G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

G2 Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

September 2018

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Lab Institute 2018

Surviving Disruption: Rethinking Business Models, Technologies, and Competitive Strategies in a Changing Lab Market

Oct. 24-26, Washington, DC
www.labinstitute.com

Compliance Perspectives: Keeping Employees from Damaging Your Lab on Social Media

In the cyber age, protecting your lab from the potential threat posed by employee blogging, tweeting, Instagramming and other social networking is a business imperative. But how? To find out, keep reading...

It *Is* Your Business

The starting point is recognizing that social networking by employees is not purely a private matter. Over the past decades, courts and arbitrators have consistently recognized an employer's right to intervene to prevent activity that harms or has the potential to harm the organization's business or reputation, including:

1. Productivity Losses

Anyone who has at least dabbled in it understands how addictive social networking can be and how easily it can suck up your time. What may be intended as a simple exchange can turn into a day-long interaction. And, of course, many employees choose to do their social networking at work. According to one recent study, the average employee spends 2.35 hours on social media during every work day(!), resulting in productivity losses of 13%.

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Brief Your CEO: Real Stark Law Relief Might Actually Happen

Fool me once, shame on you; fool me twice, shame on me.

That may have been your reaction when you first heard about the new CMS Request for Information (RFI) seeking input on ways to alleviate the Stark Law's "undue regulatory impact and burden." But while your skepticism is understandable, this time it might actually happen. That's why we're suggesting that you let your C-Suite people know what's going on. Here's how:

Setting the Stage

When talking to the lab executives, it's generally advisable to relate your issue to business considerations. So, start your briefing by pointing out that what you are about to discuss is a law that

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Keeping Employees from Damaging Your Lab on Social Media, *from page 1*

2. Threats to Business Confidentiality

One of the things people like to talk about is their jobs. And in a social context, they tend to speak candidly. Such conversations can be kept private when they occur face-to-face or on the phone. But keeping such interactions private is more problematic when they occur online, especially within an external social network that anybody with internet access can join like Facebook or LinkedIn. *The result:* damaging leaks, whether deliberate or inadvertent. Example: An employee tells her Facebook chum that your lab is in secret merger talks with a local hospital and expresses concerns about her job.

3. Undermining of Management

Complaining to friends about work, bosses and colleagues is a venerable and largely harmless social tradition. But when it happens online, it's not so harmless, even if the whole conversation takes place while the employee is off duty and at home. In a cyber world, gripes get expressed in the form of inappropriate postings, pictures and jokes about doctors, patients and colleagues online where anybody can see them. In addition to harming morale, such communications can expose the lab to risk of liability for harassment, discrimination and other violations.

4. Harm to Reputation

The unflattering things or inappropriate materials say or post online on their networking page about your lab, its staff and the doctors or patients it serves may harm your reputation and standing in the community.

Example: In her blog, a hospital RN referred to the nurse who supervised her as "Nurse Ratched"—the nurse from hell in *One Flew Over the Cuckoo's Nest*. Although the employee didn't use her name in the blog, she didn't bother to hide the fact that she worked as a nurse for a hospital in a particular county that had only one hospital. So, it was pretty easy to figure out who "Nurse Ratched" was. An arbitrator found the blog grounds for termination.

5. Violations of Patient Privacy

Employees may reveal patient records and other PHI that violate HIPAA and undermine your relationship with referring physicians, not to mention the physician-patient relationship.

6. Discrimination & Harassment of Other Employees

Online comments about co-workers may constitute harassment or discrimination and expose your lab to liability. Employees may also download, view or transmit pornographic, racist and other offensive material from the internet at work in violation of your harassment or discrimination policies.

7. Liability for Illegal Activities

Employees may conduct illegal activity on the internet at work, such as distributing child pornography or downloading material in violation of copyright law. There's no shortage of legal theories that can be used to hold your lab vicariously liable for such activities especially when employees use your computer and network to conduct them.

