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

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As Interest in SDOH Grows, Hospitals May Turn to CMP Exceptions, Privacy Rule Proposal

As part of its initiative to increase education for at-risk populations, a hospital threw baby showers for low-income expectant mothers. The moms-to-be received takeaway baskets with diapers and other goodies to help them with their newborns only after they attended prenatal education classes. Although the program, a hypothetical, has good intentions, it could expose the hospital to risks under fraud and abuse laws, including the civil monetary penalty (CMP) law prohibiting beneficiary inducements.[1] But there are fraud and abuse exceptions that allow hospitals to provide noncash goods and services that are nominal and/or promote access to care, and hospitals may increasingly capitalize on their availability as they address the social determinants of health (SDOH), said Danette Slevinski, chief compliance officer and HIPAA privacy program executive at University Hospitals in New Jersey. At the same time, doors may open wider for SDOH programs because of proposed revisions into the HIPAA privacy rule affecting care coordination and case management.[2]

It would be important for the baby showers not to include giveaways of "diamond-studded diaper bags," Slevinski said. But if the pregnant women received some basic necessities valued at less than a total of $75, the items would likely fall within the exception for annual per-person gifts under the beneficiary inducement prohibition of the CMP law. To help properly structure a program like this, the hospital should review advisory opinions from the HHS Office of Inspector General on the provision of similar types of items to patients.

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Errors in References Could Undo Claim Denials; DRG Validations Hit on Multiple Fronts

In a vivid example of why hospitals should pore over the references that auditors use to deny claims, the secondary diagnosis of blood loss anemia was removed from a Midwest hospital's claim for a male patient's admission based partly on several resources that weren't relevant or binding, an attorney said. They included an American College of Obstetricians and Gynecologists' practice bulletin on postpartum hemorrhage, Common Terminology Criteria for Adverse Events (CTCAE), and a well-known blog.

"CTCAE is a set of criteria for reporting adverse events of cancer therapy. This patient did not have cancer," said Richelle Marting, an attorney and certified coder in Olathe, Kansas. The postpartum article obviously isn't relevant to a man, and blogs aren't binding.

The use of references that don't support the reasons for removing a secondary diagnosis from a claim or denying the claim, sometimes in the form of outdated coding guidance, is not uncommon, she noted. It's a compelling avenue of appeal as hospitals straddle three parallel worlds: DRG validation, clinical validation (or both simultaneously for the same claim), and "holding payers accountable" to policies and

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HCCA

Managing Editor
Nina Youngstrom
nina.youngstrom@hcca-info.org

Senior Copy Editor
Bill Anholzer
bill.anholzer@hcca-info.org

contract terms that may be independent of the merits of a claim denial. The reason for the Medicare Advantage plan or commercial payer's denial—coding or clinical—may not always be clear. DRG and clinical validations may be conflated by payers and the audit contractors they hire to review claims, she said, and "sometimes I write up an appeal that addresses both just in case."

Against this backdrop, Marting suggested hospitals highlight information in their response to documentation requests that supports the substance of the claims and ties it back to contract provisions, policy language or manual language. When the volume of the payer's denials of claims and appeals crosses a certain threshold, particularly where a trend is identified, they may be elevated to managed care contracting and senior hospital leaders, who can reach out to the payer's senior leaders. "The hospital can say, 'This is becoming a big issue,'" Marting said. She said this strategy has started to improve one major health plan's behavior vis-à-vis the Missouri hospital that she appeals claim denials for.

DRG Validation Is 'Affecting More Dollars'

DRG validation is "affecting more dollars," Marting said at an Oct. 6 webinar sponsored by the Health Care Compliance Association.[1] The purpose of DRG validation is to determine whether principal and secondary diagnoses and procedures that potentially affect the MS-DRG match the information in the patient's medical record, including the attending physician's description.

