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Designing, Implementing & Managing a High-Profit Lab Outreach Program
Friday, April 27, 2018
www.lableadershipsummit.com

Lab Institute 2018
Oct. 24-26, Washington, DC
www.labinstitute.com

Brief Your CEO: After 36 Years, CLIA Comes Under CMS Review

Brace yourself—and your C-suite—for more sweeping legal changes. Even as your lab makes the transition to the new, supposedly market-based PAMA Medicare Part B fee schedule for tests, big changes may be in store for another rock of lab regulation stability—the *Clinical Laboratory Improvements Act* (CLIA). On Jan. 9, CMS posted a request for information (RFI) to let the industry know that it is conducting a full scale of review of CLIA requirements and asking for comments.

This is big news. And while CLIA review and reform will take months (if not years) to complete, lab compliance officers should waste no time in bringing it to the attention of their CEO and executive team. Here are the key points to cover in your briefing.

Continued on page 2

Compliance Perspectives: Can You Require Lab Workers to Get a Flu Shot?

Bottom Line on Top: Yes, a mandatory flu vaccination policy is legally justifiable as long as:

1. You can show that vaccination is a necessary health and safety measure;
2. The policy doesn't violate the contractual rights of affected lab workers;
3. The policy doesn't discriminate on the basis of religion, disability or other grounds protected by EEO laws; and
4. You don't violate workers' OSHA whistleblower protections.

But also keep in mind that even if it's legally defensible, implementing a mandatory vaccination policy may also be quite risky.

General Rule: Mandatory Vaccination Is Justifiable

In general, employers have broad authority to adopt policies to police the workplace and deal with health and safety hazards. In the context of labs and other healthcare facilities, such policies may also be justifiable to protect not just worker but public health and safety. Moreover, because most employment is "at will," workers can be fired for disobeying these policies.

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Brief Your CEO: After 36 Years, CLIA Comes Under CMS Review, *from page 1*

Backdrop

Remind the C-suiters that CLIA is the law that establishes the basic quality standards labs must meet to gain and retain CMS and state certification for diagnostic testing of human samples. Emphasize that the law was adopted in 1986 and hasn't undergone significant changes since 1992. Now, after 36 years, CMS has decided to give CLIA a good hard look.

Legal changes can be scary, as the industry just learned with the ACA and PAMA. But CLIA review is something that the lab industry is bound to welcome. In fact, it's been asking for such a review for years.

Significance & Scope of RFI

Explain that the new RFI is a kind of test balloon from CMS designed to start the process and begin the dialog. Describe how broad the scope of review is. Thus while the RFI proposes discrete and fairly narrow changes, it also invites comments on any and all other aspects of CLIA. In other words, CMS is at least prepared to listen to anybody who has a beef with CLIA and wants it changed.

The Proposed Changes

Now get into the substance of the RFI, the proposed changes. Explain that CMS is reviewing four broad aspects of CLIA and go through them one by one.

1. Personnel Requirements

The first area of review are the CLIA rules governing professional qualifications and other personnel issues. List the specific questions the CMS has posed for public comment:

- Should a bachelor's degree in nursing be considered equivalent to a bachelor's degree in biological science or a qualifying degree to meet CLIA requirements for moderate and high complexity testing personnel and technical consultants?
- Should a physical science degree be a CLIA qualification requirement and, if so, how should such a degree be defined?
- Which, if any non-traditional degrees should be considered as meeting current CLIA requirements for chemical, physical, biological or clinical lab science and/or medical lab technology degrees?
- Should general supervisors be allowed to perform competency assessment for personnel performing moderate complexity testing in labs that perform both moderate and high complexity testing?
- What lab training, experience and skills should all personnel be required to meet and how should those things be properly documented?

2. Proficiency Testing Referrals

Note that CMS is also looking into issues relating to violations of proficiency testing (PT) referrals. To start, explain that labs guilty of making intentional PT referral violations face an automatic two-year CLIA revocation. But the 2012 TEST Act (*Taking Essential Steps for Testing Act*) gives CMS discretion to impose alternative penalties based on the nature and extent of the PT

G2CA

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referral. The RFI raises questions on how the agency should use its TEST Act discretion, namely:

- Should the discretion apply to a case where a lab is found to have referred its PT samples to another lab and reported that other lab's PT results as its own and, if so, under what conditions?
- Is it feasible to impose alternative sanctions in cases of PT referrals involving waived testing?

