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

Contents

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HHS Revises Sec. 1557 Rule; Expands Definition of Sex, Adds 'Notice of Availability'

In a proposed rule again revising Sec. 1557 of the Affordable Care Act, the Biden administration would protect gender identity, sexual orientation and pregnancy from sex discrimination and bring back notice and other requirements that were dropped from the Trump administration's version of the rule.[1] The proposed rule, announced by HHS July 25, is more in keeping with the Obama administration's 2016 vision, with its notice of nondiscrimination and Sec. 1557 compliance officer, but it also introduced a "notice of availability" about language assistance and auxiliary aids. And as the latest incarnation makes clear, nondiscrimination requirements apply to telehealth services.

The ping-ponging of the protections and requirements of Sec. 1557, which prohibits discrimination on the basis of race, color, national origin, sex, age or disability, is unusual, said attorney Abby Bonjean, a former HHS Office for Civil Rights (OCR) investigator. It's been somewhat of a "roller coaster," she noted. "I have watched it from day one being at OCR when 1557 first came out, [and] then we had the Trump administration trying to roll back as many protections as they could." Now the Biden administration is moving to bring them back, said Bonjean, with Polsinelli. For now, though, she reminds hospitals and other covered entities they aren't required to post taglines because the 2020 regulation is still the rule of the land.

continued on p. 6

After Disclosing a Reportable Event Under its CIA, Hospital Settles CMP Case With OIG

William Beaumont Hospital in Michigan has agreed to pay $1.732 million in a settlement with the HHS Office of Inspector General (OIG) that had a connection to its corporate integrity agreement (CIA). The allegations centered on the hospital's physician compensation and leases under certain circumstances.

According to its civil monetary penalty settlement, which was obtained through the Freedom of Information Act, OIG alleged that William Beaumont Hospital paid physicians remuneration in two different forms: (1) excess compensation to 18 cardiologists in its cardiology reading program from Jan. 1, 2015, to Oct. 31, 2020, and (2) the free use of medical equipment and personnel by a medical group from Jan. 1, 2015, to Dec. 31, 2018. OIG alleged the hospital violated the civil monetary penalty law applicable to the Anti-Kickback Statute (AKS) and submitted Medicare claims for designated health services that resulted from prohibited referrals in violation of the Stark Law.

The settlement stems from William Beaumont Hospital's self-disclosure to OIG's Health Care Fraud Self-Disclosure Protocol (SDP). The hospital self-disclosed on June 21, 2021, and was accepted into the SDP the following month. "Also on June 21, 2021, Respondent disclosed this matter as a Reportable Event pursuant to its Corporate Integrity Agreement with OIG," the settlement stated.

continued

William Beaumont Hospital's CIA is part of its 2018 False Claims Act (FCA) settlement of four whistleblower lawsuits alleging violations of the Stark Law and Anti-Kickback Statute.[1] The hospital agreed to pay $84.5 million over allegations of sweetheart deals with eight referring physicians, including above-fair-market-value compensation and below-fair-market-value rent. Its five-year CIA describes events that must be reported to OIG. Reportable events include "a statement of the Federal criminal, civil or administrative laws that are probably violated by the Reportable Event, if any."

The CIA also specifically refers to reportable events about the Stark Law. If the hospital "solely" had a Stark violation, it should report it through CMS's Self-Referral Disclosure Protocol (SRDP) and send a copy to OIG.[2] "If WBH [William Beaumont Hospital] identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then WBH is not required by this Section III.K to submit the Reportable Event to CMS through the SRDP."

It's hard to know exactly what prompted the hospital to go the SDP route rather than the SRDP route, which tends to result in lower penalties, said attorney Larry Vernaglia, with Foley & Lardner LLP. The hospital's attorney declined to comment. Yet OIG alleged a violation of the civil monetary penalty (CMP) applicable to kickbacks.