Among other things, DRG validation reviews focus on the sequencing of the principal diagnosis, which is the "condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital for care," as defined by the Uniform Hospital Discharge Data Set (UHDDS). Payers often elbow aside the condition reported by the hospital as the principal diagnosis and substitute another condition, which may reduce MS-DRG reimbursement, Marting said.

This often plays out with respiratory conditions, including pneumonia, acute respiratory failure, chronic obstructive pulmonary disease (COPD) exacerbation, COVID-19 and asthma. Any one of them may be an "interrelated condition" if it equally meets the definition of a principal diagnosis and can be sequenced first according to coding guidelines, Marting said. "Just because the payer would choose a different condition as the principal diagnosis does not mean the hospital has committed any coding errors, and if the hospital is equally correct, there is no coding error to attempt to recover payment for."

In pointing this out to payers in an appeal, hospitals can cite the *ICD-10-CM Official Coding and Reporting Guidelines*, which state that "when there are two or more interrelated conditions (such as diseases in the same ICD-10-CM chapter or manifestations characteristically associated with a certain disease) potentially meeting the definition of principal diagnosis, either condition may be sequenced first, unless the circumstances of the admission, the therapy provided, the Tabular List, or the Alphabetic Index indicate otherwise."[2]

She noted that some payers are removing acute respiratory failure as the principal diagnosis based on 2003 guidance from *Coding Clinic* even though it was superseded by the American Hospital Association's newsletter in 2005.[3]

Code for Sepsis Is the Same, Whatever the Criteria

Clinical validations are different from DRG validations, but Marting said the result can be the same: a lower-paying MS-DRG. With clinical validations, payers often accept the condition was diagnosed and documented, but a reviewer, who should be a clinician (e.g., registered nurse under a physician's supervision) reviews the medical records for underlying clinical indicators and lab values to determine whether the physician's diagnosis is supported. Sepsis diagnoses are a popular target of clinical validation, she said. Physicians may apply Sepsis-2 criteria when diagnosing a patient, and the payer may remove the diagnosis even

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though it's supported by the documentation because the payer requires Sepsis-3 criteria.

Here's where it gets tricky with the interplay between DRG validation and clinical validation, Marting said. As *Coding Clinic* explained, "Regardless of whether a physician uses the new clinical criteria for sepsis, the old criteria, his personal clinical judgment, or something else to decide a patient has sepsis (and document it as such), the code for sepsis is the same—as long as sepsis is documented, regardless of how the diagnosis was arrived at, the code for sepsis can be assigned."[4] But some auditors are "conflating the two concepts," Marting said. When that happens, they may have blown their basis for a denial out of the water, especially if they haven't adopted a formal policy on Sepsis-3.

"It's really important to focus on payer contracts," she said. Payer contracts often must establish and make material policies, procedures and manuals available to providers before rules take effect. "If they haven't done that, some contracts may require payers to withdraw adverse findings," Marting said.

Payers Are Confusing Ileus Codes

Payers also try to remove secondary diagnoses from the claim on the grounds there's no evidence that treatment was directed at the condition, she said. This is common with hyponatremia even though the patient's sodium level was low and the physician documented the diagnosis. To appeal these denials, Marting relies on the UHDDS, which defines secondary diagnoses as "other diagnoses," and 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." The operative word in this definition is "or"; any one of the five scenarios would allow the coding of a secondary diagnosis on the claim. With hyponatremia, for example, serum sodium monitoring or nursing assessment would meet the definition of a secondary diagnosis. "I have even had payers say the IV hydration patients received cannot count because there's no documentation it's linked to hyponatremia," she noted.

Secondary diagnoses also may be knocked off claims when they're described differently by the attending physician vs. consultants, Marting said (see box, p. 4).[5] Payers contend the documentation is conflicting, but often the specialist is elaborating on the diagnosis. It's one thing if there's a true diagnosis conflict in the medical record, but another thing altogether if consultants are providing more detail based on their clinical expertise.

