



IMPLICATIONS OF CERTAIN ARRANGEMENTS FOR FLUORESCENT *IN SITU* HYBRIDIZATION (FISH) TESTING

Summary

Recently, there have been a variety of new types of abusive arrangements that have arisen that permit referring physicians to profit from their referrals in violation of Medicare fraud and abuse and billing laws. The purpose of this paper is to discuss the legal issues created by the manner in which some laboratories offer a particular type of testing often ordered by urologists and other specialists. This type of testing, fluorescent *in situ* hybridization (FISH) is used to diagnose certain forms of cancer.

As discussed below, some laboratories perform both parts of the service—both the Technical Component (“TC”) and the Professional Component (“PC”). However, they only bill for the TC and provide all of the information required for the PC to the ordering clinician, as part of their report on the TC. This permits the ordering clinician to bill for the PC, even though he did not actually perform it. As a result, the referring clinician is able to obtain a share of the revenues earned on his referrals, without providing a testing service or incurring the costs of performing it. Even in situations where the ordering physician has a pathologist under contract to furnish the PC, a situation that is sometimes arranged by the laboratory performing the service, the arrangement may still be improper under certain circumstances. Because the PC is considered a laboratory service, it must be performed in an entity that is certified under the Clinical Laboratory Improvement Amendments (CLIA) to perform FISH testing. If this requirement is not met, then the service cannot be provided (or billed for).

For these reasons, which are more fully discussed below, federal officials should make clear that physicians could be subject to enforcement action if they furnish these services in violation of these requirements.

FISH Test Service Offerings

Fluorescent *in situ* hybridization (FISH) is a type of highly complex, laboratory testing where a DNA “probe” is labeled with fluorescent molecules so that it can be “seen” with a microscope after it hybridizes (i.e., combines) with specimen cell DNA in order to evaluate the specimen DNA. FISH testing consists of two separate components: a TC in which a DNA specimen is prepared and stained with the fluorescent reagent and a PC, in which the probe hybridization results are analyzed and assessed. These steps may be done manually or with the assistance of computer technology; however, historically, FISH testing has been performed manually, both for the preparation and staining of slides, and in the scoring/assessment of probe hybridization results.

Certain laboratories are providing services involving FISH analysis to urologists and other clinicians in a way that raises legal concerns. Under these arrangements, clinical laboratories offer to provide the TC of FISH analysis (often on cells taken from a urine sample, for example, to diagnose bladder cancer, using a commercial test called “Urovysion”) and then perform additional services that appear to go well beyond the TC. The TC is generally considered to be the preparation of the slide, including staining. The PC consists of the physician’s professional analysis and interpretation of the specimen. In the case of FISH testing, some laboratories, under the guise of performing the TC not only prepare the slides for examination, but also employ personnel (including qualified cytotechnologists) who examine the specimen cells fixed on slides under a fluorescent microscope, select those individual cells which appear suspicious for malignancy, identify the number and color of signals for each cell, distinguish overlapping cells, and classify abnormal cells. Neither the referring physician nor any member of his group practice is involved in, or supervises, these functions at the laboratory. These clinical laboratories then provide the information derived from the analysis, along with data sets showing the range of signals and the results of the test, to the physician who ordered the test, along with a picture of a representative cell. This information is basically what would constitute the PC of the service. *In this way, the laboratories basically provide the referring clinician with a “cheat sheet” that gives the results of the PC analysis, an exercise that allows the clinician to bill for the Professional Component as if he had done the analysis himself.*

In some situations, the laboratories may use a slight variation on the arrangements described above, which is still subject to significant abuse. In these instances, the referring physician may contract with a pathologist on a part-time basis—often with the assistance of the laboratory performing the TC—to review the reports received from the laboratory. In these cases, the pathologist may come in one day a week, for example, and review the reports of the TC prepared by the clinical laboratory. The pathologist may then review and sign off on the reports, for which he is paid a fairly nominal amount. The referring physician is then permitted to bill Medicare at the full Medicare fee schedule amount for the PC of that service, thereby earning a significant profit.

The manner in which these tests are marketed and performed raises serious legal questions. First, because TC FISH is considered a high complexity, laboratory test, any entity performing the PC must meet the strict regulatory requirements of the Clinical Laboratory Improvement Amendments of 1988 (“CLIA”), which are particularly rigorous for cytogenetics testing like TC FISH; however, it appears that most doctors billing for this testing do not—and cannot—meet these requirements. Second, the arrangements involving these tests raise significant questions under the anti-kickback law, because it appears that the billing physician is being provided with the PC of the test surreptitiously, and at no charge. The manner in which these services are being marketed to referring physicians only underscores this conclusion.

As a result, the appropriate agencies should carefully examine these arrangements and take action against the laboratories that are marketing the tests and the physicians who are billing for them inappropriately.

A. These Arrangements Violate CLIA

These arrangements appear to violate the requirements of CLIA, the federal accreditation and quality assurance statute that applies to virtually all clinical laboratory testing in this country. Under CLIA, all clinical laboratory testing must be conducted in a CLIA-certified laboratory.¹ Any entity that qualifies as a laboratory, as defined under CLIA, must obtain a CLIA certificate and be subject to CLIA requirements. CLIA defines a “laboratory” as any facility that is involved with the “*examination of materials derived from the human body* for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or *the assessment of the health of, human beings.*”² Thus, if the physician were actually performing the service, as he purports to be, then, he would have to be certified under CLIA because the PC involves the “examination” and “assessment” of the specimen for purposes of diagnosis and treatment.