"Sometimes when evaluating the facts of these relationships, you come across some evidence, complaints or concerns that may reflect more than Stark foot faults," Vernaglia said. In cases like these, there may be knowledge of alleged wrongdoing or a "should have known" allegation, he said. "Providers make these good-faith judgments all the time. You're looking at the totality of the evidence and have to confront this potentially challenging evidence. To satisfy the commitments of your compliance plan, you have the obligation to do the right thing when confronted with these types of facts." CIA reportable-event requirements may not be the determining factor, Vernaglia said. "Sometimes you say these factors don't look good and you have to go beyond an overpayment return" to the Medicare administrative contractor or the SRDP program.

"Having a CIA doesn't really provide you with an alternate path to resolving violations," Vernaglia said. Providers still must use a self-disclosure protocol for resolving Stark violations, like the SRDP or SDP, he noted. "You still have the underlying violation but increased liability because of violations of the CIA. What the CIA does, however, is to allow an interaction between the OIG monitor and the provider. The monitor serves as another perspective for providers and their counsel to consider when evaluating on which side of the line a particular potential violation may fall."

FCA Case Alleged Below FMV Leases

In the FCA case, William Beaumont Hospital faced several Stark and AKS allegations. The whistleblowers were former employees of the hospital, and the allegations centered on physician financial relationships between 2004 and 2012. The whistleblower lawsuits were consolidated and DOJ intervened, but not in all the allegations.

The most complicated complaint was filed by neuroscientist David Felten, M.D., Ph.D., who was vice president of research and medical director of the Research Institute at William Beaumont Hospital. He claimed the alleged fraud at the hospital came down to ensuring physicians' loyalty so they would refer patients to the hospital. The complaint alleged "illegal incentives" for one of Beaumont's cardiology groups, Academic Heart and Vascular PLLC. The cardiologists received salaries from Beaumont as full-time employees and had an office on Beaumont grounds, paying less than fair market value for "prime office space," while also keeping their private practices and the income they generated. According to the complaint, in 2009, four

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of the cardiologists received Beaumont salaries that allegedly exceeded typical cardiology salaries: David Haines, M.D., was paid $753,067; Cindy L. Grines, M.D., $726,499; James A. Goldstein, M.D., $702,294; and Robert D. Safian, M.D., $702,294.

William Beaumont Hospital did not admit liability in the settlement. The cardiologists weren't named in the complaint.

Contact Vernaglia at lvernaglia@foley.com. ✧

Endnotes

1. Nina Youngstrom, "Mich. Hospital Settles FCA Case for $84.5M Over Physician Payments," *Report on Medicare Compliance* 27, no. 29 (August 20, 2018), https://bit.ly/3OTSMdz.
2. Corporate integrity agreement, United States v. William Beaumont Hospital (July 31, 2018), https://bit.ly/3BjuK8B.

Vein Ablation Denials Show Importance of Pre-Procedure Progress Notes

A hospital's recent reversal of claim denials of varicose vein ablation is an object lesson in the importance of including pre-procedure progress notes and other essential documentation when responding to an auditor's documentation request, a compliance officer said.

"It's just a matter of getting the right information" in the hands of auditors, said Peter Hughes, interim director of audit and compliance at Englewood Health in New Jersey. "It's easier said than done, but it shouldn't be." There are complications, however, related to whether the physician who performs the procedure is part of the hospital's physician network.

The recovery audit contractor (RAC) audited endovenous radiofrequency ablation (ERFA) and endovenous laser treatment (EVLT) for lower extremity varicose veins. According to the CMS website, "claims for ERFA and EVLT for Lower Extremity Varicose Veins [that] are not deemed to be medically necessary will be denied based on the guidelines outlined in the respective MAC Jurisdiction LCD(s)."[1]

During the RAC discussion period, Hughes and his team overturned 28 out of 31 claim denials. It helped to build bridges with coders in the health information management (HIM) department and have physician advisers or nurses in utilization management engage in the discussion period.