She also sees payers remove secondary diagnoses for post-operative conditions. A common one is post-operative ileus, even though the coding has changed. "The Alpha Index previously defaulted to a complication code," she said. "Providers were reluctant to assign a complication code because it may look like adverse events after surgery even though it's a common event after surgery." As a result, a new code was created to report the presence of the condition, even if it wasn't characterized as a complication by the provider. But payers are still confusing the new code with a complication. "These concepts are different and the coding is different," she said. When the physician verifies ileus is a post-op complication, coders should use K91.89 (Other postprocedural complications and disorders of digestive system), Marting said. But they should assign K56.7 (Ileus, unspecified) as an additional diagnosis to describe the specific complication. However, if an ileus is present after surgery, but not characterized as a complication, K56.7 is assigned by itself.

Hold Payers to Their Own Deadlines

There are avenues for thwarting denials and winning appeals that have nothing to do with the substance. "When developing your appeal strategy, think about whether there are any legal, statutory, contractual or policy issues you can raise outside the merits of the coding issues," Marting said. "The answer is usually yes." For example, your Medicare Advantage plan or commercial payer contract may only allow an audit look-back period of one year, and the claim may stretch back further. Also, state laws may cap the time insurers can request refunds in postpayment reviews, she said. It's 12 months in Missouri from the date of initial payment, for example, and 18 months in Kansas. She recommends hospitals track the date of the medical records request and raise the issue before sending in medical records if payers are past it.

A secret weapon: sometimes appeals are successful because Medicare Advantage plans and payers don't follow through and recoup the supposed overpayment. She has watched this happen time and again.

Contact Marting at rmarting@richellemarting.com. ✧

Endnotes

1. Richelle Marting, "Common DRG Validation Denial Reasons and Strategies for Appealing Them," webinar, Health Care Compliance Association, October 6, 2021.
2. CMS and National Center for Health Statistics, *ICD-10-CM Official Guidelines for Coding and Reporting: FY 2021 – UPDATED January 1, 2021 (October 1, 2020 - September 30, 2021*, CDC, last accessed October 28, 2021, https://bit.ly/34GFlrG.
3. American Hospital Association, *Coding Clinic*, first quarter, 2005, 3-4.
4. American Hospital Association, *Coding Clinic*, fourth quarter, 2016, 147-149.
5. Nina Youngstrom, "Example of How Payers Remove Secondary Diagnoses From Claims," *Report on Medicare Compliance* 30, no. 39 (November 1, 2021).

Example of How Payers Remove Secondary Diagnoses From Claims

Payers and/or their auditors may contend that inconsistent documentation is grounds to remove a diagnosis, said Richelle Marting, an attorney from Olathe, Kansas. But there is support from coding guidelines to appeal this and the other denials stemming from DRG validations (see story, p. 1).[1] Contact Marting at rmarting@richellemarting.com.

Inconsistent Documentation

Consider how the attending physician and consulting physicians have described the condition. Rules and responses may differ depending on how the condition is described in the record.

Payor Seeks to Ignore Attending's Documentation; Relies on Consultants or Others

"The listing of the diagnoses in the patient record is the responsibility of the attending provider."

Assigning codes based on the documentation of other healthcare providers can only occur if their documentation is not in conflict with the documentation of the patient's attending physician of record.

Payor Seeks to Exclude Diagnosis Because Attending Didn't Document

Code assignment may be based on documentation from any physician involved in the care and treatment of the patient, including documentation by consulting physicians.

Is there an inconsistency, or attending simply didn't record the condition documented by a consultant?

Applying the Rules

ABC Insurer seeks to base the patient's diagnostic code assignment on the documentation of nonattending providers in the patient's record while ignoring the attending physician's documentation of the patient's condition.

ICD-10-CM Official Guidelines for Coding and Reporting and American Hospital Association *Coding Clinic* guidelines define the attending physician as the **provider with responsibility for establishing a patient's diagnoses**. "The listing of the diagnoses in the patient record **is the responsibility of the attending provider**." "The attending physician is **responsible for and directly involved in the care** and treatment of the patient."

