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OIG Advisory Opinion Includes Convenience and Efficiency as Potentially Improper Benefits

A unique and perhaps surprising Advisory Opinion from the U.S. Department of Health and Human Services' Office of Inspector General (OIG) addresses free laboratory services and pull through strategies. A regional laboratory requested the opinion for a proposed arrangement with physicians that would waive charges for patients insured under an exclusive contract dictating another laboratory as the only covered laboratory. That way the laboratory could service all the physician's patients, making health care delivery more efficient within the physician practice.

The Facts

The laboratory explained that physicians prefer dealing with just one laboratory because it provides consistent test result reporting (avoiding use of different reference ranges) and "ease of communication"—using one interface for electronically transmitting orders and receiving results rather than multiple interfaces required when dealing with more than one laboratory. Therefore, the laboratory proposed that it would enter into arrangements with physicians and physician practices under which the physician practice would refer all patients to that laboratory. If the patient was subject to an exclusive health plan agreement that would only reimburse another laboratory, the requesting laboratory wouldn't bill that patient, the physician practice, the insurer with the exclusive contract or any secondary payer. Patients who belonged to federal programs or other private payers without contracts that excluded the requesting laboratory would be charged applicable contract rates or fee schedule rates.

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OIG Sets Enforcement Sights on Reform Efforts

The U.S. Department of Health and Human Services Office of Inspector General (OIG) doesn't just scrutinize laboratories and other providers but is also charged with overseeing government agencies and health care reform efforts. While the Affordable Care Act (ACA) celebrated its 5th birthday last month, the OIG indicated in its Health Reform Oversight Plan that it plans to scrutinize aspects of the ACA's implementation, particularly

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Physicians entering into these arrangements would need to attest that neither the physicians or the practice were receiving any financial benefit from the provision of free laboratory services to their patients—including any benefit (or penalty) derived from an incentive plan addressing laboratory utilization. The only item or service or benefit provided from the laboratory to the physician would be the limited-use interface allowing the physician to communicate with the requesting laboratory. The laboratory mentioned that some vendors charged its physician practice clients monthly maintenance fees for the interface and the laboratory wouldn't pay those fees on behalf of the physicians.

The anti-kickback law prohibits payment of any remuneration to the source of a referral or recommendation for a service reimbursed by federal health care programs.

The requestor indicated that about 70% of its physician practice clients had patients enrolled in plans that had exclusive laboratory contracts. Those physician practices reported between 10% to 40% of their patients belonged to plans with exclusive laboratory contracts. Patients in those plans didn't have primary insurers who were federal health care programs but could have federal health care programs as a secondary insurer.

The law

There are two potential violations of law involved in this proposed arrangement: kickbacks and charging Medicare substantially more than the lab's "usual charge."

Kickbacks. The anti-kickback law prohibits payment of any remuneration to the source of a referral or recommendation for a service reimbursed by federal health care programs. Violation of that law depends on the parties' intent (knowing or willful conduct is required) but even if just one purpose for the arrangement is to induce or reward referrals, it can be a violation. The penalties for violations include fines (up to $25,000), imprisonment and exclusion from participating in federal programs.

Exclusion can also result if a provider is charging Medicare or other federal programs substantially in excess of its usual charges. But what constitutes usual charges isn't perfectly clear.

The OIG's concern about waiving fees is nothing new. Maryland health care attorney Robert E. Mazer of Ober Kaler, notes the OIG specifically addressed the issue of such waivers in a 1994 Fraud Alert. He explains that the OIG's alert "says that the question is 'Did it provide a financial benefit to the physician?'" In the OIG advisory opinion, the OIG explains that the main purpose of the proposed arrangement is to "secure all of the referrals [for laboratory services], including services that would be rendered to Federal health care program beneficiaries, from participating physician practices." Thus, as in the 1994 Fraud Alert, the OIG was concerned here with "whether any remuneration could flow to a source of referrals."

Substantially in excess charges. The OIG added that the law provides for permissive exclusion from federal health care programs if a provider "charges Medicare and Medicaid programs substantially more than their usual charges to other payors for the same items or services." Noting prior attempts to provide clarity, the OIG acknowledged there were no final guidance or regulations

interpreting this prohibition or the terms "substantially in excess" or "usual charges." It did note that providers don't even need to worry about this prohibition as long as they aren't "discounting close to half of" non-Medicare or non-Medicaid business.