G2CA

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G2 Compliance Advisor
(ISSN 2332-1474) is published by G2 Intelligence, Plain Language Media, LLLP, 15 Shaw Street, New London, CT, 06320.
Phone: 888-729-2315
Fax: 855-649-1623
Web site: www.G2Intelligence.com.

8. Harm to IT Infrastructure

Employees who use the internet for unauthorized purposes may introduce viruses, worms, Trojan horses and the like into your lab's information network, causing serious problems for the IT infrastructure. Use of the lab network for personal business, e.g., downloading large files, can also slow down the system and make it harder for other employees to use the network to do their jobs.

The centerpiece of your effort to curb social networking and blogging abuses is to establish and consistently enforce a Social Networking Policy that addresses these activities.

3 Ways to Prevent Social Networking Abuses

Implement clear and specific policies to establish your right to discipline employees for social network abuses or, better yet, deter them from committing them in the first place. Three strategies that have proven effective:

1. Address Social Networking in Confidentiality Agreements

Like many labs, you may ask employees to sign confidentiality agreements banning them from disclosing confidential information. Add language to the agreement requiring employees to abide by their confidentiality obligations while engaging in social networking and other forms of online activity. Spell out that revealing sensitive organization information on an online social network at home is just as unacceptable as doing it in a business communication during work.

2. Address Social Networking in Codes of Conduct

Most labs have HR policies or standards of conduct banning unacceptable behavior like harassment, bullying and bad-mouthing bosses, clients and the organization. Indicate that these forms of misconduct are equally unacceptable and subject to discipline on a social network or other online activity, whether conducted on- or off-duty.

3. Set Specific Policy on Employee Social Networking

The centerpiece of your effort to curb social networking and blogging abuses is to establish and consistently enforce a Social Networking Policy that addresses these activities. Make sure your policy is realistic. Simply banning employees from using social networking sites or blogging altogether is impossible to enforce, especially to the extent it applies to what employees do off-duty. Although each practice must tailor its policy to its own, the Model Policy is a pretty good template. Like the Model, your social networking policy should spell out that:

- All lab computers, IT equipment and internet access is intended for business use only and may not be used for non-work-related purposes;
- Employees are expected to work while on duty;
- Employees may not post or say anything on a social networking site that harms the lab's reputation and good standing in the community;
- Employees may not insult, offend or demean the labs or its staff, clients or patients or divulge confidential information about them online; and
- The content of any employee postings must comply with all lab policies, including its code of conduct and discrimination and harassment policies.

TOOL: Model Employee Social Networking Policy

Here's a Model Policy your lab can adapt to limit potentially harmful social networking activities by employees.

EMPLOYEE SOCIAL NETWORKING POLICY

The purpose of this policy is to outline acceptable and unacceptable use of any computer equipment and other technology by all "employees" (as defined below) of XYZ Laboratories ("XYZ") as such use relates to blogs and/or social networking websites. These rules and restrictions herein are in place for the protection of XYZ and its employees, clients and patients.

1. Scope

a. Who This Policy Covers: This Policy applies to all permanent, probationary and temporary employees; contractors; consultants; and other workers at XYZ, collectively referred to as "employees."

b. What This Policy Covers: For purposes of this Policy, "social networking" refers to online interactions with individuals of common interests via chat, messaging, video, file sharing, blogs, texting, Twitter messaging, email, discussion groups and other methods on external social networks, including but not limited to sites open to all web users such as Facebook, MySpace and Bebo.