Assigning codes based on the documentation of other healthcare providers ***can only occur* if their documentation is not in conflict** with the documentation of the patient's attending physician of record. "This ensures that the documentation and the codes reported are consistent with the attending physician's interpretation, since he or she is responsible for the clinical management of the case. It is the responsibility of the attending physician to **gather and collate all of the findings** from the consultants and other providers involved in the care of the patient."

1. ICD-10-CM Official Guidelines for Coding and Reporting Section IV.
2. ICD-10-CM/PCS Coding Clinic 2016 Qtr 3, pages 25-26.
3. ICD-9-CM Coding Clinic 2008 Qtr 3, page 3.
4. ICD-10-CM/PCS Coding Clinic 2016 Qtr 3, pages 25-26.

Applying the Rules

1. Definition of Attending Physician
2. Responsibility of Attending Physician with Respect to Diagnoses
3. Criteria for Basing Code Assignment on Other Providers

Here, Dr. Smith is the patient's designated attending physician. [Citation: see claim; see discharge summary]. Dr. Smith was responsible for and directly involved in the care and treatment of Patient. [Citation: See mmdd-yyyy Progress notes]. As a result, Dr. Smith was responsible for establishing the patient's diagnosis/diagnoses. Dr. Smith documented Patient's condition as [describe]. The consultant described the patient's condition as [describe]. Where it was Dr. Smith's responsibility to gather and collate all of the findings from consultants and other providers, and after doing so Dr. Smith determined in his professional judgment and with the benefit of the entire clinical picture of the patient, that the Patient's condition was [state], differing documentation of the consultant's description of the condition is not determinative. Dr. Smith's documentation cannot be ignored in assigning the diagnosis code for this condition, and doing so contradicts *Official Guidelines for Coding and Reporting*.

ICD-10-CM Official Guidelines for Coding and Reporting Section IV.
ICD-10-CM/PCS Coding Clinic 2016 Qtr 3, pages 25-26.
ICD-9-CM Coding Clinic 2008 Qtr 3, page 3.
ICD-10-CM/PCS Coding Clinic 2016 Qtr 3, pages 25-26.

Endnotes

1. Nina Youngstrom, "Errors in References Could Undo Claim Denials; DRG Validations Hit on Multiple Fronts," *Report on Medicare Compliance* 30, no. 39 (November 1, 2021).

Private Equity Firm, Two Execs Pay $25M in Medicaid FCA Settlement

A private equity firm and two former executives of South Bay Mental Health Center Inc. in Massachusetts agreed to pay $25 million for allegedly causing the submission of false claims to Medicaid in connection with services provided to patients by clinicians who were allegedly unlicensed and unsupervised, the Office of the Massachusetts Attorney General (AG) said Oct. 14.[1]

It's the largest settlement amount ever paid by a private equity company to settle fraud allegations for a health care portfolio company, the AG said. There were allegedly staffing and supervision deficiencies at all 17 South Bay clinics in the commonwealth, according to the AG's state False Claims Act (FCA) complaint, which also described testimony from South Bay's former compliance officer, who said the compliance committee existed "in name only."[2]

The settlement[3] is a powerful reminder of the risks that may flow from private equity investments in health care entities and their owners joining the board, said Darrell Contreras, chief compliance officer of Millennium Health. "If you think about the world in which they operate, it is high finance and investments. They may not have a good background in health care compliance," he said. "It becomes the job of the chief compliance officer to educate the board on compliance and the government's expectations for board oversight."

AG, Relator Went Ahead Without DOJ

According to the complaint, South Bay ran mental health centers throughout the commonwealth. It was founded in 1986 by Dr. Peter Scanlon, who was CEO until April 2012. At that point, he sold it to Community Intervention Services (C.I.S.) and served as its chief clinical officer until December 2014. A majority interest of C.I.S. was owned by H.I.G. Growth Partners LLC and H.I.G. Capital LLC, a private equity firm. Kevin Sheehan was CEO of C.I.S. from April 2012 through November 2016.