What the OIG Decided

The OIG expressed two concerns that made this proposed arrangement suspect under the laws explained above: there could be a benefit to the referring physician via the convenience and avoidance of interface maintenance fees and the potential frequency of the waivers could render Medicare and Medicaid charges substantially in excess of the laboratory's usual charges.

Benefit to referral source. First, it's worth noting that in a footnote the OIG ruled out any concerns about remuneration being offered to patients in exchange for choosing the requesting laboratory. Its reason was that "a crucial element of the" arrangement was that no payer would be billed for services to the patients getting free services and "we have no facts to suggest that the free services would have any tie to other federally payable services that the Requestor would render to Exclusive Plan enrollees." Thus any remuneration to patients gave rise to only "a low risk of fraud and abuse."

The OIG concluded the arrangement "would offer physician practices a means to work solely with the Requestor, reducing administrative and possibly financial burdens associated with using multiple laboratories."

The OIG also conceded that provision of limited use interfaces to the physicians was not remuneration. But it qualified that there were "other facts that we believe, in combination, would amount to remuneration." Those facts were the "convenience of receiving all test results with consistent reference ranges and the efficiency gained from maintaining a single interface with a single laboratory."

Additionally, the fact that some physician practices would have been charged a monthly maintenance fee by vendors which could be avoided through this arrangement was also considered remuneration. The OIG concluded the arrangement "would offer physician practices a means to work solely with the Requestor, reducing administrative and possibly financial burdens associated with using multiple laboratories." Therefore, the OIG couldn't "rule out with sufficient confidence the possibility that" remuneration was being offered to induce or reward referrals.

Additionally, the OIG was concerned that the laboratory hadn't "presented discernable quality or safety improvements that would be gained by reducing these burdens or any other safeguards that would make this remuneration low risk under the anti-kickback statute." It also could "result in inappropriate steering of patients, including Federal health care program beneficiaries."

Substantially in excess charges. The OIG said providers don't need to worry unless they are "discounting close to half of" their non-Medicare or non-Medicaid business. In this case, the OIG was concerned that close to or more than half of non-federal health care program business was being provided for free because the data submitted indicated 70% of physician clients of the laboratory had patients subject to exclusive contracts and within those physician practices, between 10% and 40% of the patients had exclusive contracts. These

Last Minute Efforts to Repeal the SGR are Now with the Senate

In Medicare's own version of March Madness, the House of Representatives approved a bill that could provide a last minute reprieve from physician reimbursement cuts.

The Senate must vote on a House of Representatives-approved Bill "to repeal the Medicare sustainable growth rate and strengthen Medicare access by improving physician payments" and other improvements. The bill is titled the *Medicare Access and CHIP Reauthorization Act of 2015*. If the Senate fails to approve the bill or Congress doesn't take other preventive action, physician payment rates will suffer a 21% cut effective March 31 (but affected claims will be held until April 15 while the Senate action is pending).

The bill amends Section 42 U.S.C. 1395w-4 to end use of the sustainable growth rate (SGR) to determine the annual conversion factor in the formula for setting physician payment rates.

New proposed updates for the single conversion factor under the Bill are as follows: 0.0% for January 1, 2015 through June 30, 2015; 0.5% for July 1 through December 31, 2015; 0.5% for 2016-2019; 0.0% for 2020 to 2025; and for 2026 and thereafter, 0.75% and 0.25% depending on "alternative payment model" participation.

The bill also requires reports from the Medicare Payment Advisory Commission (MEDPAC), including reports on the following:

- The relationship between health care professionals' utilization and expenditures reimbursed under Medicare and their rates of increase; and
- The relationship between total Medicare A, B and D utilization and expenditures and their rates of increase.

Stay tuned for updates as we await the Senate's vote on this bill.