2. Prohibited and/or Restricted Uses

a. XYZ Owns Computer Equipment: All equipment and technology purchased or leased by XYZ (regardless of its location) that is accessed by its employees, including without limitation, computers, internet access, PDAs, is intended for work-related use only. Employees may not use any XYZ equipment or technology for personal purposes, including, but not limited to, maintaining, accessing or using a personal blog or social networking website.

b. No Social Networking during Work: While at the workplace during work hours, employees are expected to be working, not handling personal matters. Employees must keep their outside interests and activities, including, but not limited to, the maintenance, access or use of a personal blog or social networking website, outside the workplace.

c. No Negative Communications on Social Networks: Employee social networking communications, including, but not limited to, postings on blogs and social networking websites, must not negatively impact XYZ's reputation or standing in the community Any communications that are insulting, demeaning, or offensive to XYZ, its employees, doctors, referral sources, patients or affiliates, or that XYZ otherwise deems harmful or damaging are a violation of this Policy.

d. No Publication of Private or Confidential Information: Employee social networking communications must not include any information which XYZ deems is a trade secret or other sensitive or confidential information related to XYZ, its doctors, employees, referral sources or patients.

e. Social Networking Subject to Other Practice Policies: The content of employees' social networking communications must comply with all XYZ policies, including, without limitation, the Code of Conduct and any policies related to discrimination and harassment in the workplace.

3. Violation of this Policy

Any employee who violates this Policy will be subject to disciplinary measures up to and including dismissal.

4. Acknowledgement

I hereby acknowledge that I have received, read and understood this Policy and promise not only to follow it in all key respects but also help to enforce it by reporting to my supervisor or the XYZ HR manager any or potential violations committed by other persons that I become aware of.

Name: _____

Date: _____

Proposed 2019 Medicare HOPPS Rule: The 4 Things Labs Need to Know

Heads up to labs that bill Medicare for services to hospital outpatients: CMS issued the proposed 2019 hospital Outpatient Prospective Payment System (OPPS) on July 25, with comments scheduled to end on Sept. 24. Highlights:

1. 1.25% Rate Increase

CMS proposes increasing 2019 OPPS rates by 1.25%, based on a:

- 2.8% market basket update;
- -0.8% productivity adjustment update; and
- -0.75-percentage point adjustment for cuts under the *Affordable Care Act* (ACA).

CMS wants to modify the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) patient experience of care survey measure by removing three recently revised pain communication questions.

2. 40% Site-Neutral Payment

CMS wants to reduce the payment rate for hospital outpatient clinic visits provided at off-campus provider-based departments to 40% of the OPPS rate. The clinic visit is currently the most common service billed under the OPPS. The proposed rule would also cut payments to currently grandfathered sites for certain clinic visit services to address concerns about the trend where more services are shifting away from doctor offices and into hospital outpatient departments.

3. Hospital Outpatient Quality Reporting Program

CMS is proposing to remove one measure from the Hospital Quality Reporting Program beginning with the 2020 payment determination and remove nine other measures beginning with the 2021 payment determination. "The proposals to remove these measures are consistent with the CMS' commitment to using a smaller set of more meaningful measures and focusing on patient-centered outcomes measures, while taking into account opportunities to reduce paperwork and reporting burden on providers," the agency noted in the fact sheet for the proposed rule.

4. Opioid-Related Policies

CMS wants to modify the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) patient experience of care survey measure by removing three recently revised pain communication questions. The change stems from concerns that providers may feel unduly pressured by patients seeking opioid-based therapies who can, in turn, report the physician neglected their preferences, as well as an intent to avoid any potential unintended consequences of possible opioid overprescribing. In addition, the *President's Commission on Combating Drug Addiction and the Opioid Crisis* has recommended that CMS review its payment policies for certain drugs that function as a supply: specifically, non-opioid pain management treatments.

Labs IN COURT

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

Kickback Settlement Costs Pennsylvania Hospital $13.1 Million

Case: The most expensive kickback settlement of 2018 to date features Post Acute Medical, LLC (PAM) in the starring role. The case which began as a whistleblower lawsuit, claims the Pennsylvania-based rehab hospital paid physicians and other providers to generate millions of dollars in referrals for medical services which it then falsely billed to Medicare and Texas and Louisiana Medicaid. For his part in initiating the case, the whistleblower will pocket a tidy $2,345,670 share of the recovery.