But it was a near miss, and Hughes looked at what almost went wrong. His conclusions: When the additional documentation request (ADR) came in, the hospital didn't initially submit all the documentation required to support the medical necessity of the endovenous procedures, Hughes said. That led to the claim denials, which weren't small potatoes. Medicare reimburses $2,690 for the outpatient vein ablations, so the hospital was looking at a total hit of $73,000. "You risk losing the payment and the additional labor time chasing it down if you don't identify the need at the front end" or when first responding to the ADR, he said.

But Hughes said he and his team fended off the denials during the discussion period. As CMS explains, "The discussion period offers the opportunity for the provider to provide additional information to the RAC to indicate why recoupment should not be initiated. It also offers the opportunity for the RAC to explain the rationale for the overpayment decision. After reviewing the additional documentation submitted the RAC could decide to reverse their decision."[2]

Varicose vein procedures typically are considered cosmetic unless patients have pain or ulceration, so physicians may perform duplex ultrasounds of the vein to support medical necessity, Hughes said. Duplex studies show blood flow and vein incompetency. Results of the ultrasounds should be included in the medical records sent to RACs (and other auditors), he explained, along with progress notes and other documentation. That's not as heavy a lift when the physician who performs the procedure is in the hospital's network and on Epic. "The person in the health information management department who is going to get the ADR" pulls up patient John Smith's records for Jan. 1, to use a hypothetical, and the "prior-procedure" progress notes are there for the plucking if the physician is in-network, Hughes said. "'Prior' is the key—prior to the procedure."

Lesson Applies to Other Procedures

It's another story if HIM must chase down prior-procedure progress notes from physicians outside the Englewood network to avoid an upfront claims denial. Hughes notes "it's more challenging when physicians are not in network," although Englewood allows non-network physicians on the medical staff to access patient records in Epic under certain conditions for the sake of continuum of care. "Their progress notes would be accessible for the person in HIM who is processing ADRs," he said. "But they have to know to go get them." It's not screamingly obvious; "you are going to do your best to get the records out the door ASAP" for the 25 patients, for example, in the RAC's ADR by its deadline. "This is another item in the workflow," Hughes said. When the ADR comes in, HIM has to determine what documentation is required and whether the physician is in or out of network, with the ticking clock perhaps making them sweat.

But it's par for the course. "This is a classic case of adding this pre-procedure information" in the ADR to avoid a denial, Hughes said. If you looked through one of the requests for ablation records, it merely says physician progress notes.

The lesson applies to other outpatient and inpatient procedures, including implantable cardioverter defibrillators. "You have to be sure the patient is thoroughly screened to meet Medicare criteria," Hughes said.

There's a list of medical necessity requirements in a national coverage determination (NCD 20.4), and in 2015 almost 500 hospitals settled false claims allegations with the Department of Justice that they implanted the cardiac devices in patients and billed Medicare without meeting coverage criteria in the NCD,[3] which has since been modified.[4]

Contact Hughes at peter.hughes@ehmchealth.org. ✧

Endnotes

1. Centers for Medicare & Medicaid Services, "0145-Endovenous Radiofrequency Ablation and Endovenous Laser Treatment for Lower Extremity Varicose Veins: Medical Necessity and Documentation Requirements," Approved RAC Topics, April 15, 2019, https://go.cms.gov/3PXRChK.
2. "Provider Options - RAC Overpayment Determination," Centers for Medicare & Medicaid Services, last accessed July 29, 2022, https://go.cms.gov/3vkqv8Q.
3. U.S. Department of Justice, "Nearly 500 Hospitals Pay United States More Than $250 Million to Resolve False Claims Act Allegations Related to Implantation of Cardiac Devices," news release, October 30, 2015, https://bit.ly/3cLtm4i.
4. Centers for Medicare & Medicaid Services, "Implantable Automatic Defibrillators," National Coverage Determination, accessed July 29, 2022, https://go.cms.gov/3JlU9k0.