Takeaway: Once again pathologists and other physicians must wait and hope for relief from the SGR.

numbers caused the OIG to be concerned: "with percentages that high, it is plausible that more than half of the non-Medicare or non-Medicaid patients would be receiving free services, while Medicare and Medicaid would be charged at the regular rate." This gave rise to a two-tiered pricing structure with "substantial number of patients" getting free services "regardless of financial need."

Why it's Important

This advisory opinion is causing a stir in the laboratory compliance industry for several reasons. First, Mazer highlights the two facts that the OIG found in combination amount to remuneration:

1. "it is more convenient, more efficient, for the physician practice to use one laboratory" and
2. "elimination of interface maintenance fees that would be paid by the physician practices."

"The first fact may be present in almost all instances," says Mazer. If the OIG is saying remuneration has been provided when an arrangement "makes it administratively more convenient or efficient," notes Mazer, that reasoning conflicts with goals of increasing efficiency and cost savings in the health care delivery system. Mazer adds, "Convenience is a slippery slope. It's hard to analyze that." Additionally, Mazer expresses surprise at the OIG's reliance on the interface maintenance fee. "Relying on a potential interface maintenance fees is the tail wagging the dog," says Mazer, "particularly because it is probably so infrequently the case that the physicians actually pay for it."

He also notes it is curious that the OIG didn't even mention its 1994 Special Fraud Alert which expressly addresses waiving charges for private plan members when the plan has a contract with other labs. In that Alert, the OIG said such waivers were permissible as long as the physician practice wasn't benefitting financially, such as through incentive plans and utilization programs. The advisory opinion does allude to such utilization incentive arrangements and states the physicians in this arrangement were required to certify they didn't receive benefits or penalties under such utilization programs. Yet, the OIG didn't highlight that fact or mention the Alert in its reasoning.

Mazer posits that it is possible the requesting laboratory wanted the negative opinion. "The OIG generally advises the requestor of an advisory opinion of its decision in advance of releasing the opinion, allowing the requestor to withdraw the request if the result is different than what it had hoped for." Mazer posits that the requesting laboratory may have wanted an opinion that says what its competitors are doing is impermissible.

While Mazer isn't sure if the OIG would "actively pursue these types of cases, particularly if the physician practice isn't paying the interface cost" he cautions that this advisory opinion could "pique the interest of qui tam relators." He also notes that an "advisory opinion isn't binding on the court and may not receive the deference that a court usually gives to an administrative determination."

Finally, Mazer suggests that laboratories with similar arrangements require physicians "sign an attestation that they don't receive any financial benefit from the free testing, including the elimination of any monthly interface fee." The arrangement in this case required similar attestations from physicians that they didn't receive any benefit but didn't mention such interface fees.

Mazer reports that to his knowledge "the OIG has never pursued a case based solely on substantially in excess provision. ... [But] You still have to do your due diligence."

Substantially in excess: The OIG's second concern was whether Medicare was being charged substantially more than the laboratory's usual charge. The OIG appears to have interpreted the substantially in excess rule in the past to mean that if 50% (or more) of the laboratory's charges (excluding Medicare and Medicaid charges) are less than what is being charged Medicare, that lower rate being charged may be considered the laboratory's usual charge. Thus, explains Mazer, if half of the laboratory's charges were waived as described in this proposed arrangement, "the laboratory's usual charge might be considered zero."

The problem, says Mazer is that there are "so many issues that are outstanding under that provision. There are no final regulations" interpreting the substantially in excess provision. Indeed, the OIG acknowledges this fact in the Advisory Opinion. Mazer explains there is lack of clarity in how to calculate the usual charge and compare it to Medicare. "When you compare it to the charge to Medicare, do you use the amount you actually charge Medicare or the Medicare fee schedule amount, which is probably lower?" A proposed regulation indicated the Medicare charge for comparison purposes was the fee schedule amount but those proposed regulations were never finalized, says Mazer.

Mazer says to his knowledge "the OIG has never pursued a case based solely on substantially in excess provision." But that is no reason to ignore this provision. "You still have to do your due diligence," warns Mazer and examine your charges to determine if there is any potential violation.