The whistleblower, Christine Martino-Fleming, a licensed mental health counselor formerly employed by South Bay and C.I.S., filed the FCA lawsuit in 2015 against South Bay and the private equity defendants under the federal FCA and Massachusetts False Claims Act. Although the Department of Justice declined to intervene, three years later, the AG filed a complaint in intervention. In 2018, South Bay and C.I.S. settled the case for $4 million. In 2019, the AG and the whistleblower filed an amendment complaint, and now H.I.G. will pay $19.95 million and Scanlon and Sheehan will pay $5.05 million, the AG said.

"This settlement resolves allegations that HIG, Scanlon, and Sheehan knew that SBMHC [South Bay Mental Health Center] was providing unlicensed, unqualified, and unsupervised services in violation of regulatory requirements and caused fraudulent claims to continue to be submitted to MassHealth by failing to adopt recommendations" to bring South Bay into compliance, the AG said. MassHealth is the state's Medicaid program.

According to the complaint, professionals diagnosing and treating MassHealth members are required to have a degree or license as a psychiatrist, psychologist, social worker, psychiatric nurse, psychiatric clinical nurse specialist, counselor, or occupational therapist. Counselors must have a master's degree in counseling and two years of full-time supervised clinical experience in a multidisciplinary mental health setting after getting a master's degree. Massachusetts Behavioral Health Partnership requires supervision of all master's-level counselors by a licensed independent clinical social worker, a licensed psychologist, an advanced practice registered nurse board-certified in psychiatric nursing, or a licensed psychiatrist.

The complaint alleged that many therapists employed by South Bay had master's degrees but weren't licensed as social workers or mental health counselors and "a vast majority of unlicensed staff therapists at South Bay clinics had no qualified supervisor during the applicable time period." Mental health clinics also were required to have a clinic director who is licensed or certified in one of the core disciplines, but that allegedly wasn't the case at many South Bay clinics. "In fact, many clinic directors were themselves unlicensed," the complaint alleged.

'Pressure to Grow Was Astronomical'

Kathy Bangerter, South Bay's director of utilization management and compliance officer from 2000 to 2012, testified in 2017 that Scanlon and another manager "were most responsible for ensuring that South Bay was complying with MassHealth regulations." According to the complaint, "Scanlon confirmed in deposition testimony on September 29, 2017 that he personally reviewed regulations promulgated by MassHealth during his tenure as President of South Bay."

Although South Bay had a "compliance committee" when Bangerter worked there, she testified that "it was a compliance committee 'theoretically' and 'in name only,'" the complaint alleged. "Bangerter testified that, throughout her tenure as South Bay's Compliance Officer, Scanlon never once asked her to ensure South Bay was compliant with supervision regulations."

The whistleblower was hired as a job coach in 2008 and promoted to coordinator of staff development and training. She allegedly observed between 2009 and 2014 that "a majority of the individuals who held the title of Clinical Director and Regional Director at South Bay either lacked a license, registration or certification completely; or lacked the correct type of license, registration, or certification in one of the core disciplines."

Things allegedly got worse after Sheehan and the C.I.S. and H.I.G. defendants took over South Bay because "the pressure to grow was astronomical compared to what it had been" before the sale, according to testimony from a former director of clinical services.

Attorneys for the defendants did not respond to *RMC*'s requests for comment.

Compliance Professional: PE 'Gets a Bad Rap'

Leslie Boles, director of compliance audit at Waud Capital Partners, said "private equity gets a bad rap. People always seem to think they don't care about compliance." But that's not the case, Boles said. "At Waud it is the exact opposite. Our job is to reinforce a culture of compliance."

Boles said the main way private equity is different from the traditional health care model is its "growth structure. A company could acquire different practices faster in some quarters of the year than others," she noted. "We as compliance professionals are prepared to identify areas of risk proactively. We do a lot of education with the mergers and acquisition diligence teams to ensure we're capturing risks that may be out there and resolve them."