In 'Dual Audit,' Lab Is Audited by Both I-MEDIC and MA Plan's SIU

A CMS program integrity contractor that focuses on Medicare Part C and D claims and a Medicare Advantage (MA) plan's special investigative unit (SIU) are simultaneously auditing the same lab, a double whammy that took its attorney by surprise because of the volume of documentation requested both on the claims and on background information of the lab, including enrollment and certifications. He's worried more provider audits may be in the works for claims submitted to MA plans by the program integrity contractor that had previously investigated only Part D fraud, waste and abuse, the attorney said.

"This is the first dual audit I have seen on MA claims," said Stephen Bittinger, an attorney with K&L Gates in Charleston, South Carolina. "The really crazy thing is two different auditors are each allowed a bite at the apple." Although the focus of the audits is different, the MA plan and the CMS program integrity contractor are auditing some of the same claims, he said.

The lab recently received requests for medical records from Qlarant, which is an Investigations Medicare Drug Integrity Contractor (I-MEDIC). Qlarant said in 2018 that it was chosen as the I-MEDIC and that it would "detect, prevent, and proactively deter fraud, waste, and abuse" in Parts C and D.[1]

While the I-MEDIC started out as a program integrity contractor for prescription drug fraud and abuse under Part D, it has moved into MA, Bittinger said. "What I have seen here is the managed care organization and the [I-MEDIC] have coordinated, and my client received requests from both," he explained. It's a departure because "traditionally MA plans have done their own program integrity work on provider claims," Bittinger said. CMS also does Risk Adjustment Data Validation audits to identify and recoup improper payments made to MA plans.

According to a presentation by Bill Gould, senior technical advisor in the CMS Center for Program Integrity, MEDICs do complaint investigations, perform data analysis, develop and refer cases to law enforcement, support law enforcement investigations and conduct audits.[2]

'It Almost Felt Like' a CID

In the lab audit, the I-MEDIC's documentation request is focused on the claims side, and it requested medical records and claims information "to determine the validity of claims," Bittinger said. The MA plan documentation request was different, focusing on the lab's marketing history, compliance plans and Clinical Laboratory Improvement Amendments certification history. Because the lab contracts with the MA plan and "the contract is super broad, the most important thing is obviously to ensure the guidance for managed care organization services are aligning with Medicare services because clearly they will target overlapping coverage," Bittinger said. In other words, the audit will determine whether the lab is providing services consistent with the national coverage determination or the contract if it's broader.

But there was overlap between the documentation requests of the MA plan and the I-MEDIC, he said. "We produced a lot of information," Bittinger said. "It was very invasive. It almost felt like I was responding to a civil investigative demand." The lab got the documentation requests in April, responded in late May, and, according to Bittinger, they are still waiting on results.

"The government isn't trusting MA plans to audit sufficiently," he said. "The I-MEDIC contract was such an oddity in that the tiny little hook on Part C seemed like it was dangling out there, but now Part C has grown so much it could be a tidal wave of new audit work. And clearly the [I-MEDIC] has to ask the MA plan for claims access. We have coordination between the [I-MEDIC] and the MA plan," he said, which is disturbing.

He can foresee the I-MEDIC coming after other provider "hot spots," such as home health, durable medical equipment and hospices in terms of the claims they submit to MA plans.

Keep an Eye on FFS Overlapping Audits

While he hasn't seen dual audits of this nature, attorney Lester Perling said there have been "overlapping" audits since CMS introduced program-integrity contractors. Medicare administrative contractors and unified program integrity contractors (UPICs) have conducted overlapping audits and the same goes for recovery audit contractors (RACs) and supplemental medical review contractors, said Perling, with McDermott Will & Emery in Miami. But that's in the fee-for-service world, where overlapping audits on the same claims are not allowed. Medicare program integrity contractors are required to run the claims

continued on p. 6

Tip Sheet to Help Prevent Inappropriate Orders of Pain Management, DME

Stormont Vail Health in Topeka, Kansas, distributes this tip sheet to physician offices to help patients avoid getting caught up in scams and potentially authorize pharmacies or durable medical equipment (DME) suppliers to ask their physicians to order prescriptions or supplies. The tip sheet gets at some of the same kinds of issues raised in the HHS Office of Inspector General's July 20 special fraud alert that urges physicians and nonphysician practices to tread carefully "and use heightened scrutiny" when entering into arrangements with telemedicine companies, although the tip sheet wasn't designed specifically for telemedicine.[1] Contact Barbara Duncan, HIPAA privacy officer, at bduncan@stormontvail.org.