Significance: The key to the case are the details of the scheme, which the feds contend began when PAM first acquired the facilities in 2006. The complaint cites two kinds of financially suspect arrangements to induce referrals:

- Bribes disguised as medical director and other administrative fees paid under physician-services contracts; and
- "Reciprocal referral arrangements" under which PAM promised to refer patients to unaffiliated home health agencies and other providers on the understanding that the provider would refer its other patients to PAM facilities.

Michigan Hospital System Settles False Billing of Kickback-Induced Services for $84.5 Million

Case: William Beaumont Hospital has agreed to cough up $84.5 million to settle False Claims Act charges. The case, which began as a qui tam whistleblower lawsuit, contends that the Detroit-based regional hospital system provided free or below-market office and employment assistance to eight physicians in exchange for referrals of lab and other services between 2004 and 2012.

Significance: Paying kickbacks to referring physicians was the primary offense (although the feds also claim that Beaumont misrepresented that its CT radiology center qualified as an outpatient department in its billings). So, it may seem odd that was this an FCA rather than an Anti-Kickback case. The explanation is simple: Beaumont brought the FCA—and its more punitive provisions—into play by subsequently billing the services generated by the allegedly ill-gotten referrals to Medicare, Medicaid and TRICARE.

Shareholders Sue Missouri Hospitals for Alleged Lab Billing Ripoff

Case: A new shareholder lawsuit targets the CEO and other individuals at a Missouri 10-hospital group called HMC Hospitals for allegedly running a $90 million lab billing fraud scheme out of the facilities. The suit claims that HMC hospitals submitted claims for lab work ostensibly performed for pain and detoxification clinics but that was actually done at other labs. By leveraging the hospitals' status as Medicare and Medicaid critical access rural hospitals, the schemers were able to command higher rates than the labs that actually performed the tests. Those other labs were then paid a portion of the reimbursement as a kickback.

Significance: This case is the most recent example of the growing role the private sector in targeting lab fraud. Of course, whistleblowers have long represented the private arm of the enforcement. But this is lawsuit is driven by corporate rather than regulatory concerns. The plaintiffs aren't whistleblowers acting as private attorneys general but as shareholders of the entity that owns the 10 HMC hospitals suing on behalf of themselves and the other shareholders.

California Lab, Owner Excluded 5 Years for Medicare Screening Test Billings

Case: Billing Medicare for screening exams is illegal. The latest providers to learn that lesson the hard way is Orange, California, independent diagnostic testing facility CHJ Diagnostics, which along with its owner, agreed to a five-year exclusion after OIG investigators discovered it submitted claims for nerve conduction studies considered to be screening exams under Medicare coverage rules.

Significance: Although it is not clear exactly what tests were involved, lab billing for Nuclear Stress Tests has become a more frequent target of federal investigators over the past two years. For more details, see "Using Nuclear Stress Tests as Screening Procedure = Medical Necessity Violation," (*NIR*, Dec. 12, 2017).

Researchers Claim Genomics Giants Stole Their Sequencing Technology

Case: A trio of medical researchers are accusing Illumina, Thermo Fisher Scientific and Affymetrix of stealing the zip code sequencing technology they developed. The trade secret theft and fraud lawsuit claims, among other things, that the peer reviewer of the grant proposal the researchers submitted to the National Cancer Institute for their technology obstructed the grant and tried to get Affymetrix, the firm for which he was chief technology officer, to re-patent the idea. The suit also contends that the founders of Illumina misappropriated and submitted patent claims for the technology and incorporated it into the firm's own SNP genotyping array and AmpliSeq reagents.

Significance: This story has a lot of tentacles. Many of the same zip code sequencing technology patents at the center of this case were also involved in the recently settled infringement lawsuit brought by Thermo Fisher Scientific against Illumina. So, stay tuned…

OIG Work Plan Monthly Review: August 2018

Of the 12 new Work Plan items, four have direct implications for labs and billing of lab tests.