All of Waud's portfolio companies have their own compliance teams, which her compliance group collaborates with. "We have weekly compliance forums to go over key areas," including Department of Justice enforcement actions, Boles noted. Board members are brought in from the compliance committees for compliance panels. "We work in an environment where we absolutely care about compliance."

But whistleblower attorney Mary Inman, with Constantine Cannon, said private equity's modus operandi is buying companies to generate revenue and flip them, which creates a "dynamic that can put additional pressures to play fast and loose" with regulatory requirements. She notes there have been two other recent false claims settlements with private equity firms in health care, including the Department of Justice's 2020 settlement with the former owners of Therakos Inc. and its private equity firm, The Gores Group.[4] "The deterrent power of whistleblowers is one of the best backstops we have," Inman said. "There's no substitute for well-placed insiders." She was heartened to see executives held accountable in the South Bay case. "It sends a strong signal."

Jeffrey Newman, an attorney for the whistleblower in the South Bay case, said private equity companies must have board members who are "medically experienced" and understand Medicare, Medicaid and TRICARE regulations, not just people who "look at finances only."

When educating new board members who come from private equity, Contreras recommends compliance professionals focus on three areas:

1. **Compliance program effectiveness**. That includes a status report on how your compliance program measures up to guidelines published by the Department of Justice and HHS Office of Inspector General.
2. **Key performance indicators (KPIs)**. A report on all KPIs should be in your quarterly report, "but bring KPIs to the board's attention if they're outside an established risk tolerance," Contreras said. "The more you can keep within the tolerance, the lower the compliance risk and the less discussion required with the board."
3. **Important information or actions needed (e.g., approving a document or chart)**. This includes the compliance education component, such as "new pieces of information" (e.g., the Massachusetts private equity settlement).

Contact Contreras at darrell.contreras@millenniumhealth.com, Inman at minman@constantinecannon.co.uk, Boles at lboles@waudcapital.com and Newman at jnewman@newmanshapiro.com. ✧

Endnotes

1. Office of Attorney General Maura Healey, "Private Equity Firm and Former Mental Health Center Executives Pay $25 Million Over Alleged False Claims Submitted for Unlicensed and Unsupervised Patient Care," news release, October 14, 2021, https://bit.ly/2ZyIKef.
2. United States ex rel. and Commonwealth of Massachusetts ex rel. v. South Bay Mental Health Center, Civil Action No. 15-CV-13065-PBS (D. Mass., January 4, 2019), https://bit.ly/3bowfE4.
3. United States v. H.I.G. Growth Partners and H.I.G. Capital, settlement agreement, September 23, 2021, https://bit.ly/3vVMamU.
4. Department of Justice, U.S. Attorney's Office for the Eastern District of Pennsylvania, "Former Owners of Therakos, Inc. Pay $11.5 Million to Resolve False Claims Act Allegations of Promotion of Drug-Device System for Unapproved Uses to Pediatric Patients," news release, November 19, 2020, https://bit.ly/3Bvfd1D.

CMS Transmittals and *Federal Register* Regulations, Oct. 22-28, 2021

Transmittals

Pub. 100-04, Medicare Claims Processing

- Calendar Year (CY) 2022 Participation Enrollment and Medicare Participating Physicians and Suppliers Directory (MEDPARD) Procedures, Trans. 11074 (Oct. 26, 2021)
- Fiscal Year (FY) 2022 Inpatient Prospective Payment System (IPPS) and Long Term Care Hospital (LTCH) PPS Changes, Trans. 10995 (Sept. 16, 2021, recommunicated Oct. 26, 2021)
- Revision to Chapter 3 to Update Instructions for Handling Inpatient Rehabilitation Facility (IRF) Claims, Trans. 11075 (Oct. 28, 2021)
- New Waived Tests, Trans. 11082 (Oct. 28, 2021)

