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INSIDE THIS ISSUE

Compliance Perspectives: Avoid HIPAA Violations When Denying Patient Requests to Amend PHI

On Sept. 9, 2019, the HHS Office for Civil Rights (OCR), the agency that enforces HIPAA rules, announced that it had done something it has never done before: settle an enforcement action for not complying with HIPAA provisions ensuring individuals access to their own protected health information (PHI). Rather than an outlier, the $85,000 settlement with a Florida hospital is an indication of where HIPAA enforcement is heading. Earlier this year, the OCR announced it was kicking off a new Right of Access enforcement focusing on the sometimes overlooked HIPAA patient access rights.

Bottom Line: This would be an excellent time to review your current PHI access policies and procedures to ensure they meet HIPAA requirements. Let's focus on a particularly troublesome aspect of PHI access: denying patients' requests to amend their own PHI.

When You Can Deny PHI Amendment Requests

HIPAA requires labs and other covered organizations to give patients rights over their own PHI. That includes allowing patients to request amendments to their PHI. But HIPAA doesn't say that you have to accept these requests. Denials are allowed in four situations:

Continued on page 2

Brief Your CEO: It May Become Easier to Get CMS Stark Clearance for Business Deals with Referral Sources

Part of the challenge of running a lab compliance program is making your officers aware of how business transactions your lab makes with a physician that refers patients to you for testing creates the risk of liability under the Stark Law. That's why it's crucial to go to great pains to structure your deals so they don't cross the Stark Law lines. Unfortunately, you can never be totally sure if your arrangement complies. One of the best ways to allay your concerns is by asking the OIG for an advisory opinion. If the OIG blesses the arrangement, you can feel good about proceeding;

Continued on page 10

Avoid HIPAA Violations When Denying Patient Requests to Amend PHI, *from page 1*

1. PHI is accurate and complete. You can deny an amendment request if you review the PHI in question and determine that it's accurate and complete, i.e., you determine that there's no erroneous or missing information that would justify making the requested amendment.
2. PHI isn't part of "designated record set." You may also deny requests that aren't part of the patient's "designated record set," which typically includes only a provider's medical and billing records, a plan's enrollment, payment and claims records and other materials used to make decisions about a patient.
3. You didn't create the PHI. You don't generally have to let patients amend PHI that you didn't create, e.g., requisitions for lab tests as opposed to lab test results. Exception: If the patient provides a reasonable basis to believe that the originator of the PHI is no longer available to the amendment request, e.g., the doctor who ordered the tests is dead and her practice is defunct, you must make your own determination about whether to grant the amendment request.
4. Privacy regulations restrict patient's access to the PHI. Right to amend doesn't apply to PHI that the regulations don't give the patient the right to inspect, e.g., psychotherapy notes and PHI compiled in anticipation of a civil, criminal or administrative action.

How to Deny PHI Amendment Requests

In addition to having a substantive basis for denial, you must comply with the rules for notifying patients when you nix their PHI amendment requests. Specifically, you must put the denial in writing and explain the rights patients have with regard to the denial. This is true even if you deny just part of the PHI requested. The deadline to furnish the written denial is 60 days from the date you receive the amendment request—subject to a 30-day extension that you may be able to get in some circumstances. The denial notice must also meet the criteria set out in the HIPAA privacy regulations, i.e., it must:

- Be written in plain language that's easy to read and understand;
- State the reason for the denial, i.e., one of the four situations described above;
- List the patient's right to submit a written statement disagreeing with the denial;
- Explain how the patient may file such a statement with the organization and any limitations on statement length that you impose;
- State that if the patient decides not to submit a statement of disagreement, he/she may ask the organization to include the amendment request and denial with any future PHI disclosures; and
- Describe how the patient can file a privacy complaint with your organization and/or to HHS; and
- List the name and title of and contact information for your privacy contact person.

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COMPLIANCE TOOL

Model PHI Amendment Denial Letter

There are two things you must do to lawfully deny a patient's request to amend his/her own PHI: i. Have a legal basis for the denial, i.e., at least one of four circumstances described in the previous article must be present; and ii. You must put the denial in writing and ensure it meets the criteria for a denial notice in the HIPAA privacy regulations. Here's a Model Letter that presses all the right buttons and you can adapt for your own use.

Denial of Patient PHI Amendment Request

Date

Re: Patient request to amend PHI

Dear Patient:

XYZ Laboratory (Lab) has reviewed your request to amend your protected health information (PHI) and has decided to deny the request for the reasons we will explain to you now.

Description of the amendment request that is being denied [*list the request date, PHI the requestor wanted to amend and any other key information about the request*].