1. Medicare Payments for Clinical Diagnostic Laboratory Tests in 2017: Year 4 of Baseline Data

Issue: Medicare is the largest payer of laboratory service in the nation. Medicare Part B covers most lab tests and pays 100 percent of allowable charges; Medicare beneficiaries do not pay copayments or deductibles for lab tests. In 2016, Medicare paid $6.8 billion for lab tests, accounting for approximately 2 percent of all Part B payments.

OIG Action: The Protecting Access to Medicare Act of 2014 requires OIG to publicly release an annual analysis of the top 25 laboratory tests by expenditures under Title XVIII of the Social Security Act. In accordance with the Act, OIG will publicly release an analysis of the top 25 laboratory tests by expenditures for 2017.

2. Blood Lead Screen Tests, Follow-Up Services and Treatment for Medicaid-Enrolled Children

Issue: There is no safe level of lead exposure for children. In the absence of timely screening, follow-up services, and treatment, children remain vulnerable to cognitive deficiencies associated with lead screening. Medicaid-enrolled children are required to receive blood lead screenings. Under the Early and Periodic Screening, Diagnostic, and Treatment program, children are also entitled to receive follow-up services and treatment for conditions identified through screenings (e.g., elevated blood lead levels (EBLLs).

OIG Action: Although previous OIG reports identified low rates of lead screenings, an evaluation of follow-up services for Medicaid-enrolled children with EBLLs has not been done. OIG will identify the percentage of children under 26 months of age who (1) received required blood lead screenings, (2) had EBLLs, and (3) received needed follow-up services and treatment. Additionally, OIG will determine why children with EBLLs did not receive screening, follow-up services, and treatment—and the extent to which the Centers for Medicare & Medicaid Services (CMS) provided guidance and technical assistance to states.

3. Medicare Market Shares of Mail Order Diabetic Test Strips from April-June 2018

Issue: The OIG is required to report on the Medicare market share of both mail order and non-mail-order diabetic test strips (DTS) before each round of the Medicare competitive bidding program, pursuant to section 50414 of the Bipartisan Budget Act of 2018.

Critical care is exclusively a time-based code in which physicians are paid based on the number of minutes they spend with critical care patients.

OIG Action: In the first of two data briefs, OIG will determine the Medicare market share of mail order DTS for the three-month period of April through June 2018. The second data brief will determine the Medicare market share of non-mail-order DTS for the same three-month period. The data will help CMS determine the relative Medicare market share of various DTS in the mail order and non-mail-order markets. These data briefs represent OIG's third round of DTS Medicare market share reports since 2010, but this is the first series of reports that will include non-mail-order DTS data.

4. Physician Billing for Critical Care Evaluation and Management Services

Issue: Critical care, whether delivered in a critical care area such as a coronary, respiratory or intensive care unit, or the emergency department is payable under Medicare as long as the care provided meets the definition of critical care, i.e., the direct delivery of medical care by a physician(s) for a critically ill or critically injured patient. Critical care is exclusively a time-based code in which physicians are paid based on the number of minutes they spend with critical care patients. The physician must spend this time evaluating, providing care and managing the patient's care and must be immediately available to the patient.

OIG Action: OIG will do a review to determine whether Medicare payments for critical care are appropriate and paid in accordance with Medicare requirements.

Proposed 2019 Medicare PFS: The 5 Things Labs Need to Know

On July 12, CMS issued the proposed 2019 Medicare physician fee schedule (PFS), with comments scheduled to end on Sept. 10. Takeaways:

1. Physician Payment Rates

CMS is proposing a 0.25% increase in physician payment rates based on a 0.12% budget-neutrality adjustment. The 2019 PFS conversion factor is $36.05, up from $35.99 in 2018.

2. Diagnostic Imaging Tests

CMS would allow diagnostic imaging tests to be furnished under a physician's direct supervision instead of personal/in-the-room supervision when performed by a radiologist assistant in accordance with state law scope of practice rules. Radiologist assistants would be required to personally perform the test and not supervise a technologist.