Tip Sheet
Integrity & Compliance

Pharmacy Pain Management and Durable Medical Supplies Marketing

Have you ever received a marketing survey online or received marketing phone calls offering prescription pain management or durable medical supplies, such as knee braces, back braces or muscle stimulators?

Here is a little information about those marketing businesses:

- They are not affiliated with Stormont Vail Health.
- You aren't necessarily dealing directly with a doctor when filling out these surveys or calling these marketing businesses.
- These businesses don't fully understand your symptoms or pain management plans.
- These marketing businesses take your information, get your permission and directly fax a request to your provider to order pharmaceuticals or supplies they say you need for your pain management.
- You have a provider who knows your health status and takes good care of you.
- Stormont Vail Health will not fill these outside order requests from pharmacies or durable medical suppliers.

What should you do to avoid these marketing businesses?

- Always consult with your provider if you have any questions about your pain management or are unsure about something.
- Avoid providing personal information on surveys unless you fully understand what the survey is for.
- Ignore scams from TV or phone calls from pharmacies asking about your pain or pain management.
- If you are receiving calls from these marketing businesses, you can contact them and ask to have your name removed from their pharmacy calling and faxing list.

What is Stormont Vail Health doing to prevent and stop this?

- When we receive faxes from these marketing businesses we send them to our Integrity & Compliance department to try to understand why they are being sent.
- The Integrity & Compliance department will contact these businesses to see if they are legitimate and get these faxes stopped.

Concerns can also be reported to the Federal Trade Commission.

- The FTC and other law enforcement agencies bring scam artists to justice and put an end to unfair and misleading business practices. If you have a complaint, file online at: FTC.gov/complaint or call 1-877-FTC-HELP.

If you have any concerns please call and ask your provider or contact Stormont Vail Health Integrity & Compliance department.

Integrity & Compliance Department
Phone: XXX-XXX-XXXX

Stormont Vail Health Mission
Working together to improve the health of our community.

Our Commitment
The importance of our pride is to be fair and have honest dealings with the public, including patients, private and governmental payers and vendors, all of whom are important to our success.

Endnotes

1. U.S. Department of Health & Human Services, "Special Fraud Alert: OIG Alerts Practitioners To Exercise Caution When Entering Into Arrangements With Purported Telemedicine Companies," July 20, 2022, https://bit.ly/3z0V3xk.

continued from p. 5

through a data warehouse, and if they're already under review by another auditor, they aren't eligible for audit.

"Sometimes you don't realize it," Perling said. Suppose a UPIC audits a year's worth of a hospital's claims and then a RAC sends an additional documentation request for claims from the last four months of the same year. Both contractors issue their findings, and the second audit is duplicative. "That's an appeals issue. The whole audit would be flawed." Perling said he has never lost an appeal based on the argument that the audit sample overlapped. Preferably, he has gotten auditors to throw out findings before an appeal when he pointed out the claims overlapped with another Medicare audit. "Auditors are supposed to check the database," he said. Perling noted, however, that it's conceivable that audits were performed close in time and claims hadn't populated yet, so auditors didn't realize they overlapped.

Contact Bittinger at stephen.bittinger@klgates.com and Perling at lperling@mwe.com. ✧

Endnotes

1. Qlarant, "CMS Selects Qlarant as the Investigations Medicare Drug Integrity Contractor to Detect, Prevent, and Deter Fraud, Waste, and Abuse," news release, October 25, 2018, https://bit.ly/3vjD986.
2. Centers for Medicare & Medicaid Services, "MEDIC and Program Integrity," slideshow presentation, accessed July 28, 2022, https://go.cms.gov/3b9baB7.