Basis for denying the amendment request [*explain the reason(s) for denial, i.e., the applicable circumstance(s) for which you can deny a PHI amendment request under HIPAA privacy regulations*].

Under the Health Insurance Portability and Accountability Act (HIPAA), you have the right to send a written statement disagreeing with this denial. If you would like to submit such a statement, please send it to [*list privacy contact's name, title, mail or email address*]. Please note that Lab rules limit statements of disagreement to [*insert number*] words.

If you choose not to submit a statement of disagreement, you may request that your original amendment request and this denial be included in any future disclosures by Lab of your PHI.

If you would like to file a complaint with Lab about our privacy practices, please contact [*list privacy contact's name, title and phone number*]. If you would like to file a complaint about our privacy practices with the Secretary of the U.S. Department of Health and Human Services, please contact [*list privacy contact's name*], who will give you instructions about how to file such a complaint.

If you have any questions or would like additional information about this letter or this matter, please contact the privacy contact named above.

Yours truly,

Labs IN COURT

A roundup of recent cases and enforcement actions involving the diagnostics industry

Quest Pays $88.7K to Settle Specimen Collection Fee Kickback Charges Against Its Subsidiary

Case: After self-disclosing, Quest has settled kickback claims against its wholly-owned subsidiary, Quest Diagnostics TB LLC, for $88,780. The OIG alleges that from June 2011 to December 2016, the lab that was then known as Oxford Immunotec, Inc. (OI) made improper payments to physicians and physician groups in the form of blood sample collection, processing and handling fees. Quest acquired OI in December 2018.

Significance: The OIG has repeatedly reminded labs that sample collection and processing fees raise bright red flags under the Anti-kickback Statute. See Lab Compliance Advisor (LCA) Dec. 10, 2018. Considering the penalties imposed on other labs for paying collection fees, most notably HDL, and the fact that the alleged scheme in this case lasted over five years, $88.7K is a fairly light penalty and testimony to the wisdom Quest displayed in self-disclosing the conduct.

Alabama Doctors, Cardio Practice, Settle Genetic Testing Kickback Claims for $1.1 Million

Case: Three doctors and a cardiology practice, all based in Alabama, have agreed to shell out $1.1 million for allegedly taking bribes from a now-bankrupt genetic testing company in the Seattle area. The DOJ claims that Natural Molecular Testing Corporation (NMT) paid doctors as much as $10,000 per month in consulting fees in exchange for referrals of high-complexity tests that were then billed to Medicare.

Significance: In 2015, after entering Chapter 11, NMT settled claims related to its part in the scheme for $71.1 million. In addition to paying kickbacks, the genetic test lab was accused of a litany of billing violations, including billing for tests that weren't medically necessary, failure to document completion of the testing, submitting multiple billing claims for the same date of service and billing genetic tests used for screening purposes (which Medicare doesn't cover).

New Jersey Lab Hit with $144.6K Settlement Tab for Improper Billing of Nerve Conduction Studies

Case: OIG investigators concluded that MDR Diagnostics, LLC, of New Brunswick, NJ, billed for nerve conduction studies that are considered screening exams not covered by Medicare. Rather than duke it out in court, MDR has decided to pay $144,621 to settle the charges.

Significance: Nerve conduction studies (NCS), which measure action potentials resulting from peripheral nerve stimulation that are recordable over the nerve or from an innervated muscle, are covered for use in diagnosing peripheral nervous system disorders in symptomatic patients but not for use as part of a routine physical screening exam used on all patients.

Kentucky Lab Settles Self-Disclosed SVT False Billing for $88.2K

Case: After self-disclosing, Kentucky lab Ethos Laboratory has agreed to pay $1,345,959 to settle charges for improper billing of specimen validity tests (SVT), a quality control process designed to catch drug test cheaters by verifying that a urine drug screen sample is consistent with normal human urine and hasn't been

adulterated, diluted or substituted. While urine drug testing for medical treatment purposes meet Medicare medically necessary criteria, SVT is a non-covered service.