Source: U.S. Department of Health and Human Services, Office of Inspector General, Advisory Opinion 15-04 (March 18, 2015)

Takeaway: Laboratories waiving or writing off charges for patients subject to exclusive contracts involving other labs beware: The OIG is concerned physicians can benefit even subtly from these arrangements and such arrangements may render Medicare charges substantially in excess of usual charges. G2

Physicians Sentenced to Prison for Accepting Bribes for Test Referrals

More prison terms have been handed out to physicians who have pleaded guilty to accepting bribes from Biodiagnostic Laboratory Services, LLC (BLS) of Parsippany, NJ. According to separate press releases, three New Jersey physicians are the most recent individuals to admit involvement in a laboratory pay for referral case that began in April 2013 with the arrest of BLS president David Nicoll and several others.

Wayne Lajewski of Madison, NJ, and Glenn Leslie of Ramsey, NJ, were sentenced to 14 months and 24 months respectively according to a March 31 Department of Justice (DOJ) press release. Lajewski admitted receiving $2,000 a month for over two years while Leslie admitted to receiving $5,000 a month. In addition to jail time, the federal judge imposed one year supervised release and fined each $10,000. Lajewski also forfeited $48,000 and Leslie $350,000.

In a separate DOJ press release on April 2, U.S. Attorney Paul J. Fishman announced the sentencing of Dr. Angelo Calabrese of Pine Brook, NJ, to three years and one month in prison, one year supervised release, a $5,000 fine and forfeiture of $334,000. Calabrese admitted accepting $130,000 in bribes through consulting and rental agreements.

And additional sentencings relating to this matter may be forthcoming. A separate April 2 press release from U.S. Attorney Fishman announced that Dr. Brett Halper of Glen Head, New York admitted to taking bribes from BLS during the period of January 2011 through April 2013, allegedly often receiving over $5,000 a month.

In all, 38 individuals, including 26 doctors, have pleaded guilty since the initial 2013 arrests in the matter. A noteworthy aspect of this continuing case is that the government is taking action against physicians implicated in the arrangement and not just the laboratory.

OIG Sets Enforcement Sights on Reform Efforts, *Continued from bottom of p.1*

the health insurance marketplaces. Demonstrating just how big a focus the ACA is for the OIG, it noted that 27 percent of its 2014 discretionary funding was devoted to ACA oversight and it plans to give ACA issues similar priority in 2015.

The OIG lists four items as key tactical considerations: "fighting fraud, waste, and abuse; promoting value, safety, and quality; securing the future; and advancing excellence and innovation."

Although the ACA is credited with providing 16 million Americans with health insurance and a host of other benefits, according to a White House press release celebrating the five-year anniversary, it is still running into opposition. Not only are the subsidies for the exchanges currently the subject of litigation before the U.S. Supreme Court in *King v. Burwell* but the OIG's Oversight Plan targets the marketplaces providing insurance as "a primary focus" of reform oversight. Key focus areas relating to marketplaces include whether taxpayer funds are properly spent, "the right people [are] getting the right benefits" and personal information is secure. Additionally, the OIG plans to focus on the efficiency and effectiveness with which marketplace programs are managed. Future projects are anticipated to "address vulnerabilities in payment systems."

The OIG's Oversight Plan also targets eligibility issues, including enrollment safeguards, premium tax credit eligibility verification, and inconsistencies in data regarding federal marketplace applicants. "[E]merging issues" likely to receive future attention include verification of employer information, hardship waiver eligibility and reviews of the second enrollment period. As to management of the marketplace programs, the OIG is concerned about oversight of federal contractors and review of "HHS's management and implementation of the [federally facilitated Marketplace] FFM from enactment of the ACA through the second enrollment period." Future subjects for review may include financial reconciliation process and data collection relating to financial assistance payments, operation of premium stabilization programs and FFM user fees.

The OIG also will review security of personally identifiable information at FFM and state marketplaces and is working with federal and local authorities to watch for cybersecurity threats and consumer fraud.

In addition to the ACA related items included in the OIG's 2015 Work Plan, the OIG says it expects to add five to 10 ACA related reviews to its agenda during 2015.

Other reform efforts under scrutiny

In addition to the ACA marketplaces, the OIG is also concerned with reform in these four programs:

- Medicaid expansion
- Medicare payment and delivery reform (including the shift from volume to value based payment, shared savings, population based payment, and bundled and capitated payments)
- Medicare and Medicaid program integrity (including provider screening systems, provider terminations, payment suspensions and managed care encounter data) and
- public health programs.