3. Changes to E/M Coding and Payment

In a bid to reduce administrative burdens and improve payment accuracy for E/M visits, CMS wants to allow practitioners to review and verify certain information in a patient's medical record that's been entered by ancillary staff or the patient and not have to re-enter the information themselves. A new multiple-procedure payment adjustment would also apply when E/M visits are provided in conjunction with other procedures.

4. New Telehealth Payment Policies

CMS proposes paying physicians for the time it takes to review a video or image sent by a patient to assess whether a visit is needed in addition for their time when they check in with beneficiaries via telephone or other telecommunications device.

5. The Lack of Changes to OPPS Site-Neutral Payment Policies

Also of note is that CMS is not proposing to change its site-neutral payment policies under Section 603 of the Bipartisan Budget Act. Much to the consternation of hospital groups, the agency wants to continue allowing nonexcepted provider-based departments to bill for nonexcepted services on the institutional claim and maintain payment for nonexcepted services at 40% of the OPPS amount for calendar year 2019. Section 603 requires, with the exception of dedicated emergency departments, services furnished in off-campus provider-based departments that began billing under OPPS on or after Nov. 2, 2015 no longer be paid under OPPS, but under another applicable Part B payment system.

OTHER PROPOSED CHANGES

Some of the other proposed changes in the new CFS potentially affecting labs include:

- Implementation of a *Bipartisan Budget Act of 2018* provision pertaining to writing and signature requirements in certain compensation arrangement for purposes of Stark Law exceptions;
- Addition of mobile stroke units, renal dialysis facilities and the homes of ESRD beneficiaries as Medicare telehealth originating sites;
- Payment for new communication technology-based service codes; and
- Discontinuation of certain functional reporting requirements for outpatient therapy services and creation of payment modifiers for services furnished by therapy assistants, which will be paid at 85% of the applicable Part B payment.
- Changes to the definition of "applicable laboratory" for clinical laboratory fee schedule purposes. (See related PAMA below).

PAMA: OIG Backing of CMS Heats Up Market-Based Lab Rates Controversy

CMS did it right and saved Medicare a boatload of money in the process, concludes a new OIG report reviewing the methods CMS used to establish "market-based" rates for Medicare Part B lab tests. Of course, the lab industry begs to differ with that conclusion and has even taken CMS to federal court in an attempt to get the new rates set aside. And to the extent

it was intended to quell the PAMA controversy, the new OIG report has already proven a dismal failure.

The Context

At heart of the controversy is CMS's decision not to count hospital outreach labs as "applicable labs" in calculating market rates for lab tests. Since hospital labs generally command higher rates than freestanding labs, excluding their pricing data from the calculation artificially skewed downward the prices CMS used to set the 2018 Clinical Laboratory Fee Schedule. CMS has repeatedly defended its methods and now the OIG has stepped in to provide cover.

"Any analysis by OIG that fails to recognize that fact does a disservice to Congress and to the millions of seniors who depend on access to lab testing through Medicare."

—Julie Khan, President, ACLA

The Affordable Care Act legislation requires the OIG's to review CMS' implementation of the new PAMA system. But if the lab industry was hoping for vindication from the OIG, those hopes have been decisively dashed. The new OIG report is not only lacking in criticism but highly commendatory of CMS' efforts. They were able to cut rates for 75% of tests and save Medicare $670 million in 2018, the report gushes.

What's so infuriating about this conclusion is how it glosses over concerns that CMS didn't play fair in achieving this result. Sure, the new pricing data sample size was smaller than it should have been, the report acknowledges. "Some labs reported difficulty in interpreting the reporting requirements," it blithely explains. But "CMS modeling demonstrated that increased reporting from more labs would not have had a meaningful effect on 2018 payment rates," the report concludes.