Significance: This is by far the largest settlement over SVT billings. The crackdown began in Feb. 2018, when the OIG cited Medicare for making $66.3 million in improper SVT payments to nearly 4,500 labs and physician offices. In response, CMS ordered Medicare contractors to take measures to get that money back. In 2019, eight different urine drug testing labs have come forward to self-disclose improper SVT billing, most of them providers from the Ohio Valley, generating over $2.6 million in total recoveries:

Urine Drug Testing Lab SVT Billing Settlements (Jan. thru Aug. 2019)

Date	Lab	Settlement Amount
Jan. 24	Northern Kentucky Center for Pain Relief	$126,799
Feb. 6	Wheelersburg Internal Medicine Group + Mohammad Mouhib Kalo, MD (Ohio)	$111,706
March 13	VerraLab JA, LLC (Louisville, KY)	$125,983
March 13	Medical Specialist of Kentuckiana, PLLC (Louisville, KY)	$69,776
May 30	Commonwealth Pain Associates, PLLC (Louisville, KY)	$88,214
June 28	Ethos Laboratory (Newport, KY)	$1,345,959
Aug. 7	Discover Diagnostic Laboratory, LLC (Oak Ridge, TN)	$95,882
Aug. 22	American Clinical Solutions, LLC (Boca Raton, FL)	$61,546

Kickbacks Scorecard: Medical Practices and Doctors Settlements for Accepting Millennium Freebies

In 2016, Millennium Health settled one of the largest lab kickback schemes ever concocted for $256 million. In September 2017, federal enforcers turned their attention to the practices that accepted bribes from Millennium in the form of free point of care test cups. In July, Anesthesia Services P.C. d/b/a University Pain Clinic of Detroit became the tenth practice to settle charges for taking the free cups. Settlement total: $44,900. Here's a rundown of all the announced settlements to date.

Millennium Free POCT Cup Physicians Settlement Scorecard (as of Sept. 20, 2019)

Date	Provider(s)	Settlement Amount	Individual Physicians Also Charged?
July 12, 2019	Anesthesia Services P.C. d/b/a University Pain Clinic (Detroit)	$44,900	NO
June 14, 2019	HKD Treatment Options, P.C.	$87,650	NO
Dec. 21, 2018	Tulsa Pain Consultants, Inc.	$98,942	YES
Sept. 6, 2018	Doctor's Inlet Pediatrics and Primary Care, P.A., and Avenues Pediatrics and Internal Medicine (Florida)	$58,370	YES
May 24, 2018	Recovery Pathways, LLC (Michigan)	$64,555	NO
April 5, 2018	Affordable Medical Care f/k/a Andalusia Medical Center (Alabama)	$40,500	YES
Feb. 28, 2018	The Pain Institute, Inc. d/b/a Space Coast Pain Institute (Florida)	$95,302	YES
Dec. 5, 2017	Addiction Medical Care of Norwalk, Practice Management Associates Norwalk, LLC, Addiction Medical Care of Columbus, and Practice Management Associates, LLC (collectively, "AMC") (Ohio)	$79,880	NO
Sept. 27, 2017	Advanced Pain Management (Arizona)	$186,210	NO
Sept. 18, 2017	Parallax Center, Inc. (New York)	$64,203	NO

You Make the Call: Does Lab Manager Have a Valid Claim for Age Discrimination?

What's At Stake

As lab manager involved in personnel decisions, you have a responsibility to ensure your lab complies with the Age Discrimination in Employment Act (ADEA), which bans taking "adverse action against an employee because of his or her age." So, being able to recognize what is and is not age discrimination would certainly come in handy. To test—and expand—your current understanding of ADEA, consider the following scenario, which is based on an actual case in which a lab manager claimed she was fired because of her age. Your assignment: Determine if she has a legally valid claim.

What Happened

A lab technician hired in 2005 was promoted to lab manager in 2009. Her performance evaluations indicated that she had "met or exceeded expectations." By 2018, she was "one of the oldest and highest paid employees of" the lab. That year was also the year she got terminated. The manager claimed that this was no coincidence and that she was the victim of age discrimination. The fate of her case would come down to whether she could back that up. We'll get into the details later; but first, we need to frame the legal context.

How Discrimination Litigation Works

As with any other employment discrimination claim, employees claiming age discrimination have the burden of making out what's called a *prima facie* case. That doesn't mean proving the claim; at this point in the proceedings, it just means making a strong enough case to persuade the judge that they have a chance to win and deserve the chance to go to trial.

While this might sound like something that only a litigator would care about, it actually has enormous real-world significance should your lab ever be sued for discrimination. Reason: If the employee doesn't make out a *prima facie* case, you can get the court to dismiss the case on the spot; but if the employee does make out a *prima facie* case, you have to go to trial to defend yourself. And trials are unpredictable and risky (that's why the vast majority of cases settle before trial). Accordingly, the negotiating leverage shifts in favor of the employee who is now in a stronger position to command money to settle the case.

What the ADEA Requires

There are four things employees must show to make out a *prima facie* case under ADEA:

- They're over 40-years-old;
- They're qualified for their job;

Does Lab Manager Have a Valid Claim for Age Discrimination?, From Page 7

- They've suffered "an adverse employment action" at the hands of their employer; and
- There's some evidence of a "causal connection" between their age and the adverse employment action.