Pub. 100-20, One-Time Notification

- Skilled Nursing Facility (SNF) Claims Processing Update to Fiscal Year End (FYE) Edits, Trans. 11060 (Oct. 22, 2021)
- International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs) -- April 2022 (CR 2 of 2 for April 2022), Trans. 11083 (Oct. 28, 2021)

Federal Register

Notice

- Medicare, Medicaid, and Children's Health Insurance Programs; Provider Enrollment Application Fee Amount for Calendar Year 2022, 86 Fed. Reg. 58,917 (Oct. 25, 2021)

CMP Exceptions May Help SDOH Programs

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Reaching out to underserved populations directly or in partnerships with community-based organizations is key to addressing SDOH, which are coming into play more as evidence mounts that health outcomes and costs are affected by the way people live.

SDOH "is the idea that there are things outside of traditional blood tests, scans and stethoscopes that affect patient health, whether it's where patients live and what they eat or access to care," said New Jersey health care attorney John Barry. Impacting these things can lead to a healthier population that needs less care and less costly care, he said.

"SDOH is not a new concept in health care, but we have seen it come to the forefront during the pandemic," Slevinski said. "People continued to have barriers to care." The HHS Office of Disease Prevention and Health Promotion (ODPHP) defines SDOH as "conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks."[3]

Emergency departments, for example, can keep treating a patient's asthma, but if the patient is returning to a moldy home, this expensive, unhealthy cycle won't be interrupted, Slevinski said. Similarly, when patients don't have cell phones, transportation or housing, they may be unable to keep appointments or fill prescriptions. "We found that our population health team was trying to get prescriptions to patients who couldn't easily get to pharmacies," she said.

Hospitals are doing outreach (e.g., OhioHealth's Wellness on Wheels mobile primary care unit) and partnering with community organizations to take on the SDOH, but there may be compliance risks. Slevinski said she has "regular interactions with the population and community health teams, so when they have an idea or are approached by a community-based organization, I am brought in at the planning stages." They discuss concerns about data sharing, the potential for giving free items to people in the community/patients "or other nuances that need attention from a legal or regulatory or proactive perspective." Slevinski recommends compliance officers develop relationships with people in their hospital, home care agency or other entity that has its hands in population health. "Seek them out" so they know you're there to help, she advised. "Issue spot for them."

Keep in mind that while "you can look at the SDOH from an altruistic perspective," health care organizations are businesses, Barry said. When partnering with an agency, offering an incentive or doing some other SDOH activity, "you need to understand the specifics of what a provider or facility is trying to accomplish to properly assess all the fraud and abuse risks involved." For example, the government may wonder why a hospital rolled out free transportation to its most lucrative services first (e.g., imaging). "Was there a particular need there, or is it just to drive a high-profit service line? The social determinants of health should be used to drive better health outcomes, increase efficiency and lower costs. A government regulator would likely view a SDOH program negatively if its purpose is to drive business," Barry said.

Knocking Down Privacy Barriers

There are several issues raised by the information sharing and free goods and services that are part and parcel of tackling SDOH. For one thing, the HIPAA privacy rule doesn't allow covered entities, such as hospitals, to disclose patient information to noncovered entities, such as food banks, shelters and violence prevention programs, without the patient's written authorization.

But the HHS Office for Civil Rights (OCR), in its proposed changes to the privacy rule, "acknowledges explicitly the concept that there are other entities outside the traditional health care entities that are really integral and have become a part of health care treatment," Barry said.

According to the proposed regulation, the privacy rule "would expressly permit covered entities to disclose PHI to social services agencies, community based organizations, HCBS [home community based services] providers, and other similar third parties that

provide health-related services to specific individuals for individual-level care coordination and case management, either as a treatment activity of a covered health care provider or as a health care operations activity of a covered health care provider or health plan. Under this provision a health plan or a covered health care provider could only disclose PHI [protected health information] without authorization to a third party that provides health-related services to individuals; however, the third party does not have to be a health care provider. Instead, the third party may be providing health-related social services or other supportive services—e.g., food or sheltered housing needed to address health risks."