3. Histocompatibility Requirements

Continue the briefing by noting that the next focus area CMS is reviewing is current CLIA histocompatibility rules in light of advances in transplant medicine and lab testing. Specific issues for which the agency has requested comments:

- Should virtual crossmatching in lieu of physical crosswalking be allowed for transplantation? If so, what criteria and decision algorithms should be used for virtual crossmatching?
- Should current CMS-3326-NC20 histocompatibility regulations be revised or totally eliminated given obsolescence and redundancy with other CLIA regulations?

4. CLIA Fees

Finally, explain that the other issue on the table are current CLIA fees, specifically the current methods used by CMS to determine fees it charges labs:

- For seeking a revised CLIA certificate due to changes in the lab's name, location, director, services or certification type;
- For determination of program compliance?
- As additional fees based on type and/or volume of testing performed and other criteria CMS deems appropriate; and
- For performing other CLIA compliance performance activities such as follow-up visits, complaint investigations and activities associated with imposition of sanctions.

What Happens Next

Conclude your briefing with a projected timeline and explanation of what happens next. The key date to emphasize is March 9, 2018: That is the deadline to submit comments on the RFI. Once the comment period closes, CMS will have 90 days to prepare a Proposed Rule summarizing and responding to those comments and laying out a formal CLIA reform proposal.

Case of the Month: Judge Who Said Labs Must Independently Verify Medical Necessity Takes It Back

"That CAN'T Be Right: Court Says Labs Must Independently Verify Medical Necessity of M.D. Ordered Tests"

That was the headline we used in reporting a highly disturbing federal court ruling allowing a whistleblower to sue Boston Heart Diagnostics for falsely billing lab tests. The real stunner wasn't the judge's ruling but the theory on which he based it. According to D.C. District Court Judge Reggie Walton, labs have a duty to *independently verify* that tests physicians order are actually medically necessary.

Of course, Judge Walton's theory goes directly against decades of consensus, not to mention express OIG guidance, on the role of labs in verifying medical necessity of ordered tests. So it just *had to* be wrong and inevitably would be reversed. That wasn't just our opinion; it was held by almost every legal and industry expert in the country, including the influential American Clinical Laboratory Association which took the trouble to file an *amicus curiae* (friend of the court) brief asking the Judge to reconsider the decision after re-reading the OIG Guidance.

And, thankfully, that is exactly what has happened. Here is a quick summary of the *Groat* case saga, including the latest chapter.

The *Groat* Case: Part I

A former United Healthcare medical director filed a whistleblower suit claiming that Boston Heart routinely billed Medicare for tests that were medically unnecessary for certain diagnostic codes. Boston Heart asked the court to dismiss, noting that all of the tests were properly ordered and that it was up to the physicians to determine whether those tests were necessary.

But Judge Walton allowed the claim to go to trial. Having billed Medicare for the tests, Boston Heart had a duty to *independently* verify their medical necessity for the diagnostic codes cited, he reasoned. And because it didn't do this, it had to stand trial for false billing. The ruling cites a California case (called *Garcia v. Sibelius*) stating that Medicare regulations "place the burden of establishing the medical necessity of diagnostic tests on the entity submitting the claim." But, as attorneys noted at the time, it was an apples-to-oranges comparison because unlike in *Groat* where the lab billed for the tests, the ordering physician was the billing entity in the *Garcia* case [*U.S. ex rel. Groat v. Boston Heart Diagnostics Corp.*].

The Groat Case: Part II (What I really meant…)

On Dec.11, Judge Walton took back what he said—at least in part. I "overstated" that whole independent medical necessity duty of labs business, he wrote. "The Court is now convinced that a laboratory cannot and is not required to determine that tests billed to Medicare are medically necessary,"

he said. "The OIG Guidance makes clear that 'laboratories do not and cannot treat patients or make medical necessity determinations,' but 'should be able to produce or obtain from the treating physician. . . the documentation to support the medical necessity of the service the laboratory has provided," he added.