HHS Rule Would Change Sec. 1557 Again

continued from page 1

HHS also introduced something novel that's consistent with the Biden administration's emphasis on health equity, said Tamra Moore, an attorney with King & Spalding. It would be a violation of 1557 if a covered entity discriminates against individuals "on the basis of race, color, national origin, sex, age, or disability through the use of clinical algorithms in its decision-making," according to the proposed rule. Moore noted that "HHS is requesting comment, and I suspect they want to hear from health systems and hospitals about whether to implement this."

The most high-profile aspect of the Sec. 1557 regulation is the back and forth over the definition of sex discrimination. In interpreting the Affordable Care Act, HHS in the 2016 version defined discrimination "on the basis of sex" to include termination of pregnancy and gender identity, which it described as a person's internal sense of being "male, female, neither, or a combination of male and female." OCR in the 2020 rule, however, eliminated gender identity and termination of pregnancy from that definition. "'Sex' according to its original and ordinary public meaning refers to the biological binary of male and female that human beings share with other mammals," according to the 2020 regulation.

CMS Transmittals and *Federal Register* Regulations, July 22-28

Transmittals

Pub. 100-04, Medicare Claims Processing

- Masking the Medicare Beneficiary Identifier (MBI) on the Medicare Summary Notice (MSN), Trans. 11510 (July 28, 2022)
- Cessation of Use of MyMedicare.gov Web Address, Trans. 11509 (July 28, 2022)

Pub. 100-08, Medicare Program Integrity

- Update of Chapter 3 in Publication (Pub.) 100-08, Including Update to Medicare Program Integrity Contractor Post-Payment Review Process, and Update of Chapter 8 Pub. 100-08, Including Revision to When Contractor Suspects Additional Improper Claims, Trans. 11529 (July 28, 2022)

Pub. 100-19, Demonstrations

- Remove Beneficiaries Below 18 Years Old From Model Adjustments - Correction for CR 11390, Trans. 11517 (July 28, 2022)
- Federally Qualified Health Center (FQHC) Participation in and Payment Under the Maryland Primary Care Program (MDPCP) - Implementation Change Request (CR) to correct Business Requirement (BR) 12326.7.2., Trans. 11515 (July 28, 2022)
- Monthly Report of Performance Payment Adjustment (PPA) Claims - Addition to Change Request (CR) 12404 - Implementation CR, Trans. 11516 (July 28, 2022)

Pub. 100-20, One-Time Notification

- Multi-Carrier System (MCS) Removal of the Physician Pay for Reporting (P4R), Physician Quality Reporting System (PQRS) and Electronic Prescribing (ERx) Incentive Payments Financial Logic from the Claims Processing System, Trans. 11521 (July 28, 2022)

Federal Register

Proposed rules

- Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories, 87 Fed. Reg. 44,896 (July 26, 2022)
- Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating, 87 Fed. Reg. 44,502 (July 26, 2022)

Then came the landmark ruling from the U.S. Supreme Court in *Bostock v. Clayton County* on June 15, 2020.[2] The high court ruled that the Civil Rights Act of 1964, which bans sex discrimination, applies to discrimination against gay and transgender people in the workplace. It was followed by a 2021 notice from the Biden administration, which said it "will interpret and enforce Section 1557's prohibition on discrimination on the basis of sex to include: (1) discrimination on the basis of sexual orientation; and (2) discrimination on the basis of gender identity."[3] The notice guides OCR as it processes complaints and does investigations, and that's where things stand until the proposed rule is finalized.