Industry Reaction

Needless to say, the industry wasn't impressed. The American Clinical Laboratory Association (ACLA), which is plaintiff in the federal lawsuit challenging CMS' implementation of PAMA, took the lead in criticizing the report. "Today's OIG report skirts the central issue: that HHS deliberately chose to ignore Congressional intent in its implementation of PAMA – cherry-picking data from fewer than 1% of labs," according to ACLA President Julie Khan. "Any analysis by OIG that fails to recognize that fact does a disservice to Congress and to the millions of seniors who depend on access to lab testing through Medicare."

Signs of Hope?

Although the sides are likely to remain firmly entrenched until the federal court weighs in, there are also subtle signs of accommodation from CMS. In its proposed 2019 Part B Physician Fee Schedule of July 12 (see related story on page 8), CMS calls for public comments on "alternative approaches for defining an applicable laboratory, for example, using the Form CMS 1450 14x bill type or CLIA certificate number." While not the paradigm shift demanded by CLIA—the request suggests that CMS is interested not in expanding the applicable lab tent so much as modifying the low expenditure threshold for labs already included—this is the first sign of any kind from CMS indicating flexibility on the PAMA formula.

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stifles business innovation, not to mention critical lab-physician collaboration, particularly regarding new integrated care models.

Now lay out the legal fundamentals. Remind the execs that The Stark Law, aka Physician Self-Referral Law, bans physicians from referring Medicare or Medicaid patients to labs in which the physician or a family member has a financial relationship unless the transaction meets a specific exception or "safe harbor." While nobody disputes the necessity of reining in crooked physician kickback arrangements, explain that the law has drawn decades of industry criticism for being overly strict and not allowing the health care business to breathe and develop the way other sectors do.

The RFI

Next, explain that on June 20, the CMS issued a new RFI signaling its sympathy for industry views and openness to meaningful changes. "CMS is aware," the RFI notes of the Stark Law's effect "on parties participating or considering participation in integrated delivery models, alternative payment models and arrangements to incent improvements in outcomes and reductions in cost." The RFI invites the public to vent their concerns and suggestions for fixing the problem.

Anticipating the Skepticism

Chance are, that at least some of your lab execs have heard this before, especially if they've been around the industry a while. So, acknowledge that this is hardly the first time that the government has dangled vague promises of Stark relief. Point out that two years ago, Congress held hearings to discuss whether Stark should be rolled back to allow for value-based, coordinated health care service business models and arrangements. (See *GCA*, Aug. 15, 2016.) Until now, little has come from any of this.

But explain why, at least on the surface, things appear to be different this time. First, cite the broader context of a new administration dedicated to liberating private business from the burden of government regulation. More significantly, explain that while the RIF is ostensibly focused on new coordinated care and payment models, it indicates CMS's willingness to delve into core principles of the Stark Law covering the entire gamut of covered business arrangements, including:

- The definitions of "commercial reasonableness" and "fair market value";
- When compensation is deemed to "take into account" physician referral volume or value and "other business generated" between parties to an arrangement; and
- Whether requiring greater transparency for business arrangements instead of banning them altogether might allow for achievement of basic Stark Law objectives.

What's on the Table

If you want to provide a more complete list, here are all of the key issues on which CMS is seeking input:

1. How Stark is affecting commercial alternative payment models and whether additional safe harbors are necessary to protect such arrangements;
2. The effectiveness of the current Stark risk-sharing arrangement exception;
3. Whether CMS should add a "special rule for compensation under a physician incentive plan" within the current Stark personal services arrangements exception;
4. The barriers physicians face in qualifying as a "group practice" under the current Stark Law; and
5. How CMS could interpret the current DHS safe harbor, i.e., exception for remuneration unrelated to designated health services more expansively to cover a broader array of arrangements.

Note that the deadline to comment was Aug. 24, 2018.

Wrap-Up

Conclude by noting to the execs that the last thing you want to do is get their hopes up. But if—and acknowledge that it's a huge "if"—the agency's actions are in line with its new tone and approach, real and meaningful Stark Law relief may actually come to fruition. Promise to keep the C-Suite in the loop.

Last but not least, stay tuned to *GCA* for further developments that you'll need to cover in your follow-up briefing(s).