However, Judge Walton stopped short of dismissing the case. While breach of independent duty to verify was no longer in play, the whistleblower could still prove her false claims allegations by showing that Boston Heart's pre-printed order forms encouraged physicians to order screening tests that were not medically necessary [*U.S. ex rel. Groat v. Boston Heart Diagnostics Corp.*].

Takeaway: While Boston Heart is no doubt bummed that it still has to go to trial, Judge Walton's reversal on medical necessity is a huge relief for the lab industry as a whole.

Lab Quality & Safety: JCAHO to Crack Down on Handwashing Shortcuts

You can preach hygiene until the cows come home but it may not be enough to get busy and distracted lab employees to wash their hands properly. In addition to undermining test integrity, effective Jan. 1, handwashing shortcuts can earn you a JCAHO citation if surveyors see them happening while visiting your lab.

What's At Stake

Why the rule wasn't already in the JCAHO books is a bit unclear; but what is clear is how improper hand hygiene by healthcare employees increases the risks of hospital-acquired infections. About 722,000 of such infections occurred in 2011 resulting in the death of 75,000 inpatients, according to the Centers for Disease Control and Prevention (CDC). While the infection risks are more remote, poor employee hand hygiene also poses safety and quality risks in the lab setting,

The New Rule

Of course, JCAHO does consider hand hygiene. In 2004, it adopted a rule requiring healthcare organizations to implement a hand hygiene program and document steady improvement with CDC or World Health Organization guidelines to receive accreditation. The new handwashing program is designed to ensure that employees not just receive hand hygiene training but actually follow it in their day-to-day operations, according to JCAHO officials.

Practical Impact

From now on, JCAHO surveyors will be keeping an eye on employees at the sink and issuing a citation if they see them doing an inadequate job of handwashing before or after engaging with a patient or handling a sample. Once cited, the facility will have the burden of submitting a plan for corrective action.

Labs IN COURT

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

Allergy Firm Sues Quest for Antitrust Violations

Cases: Texas-based United Allergy Services (UAS) is suing Quest Diagnostics for conspiring with Thermo Fisher Scientific's Phadia business and other market players to squeeze it out of the market in a deliberate bid to eliminate lower-priced competition. The suit claims that Quest and its co-conspirators persuaded insurers and other potential customers that doing business with UAS would create "medical, legal and other risks." UAS, which provides testing and allergen immunotherapy for hay fever and other allergies, claims it lost $200 million in profits as a result of the plot.

Significance: There's a mysterious subtext. The case actually began in 2014, when UAS sued Quest's co-conspirators but not Quest. Why UAS decided to bring a separate subsequent action against the lab giant rather than naming it in the original suit is unclear. In any event, that original suit has now been dismissed. Meanwhile the plot thickens, as UAS deals with a whistleblower lawsuit by a former marketing representative accusing it of overbilling Medicare for allergy testing. It adds up to a fascinating drama and we'll keep you apprised as it unfolds.

Standing Orders Don't Prove Validity Testing Is Medically Necessary

Case: Over a five-year period, a Vermont lab routinely billed Medicare and Medicaid for urine specimen validity testing even when referring physicians did not specifically order it. Rather than slug it out in court, the lab agreed to pay $815K to settle the false claims charges.

Significance: Lab Compliance, 101: Performing and billing for tests without a physician's order is a cardinal sin. The Vermont lab almost certainly knew this but relied on standing orders executed by physicians to perform specimen validity tests automatically even without an express order. Other labs have made the same mistake. *The moral:* Seemingly standard ordering protocols like standing orders and reflex testing raise medical necessity red flags. While they're not *per se* illegal, these ordering protocols can't be used as a blank check or satisfy the requirement that medical necessity be established for each individual test performed.

Drug Test Billing Abuses Land Retired Indiana M.D.s in Hot Water

Case: A husband-and-wife physician team has been charged with falsely billing the Indiana Medicaid program for over $1.1 million in urine drug tests. The government contends that from 2011 to 2013, the now retired physicians routinely required patients seeking opioid prescriptions to furnish a urine specimen to be tested for nine different classes of drugs using a multiplex screening kit costing no more than $5 per day. They then billed and were paid $171.22 per patient, getting around the $20.83 per patient limit allowed under Indiana Medicaid billing rules by falsely certifying that they had collected and tested nine separate samples.

Significance: As the opioid crackdown continues, physicians need to be extra scrupulous in documenting the medical necessity of the drug tests they order for patients who are prescribed legal opioid and painkillers.