Bonjean said the Biden administration probably saw the *Bostock* decision as a way to move ahead with prohibiting discrimination on the basis of sexual orientation and will probably finalize the proposed rule this year or in 2023. The proposed rule "clarifies that discrimination on the basis of sex includes discrimination on the basis of sex stereotypes; sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; and gender identity." But several related issues are still being litigated, Bonjean said. "I know a lot of this is still in limbo in the courts, but I feel like the *Bostock* decision is pretty clear what the protections are," she noted.

Not Everything Is About Sex (Discrimination)

The definition of sex discrimination is not the only place where the three rules differ. The first round of regulations under the Obama administration included many compliance requirements that were eliminated by the Trump administration.

Specifically, the 2020 regulation ditched the notice and tagline requirements from the 2016 regulations. Covered entities are not currently required to post nondiscrimination notices and taglines in 15 languages "on significant documents and significant communications," which HHS called "cognitive overload." HHS also killed the requirement for covered entities with 15 or more employees to have a compliance coordinator and a written procedure for patients to file grievances alleging violations of Sec. 1557. The regulation, however, retained the requirement that covered entities provide qualified translators and interpreters to limited-English proficiency patients, and they can't require patients to bring their own interpreter or rely on a friend, family member or minor child to interpret except in an emergency. But HHS in 2020 dropped the detailed definitions of qualified bilingual/multilingual staffers, which included translators and interpreters, from the 2016 rule.

Also, hospitals and other providers still must give "primary consideration" to deaf and hard-of-hearing patients who request in-person interpreters instead of video remote interpreting services. In other words, their wishes must be honored unless a health system can provide an equally effective alternative or if the patients' preferences present an undue administrative or financial burden.

Everything Old Is New Again, Sort of

The proposed rule shakes things up, bringing back the 2016 requirements, some with a makeover, and adding some new ones.

Covered entities would have to implement Sec. 1557 policies and procedures. That's a "departure" from previous rules, HHS says, but "the Department's enforcement and compliance assistance experience demonstrates that interventions such as implementing policies and procedures can result in covered entities being better positioned to prevent discriminatory conduct and to better avoid the risk of an employee providing services in a discriminatory manner."

If the provision is finalized, there must be a nondiscrimination policy, grievance procedures for covered entities with 15 or more employees, language access procedures, auxiliary aids and services procedures, and procedures for reasonable modifications for individuals with disabilities.

"They included specific policy and procedure requirements in the notice of proposed rulemaking that weren't in 1557 final rules," Bonjean said. But she noted a lot of the policy and procedure requirements "are for the most part already required by Sec. 504 of the Rehabilitation Act. A lot of entities should already have them." The policies and procedures should just be updated to include gender identity and sexual orientation under the definition of sexual discrimination, Bonjean explained.

The rule also revives the requirements for covered entities to have a Sec. 1557 coordinator if they have 15 or more employees. "We newly propose to permit covered entities to, as appropriate, assign one or more designees to carry out some of the responsibilities of the Section 1557 Coordinator," HHS said. And for the first time, the rule specified the responsibilities, which includes reviewing grievances filed under the grievance procedure.

Instead of taglines, which were "short statements written in non-English languages that indicate the availability of language assistance services free of charge," HHS is proposing a notice of availability. It's similar to taglines but must also inform people that the covered entity provides auxiliary aids and services free.

"This notice must be provided to participants, beneficiaries, enrollees, and applicants of the covered entity's health program or activity, and members of the public. Notice can be provided through written translations or recorded audio or video clips," the proposed rule states. HHS requires the notice to be written in English and at least 15 of the most common languages spoken in the "relevant state" and in alternative formats for people who request auxiliary aids and services. Covered entities must distribute the notice annually and on request and place it in a "conspicuous location" on the covered entity's website, same as the notice of nondiscrimination, and in "clear and prominent physical locations." The notice of availability must be handed to patients with other required documents, including the notice of privacy practices.

But HHS also is asking for feedback on whether the notice of availability "is practical and responsive to concerns raised regarding the 2016 and 2020 Rules, including the sufficiency of the content of the Notice of Availability and requirements on when and where covered entities must provide the notice. We also seek comment as to whether it adequately addresses the specific concerns raised regarding the burdens associated with the 2016 Rule requirements by providing a list of specific documents with which the Notice of Availability must be provided."