OCR also proposed to clarify the definition of health care operations to include "population-based activities relating to improving health or reducing health care costs; protocol development; case management and care coordination; contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment." Disclosures that fall under treatment, payment and operations, of course, don't require patient authorizations.

Depending on how these provisions are worded when the rule is finalized, Barry said they "may go a long way to removing barriers and making it less burdensome for providers to help patients." For example, if a provider is treating a patient who lives in a shelter, it may be easier to track the patient down if the patient has left the shelter.

Access to Care Exception Helps SDOH Programs

Hospitals and other providers also must factor in the CMP laws and Anti-Kickback Statute (AKS) when thinking about SDOH, Barry said. The beneficiary inducement CMP prohibits offering remuneration to Medicare and Medicaid beneficiaries that the provider knows or should know would influence the beneficiary's choice of provider or service or the supplier of items. "It begs the question, if I am going out in the community and trying to influence the social determinants of health by offering free patient transportation, isn't that fitting squarely in the beneficiary inducement CMP?" But the beneficiary inducement CMP has relevant exceptions, including the Promotes Access to Care exception.

The exception states that remuneration doesn't include "remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs." As OIG has explained in several advisory opinions, including 20-02, "we have interpreted this provision to apply to: [i]tems or services that improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid, and pose a low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs by—(i) [b]eing unlikely to interfere with, or skew, clinical decision making; (ii) [b]eing unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (iii) [n]ot raising patient safety or quality-of-care concerns."[4]

Running a shuttle in the community to take women to get mammograms may qualify, but giving them a $100 Amazon gift card if they have the imaging test probably won't, Barry said. "Is it promoting or allowing a person to access care? The more tangential, the riskier it becomes," he said.

Free transportation also is protected under certain circumstances by a safe harbor to the AKS.

Contact Slevinski at slevindl@uhnj.org and Barry at barry.john@gmail.com. ✧

Endnotes

1. 42 U.S.C. § 1320a–7a.
2. Proposed Modifications to the HIPAA Privacy Rule To Support, and Remove Barriers to, Coordinated Care and Individual Engagement, 86 Fed. Reg. 6,446 (January 21, 2021), https://bit.ly/3asDtpI.
3. "Social Determinants of Health," Healthy People 2030, Office of Disease Prevention and Health Promotion, accessed October 28, 2021, http://bit.ly/3tmQjOa.
4. OIG, "OIG Advisory Opinion No. 20-02," January 15, 2020, https://bit.ly/3nEkLSD.

NEWS BRIEFS

◆ **President Biden on Oct. 29 proposed to repeal a rule requiring review of most regulations every 10 years.**[1] The Securing Updated and Necessary Statutory Evaluations Timely (SUNSET) rule, finalized in the waning days of the Trump administration, said rules expire if they aren't reviewed in a decade, but the new proposal would reverse that.

◆ **The HHS Office of Inspector General has posted the 2021 version of its *Top Unimplemented Recommendations: Solutions to Reduce Fraud, Waste and Abuse in HHS Programs*.**[2] For Medicare Parts A and B, they include CMS recovering "overpayments of $1 billion resulting from incorrectly assigning severe malnutrition diagnosis codes to inpatient hospital claims, ensure that hospitals bill appropriately moving forward, and conduct targeted reviews of claims at the highest severity level that are vulnerable to upcoding" and analyzing "the potential impacts of counting time spent as an outpatient toward the 3-night requirement for skilled nursing facility (SNF) services so that beneficiaries receiving similar hospital care have similar access to these services."

Endnotes

1. Securing Updated and Necessary Statutory Evaluations Timely; Proposal To Withdraw or Repeal, 86 Fed. Reg. 59,906 (Oct. 29, 2021), https://bit.ly/3Bstpsc.
2. HHS, Office of Inspector General, OIG's *Top Unimplemented Recommendations: Solutions to Reduce Fraud, Waste and Abuse in HHS Programs*, accessed October 29, 2021, https://bit.ly/3vUC4Ta.