Self-Disclosure Pays Off for Clinic Accused of Taking Illegal Consulting Fees

Case: A cardiovascular clinic in Philadelphia has agreed to pay $50,000 to settle charges of taking kickbacks from a lab company in the form of:

- Blood collection processing, handling and collection fees; and
- Consulting fees.

Significance: The clinic self-disclosed the violations in this case. It appears to have been a very wise decision. The normal price tag for violations involving questionable consulting and processing fee arrangements run into the six- and seven-figure ranges. While other factors may have been at work, voluntary self-disclosure probably played a key role in the relatively small size of the settlement.

Owners of NYC Testing Clinics Charged in $44 Million Fraud Scheme

Cases: Kickbacks were just the tip of the iceberg. According to the indictment, the three co-owners of diagnostics clinics in Brooklyn not only solicited and received roughly $19 million in bribes for test referrals but compounded their sins by misrepresenting which clinic actually did the tests and using shell companies to conceal payments in violation of money laundering and tax laws.

Significance: Less than a month after the federal indictment came down, New York State brought parallel Medicaid fraud criminal charges against two of the co-owners for their role in the scheme. And just for good measure, the State Attorney General filed a $24 million civil lawsuit under the New York version of the *False Claims Act*. *The moral:* Fraud scams can lead to criminal AND civil charges; and when Medicare and Medicaid are targeted, parallel criminal and civil charges can be brought but under BOTH federal and state law.

Compliance Perspectives: Can You Require Lab Workers to Get a Flu Shot, From Page 1

OSHA's Policy on Mandatory Flu Vaccination

OSHA has also given mandatory flu vaccination the green light. No OSHA standard specifically addresses the subject. But OSHA guidelines on influenza preparedness for healthcare facility employers say it's "advisable" for such facilities to "encourage and/or provide seasonal influenza vaccination for their staff, including volunteers, yearly, during October and November."

Admittedly, this language is pretty wishy-washy. But an OSHA Interpretation Letter from 2009 (during the influenza pandemic) not only reiterates the "encouragement" line but also adds the following: "Although OSHA does not specifically require employees to take [seasonal and H1N1] vaccines, an employer may do so." Significantly, the Letter specifically addresses healthcare facility employers [OSHA *Interpretation Letter*, Nov. 9, 2009].

3 Situations When Mandatory Vaccination Is Not Okay

You need to take all this with a grain of salt. After all, OSHA guidelines and Interpretation Letters are not laws. More importantly, you also need to realize that OSHA is not the sole arbiter and that mandatory vaccinations are illegal if they run afoul of other employer legal obligations. Examples:

1. Violation of Employment Contract

Forcing workers to get vaccinated could violate the terms of the employment contract—or collective bargaining agreement (CBA) if the workers belong to a union.

Example: A Washington hospital requires employees to get a flu vaccination to be considered "fit for duty." Nurses sue and the court rules that unilaterally implementing the policy violates the hospital's CBA duty to collectively bargain all employment terms and conditions [*Virginia Mason Hospital v. Washington State Nurses*].

2. Religious or Disability Discrimination

Mandatory vaccination might also violate employment discrimination laws. According to EEOC guidance, forcing a worker to get vaccinated might violate his/her "sincerely held religious belief, practice or observance;" the *Americans with Disabilities Act* would also kick in if the worker has a disability that prevents him from taking the vaccine. In either case, exempting the worker from the policy might be one of the "reasonable accommodations" you'd have to make to accommodate the worker's religion/disability.

3. OSHA Whistleblower Discrimination

Section 11(c) of the *Occupational Safety & Health Act* makes it illegal to "discharge or in any manner discriminate against" a worker for filing a safety complaint or exercising other rights under the OSHA law. As noted by OSHA in the 2009 Interpretation Letter mentioned above, firing a worker for defying a mandatory vaccination policy could violate the whistleblower protections of Sec. 11(c) if the worker's refusal is based on a "reasonable belief" that he has a medical condition, e.g., an allergy, that could result in serious injury or death if he gets the shot.