It's possible many hospitals and health systems continued to post notices of nondiscrimination and taglines even after the 2020 rule came out, Bonjean said. If not, until HHS finalizes the 2022 proposed rule, "the Biden rule is not in effect, so no one needs to implement the notice of availability" for the time being, she noted.

New to the Rule: A Provision on Clinical Algorithms

The 2016 and 2020 rules said nothing about clinical algorithms, but this proposed version includes a "completely new area for HHS under this statutory scheme," Moore said. It presents clinical algorithms as a basis for liability if they have a discriminatory impact.

Clinical algorithms are used to guide health care decisions and include tools like flowcharts, clinical guidelines, computer algorithms and decision support interventions, HHS said. End-users, such as hospitals, providers and payers, use the tools to help with screening, diagnosis, prognosis, clinical decision-making, treatment planning and other functions. But HHS wants to address recent research showing that clinical algorithms may result in discrimination.

"HHS is also suggesting that hospital systems and any covered entity start thinking about ways to mitigate the use of race-based algorithms. They recommend policies and procedures for when and how to rely on clinical algorithms, monitoring potential impacts and training staff," said Moore, a former Department of Justice attorney.

Contact Moore at tmoore@kslaw.com and Bonjean at abonjean@polsinelli.com. ✧

Endnotes

1. Centers for Medicare & Medicaid Services, "Nondiscrimination in Health Programs and Activities," unpublished rule, accessed July 28, 2022, https://bit.ly/3zewzRl.
2. Bostock v. Clayton County, 590 U.S. ___ (2020), https://bit.ly/2zN7LW8.
3. U.S. Department of Health & Human Services, "Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972," May 10, 2021, https://bit.ly/3oe5yrC.

NEWS BRIEFS

◆ **CMS didn't collect $416 million of the overpayments identified by the HHS Office of Inspector General (OIG) during the 27-month period from Oct. 1, 2014, through Dec. 31, 2016, according to an OIG report posted July 28.**[1] There wasn't documentation to support that CMS collected another $152 million in overpayments flagged by OIG, bringing the total to 55% in unconnected overpayments. According to the report, CMS had various reasons for not collecting overpayments, including provider appeals and redeterminations of overpayment amounts by CMS and Medicare administrative contractors (MACs). To improve overpayment recoupment, OIG made nine recommendations, such as establishing policies and procedures "that define and require retention of documentation that is needed for independent verification of the collection of overpayments." In its response, CMS agreed with one recommendation, agreeing they should "promptly collect our recommended and sustained overpayments, and when CMS and the MACs do so, they must retain the documentation needed to create an audit trail." But CMS didn't agree with seven recommendations and was noncommittal on another.

◆ **CMS will soon flesh out the details of the new process for Medicare patients to appeal a hospital's decision to change their status from an inpatient to an outpatient receiving observation services, according to its website.**[2] The appeal process will only be available to certain patients, as the website explains, and it sprouted from a Jan. 25 federal court decision.[3] The U.S. Court of Appeals for the Second Circuit ruled the constitutional rights of Medicare beneficiaries are violated when they can't appeal a hospital's decision to change their status from an inpatient to an outpatient receiving observation services.

Endnotes

1. Christi A. Grimm, *CMS Reported Collecting Just Over Half of the $498 Million in Medicare Overpayments Identified by OIG Audits*, A-04-18-03085, Office of the Inspector General, U.S. Department of Health and Human Services, July 2022, https://bit.ly/3vpiRdi.
2. "How do I file an appeal?" Medicare.gov, last accessed July 29, 2022, https://bit.ly/3oCoLUG.
3. Barrows v. Becerra, No. 20-1642-cv (2nd Cir. Jan. 25, 2022), https://bit.ly/3fZFcGr.