Meeting the first three prongs is usually a mere formality. It's prongs three and four where most ADEA cases are decided. In other words, employees' biggest challenge in making out a *prima facie* case is demonstrating that they have a shot at showing that being over age 40 didn't diminish their skills or otherwise render them unqualified for their job and that the real reason they suffered the adverse action was, at least in part, due to their age.

Applying the Rules to the Case

Now let's look at the lab manager's case, starting with the facts on which all sides agreed:

- She was over age 40; and
- She suffered an adverse employment action, namely, she was fired.

The court also ruled that the manager's positive performance reviews was enough to show that she was qualified to do her job. So, the case came down to prong four. In deciding whether there was a causal connection between her age and her firing, the court would just assume that her version of events was true. The lab would get its chance to debunk those facts at trial when and if the manager made out a *prima facie* case.

The Manager's Side of the Story

The problems began a year earlier, the manager contended. The lab had just implemented a new work share program. The manager defended the program when an employee confronted her over it. But the lab director fired the objecting

employee while at the same time warning the manager that he could do the same to her. From that point on, the manager said she was "systematically phased out of management decisions" and that the director began demeaning her in front of co-workers, often referring to her as "irrelevant." Then came a sexual harassment incident involving the director's wife that the manager reported to HR, followed by threats from the director that caused the manager to tell HR that she feared for her safety.

You Make the Call: Did the Manager Meet Prong 4?

The court said no. Explanation: Even if the manager's story was true, it wouldn't be the basis of a valid claim for age discrimination. The manager alleges no facts "demonstrating a causal connection between her age and her firing," the court reasoned. The only mention of age was the reference to her being one of the lab's oldest employees and the director's calling her irrelevant, evidence which was too "speculative" to support a finding of age discrimination. So, the court found that the manager didn't make out a *prima facie* case and tossed the claim without a trial.

Merrick v. Franey Med. Lab, 2019 U.S. Dist. LEXIS 159454, Sept. 19, 2019

It May Become Easier to Get CMS Stark Clearance for Business Deals with Referral Sources, From Page 1

if not, you can take the proposed deal off the table or restructure it to address the OIG's Stark Law concerns.

At least that's how it's supposed to work. But in the real world, getting Stark Law advisory opinions is tricky and thus not resorted to as often as you'd expect. The good news that you should convey to your C-Suite is that getting an advisory opinion may be back in play soon. In late July, CMS proposed to update the advisory opinion process to make it easier for labs and other providers to get an OIG determination about whether a proposed business arrangement would violate the Stark Law. Here are the key things you need to know to brief your CEO and officers on the situation.

The Current Process

The first thing the officers need to understand is how the current CMS Stark Law advisory opinion process works. The process is modeled on the one the OIG uses to issue advisory opinions under Stark's sister law, the Anti-Kickback Statute (AKS). That's not surprising. After all, both laws are designed to prevent conflict of interest and payment for referrals. But there are also important differences between the laws that makes the AKS advisory opinion model unsuitable for Stark.

For one thing, Stark Law advisory opinions are more badly needed. Explanation: AKS is a criminal statute while the Stark Law is a strict liability civil payment statute. And unlike the AKS, qualifying for an exception is mandatory to avoid

It May Become Easier to Get CMS Stark Clearance for Business Deals with Referral Sources, From Page 9

liability under Stark. That makes the need for Stark guidance through the advisory opinion process more important than it is for the AKS. But in spite of this, CMS has issued only 30 advisory opinions since the advisory opinion regulations were adopted in 1998.

Another big difference is that unlike the case with AKS, only the requestor, i.e., the provider that asks for the advisory opinion, is allowed to rely on a Stark Law advisory opinion. In other words, the opinion doesn't apply to the other non-requesting parties to the arrangement nor third parties seeking to use the advisory opinion as guidance for their own transactions. That substantially limits the value of an advisory opinion.

The 5 Proposed Changes

The fact that the Stark Law process is troubled has been obvious to providers for decades. But CMS didn't get the memo. For CMS, the need to fix the Stark Law advisory opinion process came to light in July 2018 when the agency issued a Request for Information (RFI) on adapting Stark to value-based care. See Lab Industry Report (LIR), July 16, 2018. The advisory opinion process was the subject of many of the comments, even though it wasn't one of the issues listed in the RFI. The good news is that CMS got the message and decided to tinker with the process. The July 2019 proposal suggests five changes to the Stark Law advisory opinion process that you should go over with your officers.