How to Manage Liability Risks

Vaccination is clearly one of the best ways to prevent outbreak of flu and other infectious illnesses at your lab. But requiring lab workers to be vaccinated and disciplining them if they refuse is fraught with legal risks. A better option may be to encourage workers to get shots without ordering them to do so. Some of the things you can do to get your workers to agree to vaccination voluntarily:

- Provide the vaccination yourself at no cost to workers;
- Vaccinate workers right on the worksite and at convenient times; and
- Educate workers about the benefits of the vaccination and address any concerns they raise about its safety.

For More Help

See page 9 for Model Policies you can use to implement either a mandatory or voluntary vaccination policy at your lab.

Tools: Model Flu Vaccination Policies—Mandatory & Voluntary

Vaccination is the most effective defense against flu viruses. So it behooves you to ensure that lab workers get flu shots every year at the start of every flu season. But what if workers neglect or just plain refuse to be vaccinated?

There are two basic options:

- Option 1: Require lab workers to be vaccinated
- Option 2: Encourage lab workers to be vaccinated voluntarily

Here's a Model Policy you can use to implement each option. For an analysis of the legal implications of mandatory v. voluntary vaccination policies, see the related story beginning on page 1.

VERSION 1: MANDATORY FLU VACCINATION POLICY

XYZ LABORATORIES
INFLUENZA VACCINATION POLICY

PURPOSE

The purpose of this policy is to ensure that all XYZ Laboratories (XYZ) staff are vaccinated against both seasonal and novel influenza strains like H1N1 once vaccines become available to protect their own health, the health of their co-workers and the health of their patients.

XYZ management has chosen to implement this policy after considering the costs, risks and benefits of vaccination. We recognize that vaccination is personally invasive and that some individuals may object to it. However, we also recognize that all responsible and knowledgeable experts in public health agree that the scientifically demonstrated benefits of the flu vaccination greatly exceed the risks of receiving it.

POLICY

All XYZ workers are required to obtain influenza vaccinations annually according to schedules established for each particular year. Vaccinations will be made available to staff members free of charge.

EXCEPTIONS

XYZ personnel who have been recently vaccinated elsewhere may satisfy this requirement by providing written documentation of the vaccination they received. Such personnel will also be excused from this requirement if they have legitimate religious objections to being vaccinated.

CONSEQUENCES OF NON-COMPLIANCE

XYZ reserves the right, at its sole discretion, to impose disciplinary actions on employees who refuse to receive a flu vaccination as required by this policy up to and including termination in accordance with applicable laws, contracts and collective bargaining agreements.

VERSION 2: VOLUNTARY FLU VACCINATION POLICY

XYZ LABORATORIES
INFLUENZA VACCINATION POLICY

PURPOSE

Influenza (the flu) is a contagious respiratory illness caused by influenza viruses. It can cause mild to severe illness, and, in some cases, death. Annual vaccination is the most effective way to prevent influenza virus infection. Vaccination protects you, your co-workers and your patients.

POLICY

XYZ Laboratories (XYZ) will develop, implement and evaluate a program to offer annual influenza vaccination for XYZ personnel. In the event of limited vaccine availability, flu vaccination will be allocated on the basis of regulatory requirements and occupational risks. All XYZ personnel are required to either receive annual influenza vaccination or complete a statement:

- Acknowledging that they were offered vaccination;
- Indicating that they voluntarily declined it; and
- Listing the reasons for declining vaccination.

Enforcement Trends: Whistleblowers Get in on the EHR "Meaningful Use" Action

Wrongful payment of electronic health records (EHR) "meaningful use" incentives has become a growth area in government health fraud enforcement. (See *GCA, July 10, 2017*). And now private whistleblowers are joining the party.

The Government Crackdown

2017 was a breakthrough year for government EHR enforcement. In May, the Justice Department announced that leading EHR software vendor eClinicalWorks had settled false claims charges stemming from allegedly overstating the capabilities of its product. In addition to paying $155 million, the Massachusetts-based vendor agreed to enter into a Corporate Integrity Agreement imposing onerous restrictions.

Less than two weeks later, the OIG issued a report noting that CMS paid $729.4 million's worth of wrongful EHR incentive payments between May 2011 and June 2014 and declaring the OIG's determination to get all that money back.