Source: U.S. Department of Health and Human Services Office of Inspector General, Health Reform Oversight Plan, Fiscal Year 2015 (Feb. 2015)

Takeaway: The OIG is not only concerned with laboratories and other providers' compliance but also with efficient and effective administration of reform efforts. G2

CMS Withdraws Memorandum, Seeks Public Comment on Blood Glucose Monitoring

The Centers for Medicare & Medicaid Services (CMS) has backed off on some of its CLIA mandates regarding blood glucose monitoring systems (BGMS) for off-label use. CMS issued a memorandum in November 2014 addressing point-of-care use of BGMS, which it has now withdrawn, revised and re-issued in draft form for public comment. That memorandum pertained to the use of such monitors for off-label uses, which implicates virtually every hospital use of such monitors (the monitors are mostly designed and marketed for personal use).

According to the memo, hospitals that deployed monitors in situations considered off-label would have to operate laboratories that qualified under CLIA as high-complexity laboratories. The Clinical Laboratory Management Association reported in a January article in *CLMA Advocacy* that the memorandum affects "every CLIA licensed laboratory using glucose strip meters in nursing homes, provider offices, urgent cares, clinics and in hospitals whose staff use them in their intensive care units, patient units or emergency rooms for patient assessments."

As we reported in our sister publication, *Laboratory Industry Report (LIR)*, concerns have been raised by the hospital community that the requirements are too onerous, and would prompt many hospitals instead to turn to blood gas monitors, which are much more costly instruments. CMS met with representatives from both the American Hospital Association and state hospital lobbies on Jan. 28, 2015.

CMS officials observed in the reissued memorandum that "there may be significant confusion as to what hospitals, or other providers, must do to meet the CLIA requirements for off-label use of a (sic) waived test systems." CMS found

this "particularly concerning" because it explains there have been no new CLIA policies and the regulations and statute remain unchanged. So, CMS described the two-fold purpose of its revised draft, released in March:

- Gather additional feedback regarding use of Waived BGMS, "environments in which BGMS are currently used," and any issues with their use.
- "Promote added education regarding the current CLIA requirements."

CMS acknowledged and clarified in the revision that "using a device within the limitations or precautions and intended use indicated by the manufacturer would not constitute off-label use, and not cause such use to constitute high complexity under CLIA," and thus under such conditions the device would maintain its CLIA waiver status. However, CMS explains that there is a risk to patients when BGMS are used off label—in other words, outside the manufacturer's limitations, precautions and intended use—"without the necessary performance specifications" for that use.

CMS cites a common limitation set by manufacturers affecting critically ill patients and acknowledges that "[n]either the FDA nor CMS define the term 'critically ill.'" CMS indicates when hospital laboratories want to use waived BGMS for such patients they need to set performance specifications for that use, such as identifying who is critically ill. Alyssa Keefe, vice president of federal regulatory affairs for the California Hospital Association (CHA), which represents about 350 hospitals, told LIR that having each hospital define who is critically ill would be extraordinarily difficult, and such a lack of clarity could prompt some to back away from using the monitors on their most acute patients, "limiting the use of a valuable tool."

Keefe also said CHA expects to continue working with CMS to obtain further clarification in the regulations before they're finalized: "We've been really pleased that they have taken an opportunity to be very receptive to listening to many points of view." The American Hospital Association also indicated in a news release that it plans to submit comments on the draft guidance. Comments regarding the BGMS guidelines should be submitted to LabExcellence@cms.hhs.gov. CMS indicates they will hold forums for additional discussion as well.

Source: Centers for Medicare & Medicaid Services, Survey & Certification Group, Memorandum, *Reissue of S & C 15-11 as DRAFT ONLY - FOR COMMENT Off Label/Modified Use of Waived Blood Glucose Monitoring Systems (BGMS)*, 3/13/15.

Takeaway: Although CMS withdrew its blood glucose monitoring guidelines and made some revisions, the conversation is not over and difficulties, such as defining critically ill patients, remain. G2

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