution Agreement and Corrective Action Plan," resolution agreement, October 22, 2020, https://bit.ly/38JSbJN.