The Privatization of EHR Fraud Litigation

Late in the year, new ground was broken when EHR fraud became the centerpiece for a civil lawsuit for money damages by a whistleblower without any government intervention. The other novel aspect of the $325 million *qui tam* case against over 60 Indiana hospitals unsealed on Nov. 21 is the identity of the plaintiffs, namely, a group of medical malpractice attorneys who claim they were among the victims to suffer personal harm as a result of the hospitals' alleged inclusion of inaccurate and untimely data about their medical records processing practices in their EHR meaningful use attestations. The relators claim they relied on the faulty data in bringing malpractice claims on behalf of their clients. The relators also claim that a national "release of information" provider overcharged patients for copies of their records in violation of HIPAA.

OIG Work Plan Monthly Review: January 2018

Opioid drug-related issues continue to command the lion's share of OIG Work Plan attention, including two of this month's six new items. While none of the new initiatives directly affect labs or lab services, five may have an indirect impact on at least some lab providers.

1. State Use of Automated Child Welfare Information System to Monitor Psychotropic & Opioid Drugs to Kids in Foster Care

Concern: To receive federal funding for child welfare services, States must have a plan for oversight and coordination of health care services for any child in foster care placement, including protocols for appropriate use and monitoring of psychotropic and opioid drugs for treating ADHD, schizophrenia, depression, bipolar disorder, anxiety and other mental health disorders.

OIG Action: The OIG will review State child welfare agency use of SACWIS, the Statewide Automated Child Welfare Information System, for monitoring psychotropic, ADHD and opioid medications prescribed to kids in foster care and the extent to which the ACF, Administration for Children and Families (ACF), ensures that kids in foster care receive medication in accordance with State requirements.

2. OIG Toolkit to Identify Patients at Risk of Opioid Misuse

Concern: In a July 2017 data brief (Opioids in Medicare Part D: Concerns About Extreme Use and Questionable Prescribing (OEI-02-17-00250)), the OIG reported that in 2016, a half-million Medicare Part D beneficiaries received high amounts of opioids and nearly 90,000 of them were at serious risk of opioid misuse or overdose.

OIG Action: As a follow up to the data brief to help public and private sectors deal with the opioid epidemic, OIG will release a toolkit containing information about its analysis of a large dataset of opioid claims to produce patient-level opioid data and its calculation of Morphine Equivalent Dose (MED) levels for these patients.

3. Financial Impact of Health Risk Assessments & Chart Reviews on Medicare Advantage Risk Scores

Concern: Medicare Advantage (MA) organizations submit records of services provided to beneficiaries, including all diagnoses, during the previous year. CMS then uses this encounter data to adjust Medicare Part C monthly payments to ensure MA organizations get paid more for beneficiaries with higher expected costs. CMS also includes diagnoses from health risk assessments and chart reviews in calculating risk scores and risk-adjustment payments regardless of whether these diagnoses are supported by another service provided to the beneficiary during that year.

OIG Action: The OIG will do a study to determine the extent to which diagnoses solely generated by health risk assessments and chart reviews were associated with higher risk scores and higher MA payments, as well as the extent to which diagnoses removed by chart reviews were associated with lower risk scores and lower MA payments.

4. Potential Abuse & Neglect of Medicare Beneficiaries

Concern: Previous OIG reviews have found problems with the quality of care and the reporting and investigation of potential abuse or neglect of Medicare beneficiaries, including the disabled and elderly at group homes, nursing homes and skilled nursing facilities.

OIG Action: Based on analysis of treating medical facilities' diagnoses, OIG will determine how widespread the potential abuse or neglect of Medicare beneficiaries is, as well as whether the potential abuse or neglect occurred at a medical facility or another location like the beneficiary's home.

5. Questionable Billing for Off-the-Shelf Orthotic Devices

Concern: Since 2014, there's been a 97% increase in claims for three off-the-shelf orthotic devices (L0648, L0650 and L1833) and a 116% increase in associated allowed charges. A Medicare Administrative Contractor (MAC) found that within its own jurisdiction improper payment rates were as high as 79% for L0648, 88% for L0650 and 91% for L1833. One of the MAC's top concerns was lack of documentation of medical necessity in patients' medical records.

OIG Action: OIG will study factors associated with questionable billing and billing trends for the three devices from 2014 to 2016 focusing on the extent to which Medicare beneficiaries were supplied the devices without an encounter with the referring physician within 12 months before their orthotic claim.