1. Broaden Scope of Issues Advisory Opinion Can Cover

   Current Process: CMS will not provide a Stark Law opinion if:

   The request is not related to a named individual or entity;

   CMS is aware that the same or substantially the same course of action is under investigation or is or has been the subject of a proceeding involving HHS or another governmental agency; or

   The agency believes that it can't make an informed opinion or could only make an informed opinion after extensive investigation, clinical study, testing or collateral inquiry.

   Proposed Change: The agency wants to loosen these restrictions so it can issue advisory opinions on any conduct that's the subject of a current government investigation or other proceeding.

2. Shorten Timeline for Issuing Advisory Opinions

   Current Process: CMS has 90 days to issue a Stark Law opinion, as compared to the 60 days the OIG has to issue an AKS advisory opinion.

   Proposed Change: CMS proposes to shorten the deadline to 60 days, which would begin on the date that CMS formally accepts the request for an advisory opinion. The clock would also continue to tick while a request is revised and/or while CMS awaits information from the requestor. CMS is even considering providing an option to request an expedited 30-day review.

3 Ease Certification Requirements

Current Process: Labs and others requesting advisory opinions must certify that, to the best of their knowledge, all of the information provided as part of the request is true and correct and constitutes a complete description of the facts on which the advisory opinion is being requested. Of particular interest to your officers is the rule that if the lab is a corporation, the certification must be signed by the CEO or comparable officer.

Proposed Change: CMS proposes to allow the certification to be signed by any officer that's authorized to act on behalf of the lab requesting the advisory opinion. Alternatively, CMS is considering whether to eliminate the certification requirement altogether since it may be unnecessary given that federal laws already exist that criminalize the submission of material false statements to a federal agency.

4 Revise Fee Structure for Processing Advisory Opinions

Current Process: To cover costs, CMS charges requestors an initial fee of $250 and holds requestors responsible for any costs incurred in excess of the initial $250 payment.

Proposed Change: CMS is proposing to adopt an hourly fee of $220 for preparation of an advisory opinion—$440 per hour for an expedited opinion. CMS is also considering whether to eliminate the initial fee and whether to establish a cap on fees.

5 Let Third Parties Rely on Advisory Opinions

Current Process: Only the provider that requests a Stark Law advisory opinion is legally allowed to rely on it. CMS takes the position that persons who aren't a party to the transaction may misuse an advisory opinion to evade liability.

Proposed Change: Under the CMS proposal, a favorable advisory opinion, i.e., one finding an arrangement not to raise Stark Law concerns, would preclude penalties against not only the parties requesting the opinion, but also any other individuals or entities that are parties to the specific arrangement for which the advisory opinion is issued. CMS also proposes not to pursue sanctions against parties to an arrangement that CMS determines to be "indistinguishable in all material aspects" from an arrangement that was the subject of a favorable advisory opinion. Last but not least, CMS wants to expressly recognize that other third party individuals and entities may reasonably rely on an advisory opinion as non-binding guidance.

What is the CMS Not Proposing?

While the proposed changes are certainly welcome, let your officers know about one of the changes that didn't make the cut. Specifically, CMS is sticking to its guns about not accepting advisory opinion requests based on hypothetical fact patterns. Many RFI commenters called on CMS to allow

Continued on page 12

It May Become Easier to Get CMS Stark Clearance for Business Deals with Referral Sources, From Page 9

advisory opinion requests that involve hypothetical fact patterns and general questions of interpretation, especially given the strict liability nature and outsized payment penalty risks for violations of the law.

CMS, however, for the time being, declined to expand the scope of requests it will consider to hypotheticals or general interpretation questions, but agreed to accept comments on whether CMS should propose such an expansion in the future. CMS declined to do so at this time out of concern that the agency would be overwhelmed with requests. CMS, however, will consider requests for opinions that involve existing arrangements and arrangements into which the requestor plans to enter.

6 Stark Law Advisory Opinion Process Changes Still on the Table

Remind your officers that the July proposals are just that—proposals and that the agency is still fielding public comments. Among the issues CMS is still considering is whether it should:

- Remove limits on the universe of individuals and entities that can rely on an advisory opinion;
- Add language listing the permissible uses of an advisory opinion;
- Limit its right to rescind an advisory opinion to only when: (1) there's a material regulatory change that impacts the conclusions reached; or (2) a party that receives a negative advisory opinion asks the agency reconsider in light of legal or factual developments;
- Issue advisory opinions based on hypotheticals or general questions of interpretation;
- Establish an expedited process for obtaining advisory opinions; and
- Cap fees for advisory opinions and/or eliminate the initial fee.