CLIA-certified facilities are subject to a variety of requirements in the areas of quality control, quality assurance, personnel requirements, proficiency testing and inspection. For example, the CLIA personnel requirements that apply to laboratories doing highly complex testing, such as FISH, establish educational and experience requirements for all of the key laboratory personnel, including the laboratory director, general and technical supervisors and testing personnel.

CMS has itself recognized that the PC of FISH testing (as well as the TC) constitute testing that is subject to CLIA. CMS regularly posts on its website a document that contains CPT codes for laboratory tests along with the laboratory certification code for the specific laboratory service. The “Laboratory Certification Code” indicates the type of CLIA certification by specialty and subspecialty that is required for each listed laboratory test. The modifier “TC” refers to the “Technical Component” and the “26” indicates the PC. The chart for CPT 88368, which is the CPT code used to bill FISH testing, is set out below.

HCPCS	Modifier	Description	Laboratory Certification (LC) Code
88368		Insitu hybridization, manual	610, 630, 900
88368	TC	Insitu hybridization, manual	610, 630, 900
88368	26	Insitu hybridization, manual	610, 630, 900

This chart demonstrates that CMS has assigned CPT 88368 to the following specialties and subspecialties: 900 – Clinical Cytogenetics; 610 – Pathology-Histopathology; and 630 – Pathology-Cytology.³ As such, it is clear that CMS expects that

¹ See 42 C.F.R. § 493.3.

² See 42 C.F.R. § 493.2. (emphasis added)

³ CMS, 2008 CPT-4 and HCPCS Codes Subject to CLIA Edits (Updated Aug. 13, 2008).

the PC and TC should only be conducted in entities that are certified under CLIA as highly complex laboratories that meet the applicable requirements for this type of testing.⁴

In the types of arrangements described above, the physician practice that bills for the PC of the FISH testing is often not certified under CLIA. In fact, the laboratories that offer the “TC plus” type of service described above often suggest that the physician does not require a CLIA license. Indeed, they may tout the service as a way for physicians to enter the market without incurring the costs of setting up and operating a clinical laboratory. This clearly suggests that the laboratory offering the service did not believe that it was necessary to obtain CLIA certification to perform the service.

If the practice does not have the appropriate level of CLIA certification, then CMS should take action against it. The entity should be subject to sanctions under CLIA, including civil monetary penalties, civil suits or criminal penalties.⁵ Further, Medicare should not pay for the service because an entity that is not properly certified under CLIA is not permitted to bill Medicare for the service.⁶ Further, billing Medicare in violation of these standards could subject the entity to federal sanctions, including possibly a False Claims Act action, as the entity is not legally entitled to bill for the service. CMS and the OIG should clearly state that an entity billing for the PC of a FISH service that it performed must be appropriately certified as a high complexity laboratory under CLIA, and should clearly set out what specialties are permissible for such testing.

B. The Provision of these “TC Plus” Services violates the Anti-Kickback Laws.

Because of the way this service is offered, referring physicians are basically provided with the PC of the service for free—a service that they can then turn around and bill for at a significant profit. As a result, the referring physician is not performing his own analysis of the specimen cells; rather, he simply reviews the report sent by the laboratory along with the accompanying data, verifies the image of the abnormal cell, and signs his name to the report – a process that takes only a few minutes. The laboratory bills the TC of this diagnostic test (directly to Medicare, if the specimen came from a Medicare beneficiary), while the physician bills the PC. In sum, the referring physician is able to earn a return on his referral, even though he did little, if any, work.

In essence, the clinical laboratory is performing the PC for free for the referring physician and then allowing him to bill for it, and earn a profit on that service. There is

⁴ In recent discussions, however, the federal officials supervising the CLIA Program have further interpreted these requirements. They have indicated to ACLA that laboratories performing the PC of Urovysion FISH testing must be certified in the subspecialty of Clinical Cytogenetics, one of the three specialties note above. They have commented that the two other specialties listed above—pathology and cytology—would apply to testing other than Urovysion, which is billed using the same CPT code 88368. If CMS were to impose this interpretation formally, then an entity performing the PC of Urovysion should be certified in the specialty of Clinical Cytogenetics.

⁵ *Id.* at §493.1806.

⁶ 42 C.F.R. §493.1

little question that by structuring the services in this way, the clinical laboratory is offering, and the referring physician is accepting, a kickback on these services. By providing the service in a manner that permits the physician to earn a profit without incurring any cost or requiring any work, the laboratory is providing “remuneration” to him, in exchange for his referral of the TC, which the laboratory then bills directly to Medicare. As a result, it raises significant issues under the anti-kickback law.

C. **The Improper Nature of these Services is Underscored by the Manner in which they are Marketed to Referring Physicians**

The manner in which these services are marketed underscores these significant fraud and abuse concerns. In most instances, these services are marketed to urologists or urology physician group practices in a position to profit from self-referrals of FISH tests. In fact, much of the sales effort seems to be directed toward urology groups that are in a position to make the decision to obtain the specimen and then order the test.⁷ Urology groups and similar specialists can submit claims for “performing” the PC of the test on site in their offices, ostensibly taking advantage of the in-office ancillary services exception under the Stark law to bill the Medicare program. Because some of the laboratories used by these urology group practices not only prepare the slides for examination, but also examine the specimen cells and provide substantially all of the data and analysis required for the diagnostic report to the urologist, it is highly questionable what service the urologist is actually performing or billing for. In these arrangements, the amount of physician time, effort and professional expertise expended is minimized, perhaps taking only a few minutes, and is greatly disproportionate to the reimbursement received for the PC.

Further, numerous studies, some of which formed the basis for the Stark law, have demonstrated that physician financial interest leads to increased utilization. These findings were recently confirmed by audits conducted by the Office of Inspector General relating to prostate biopsies ordered by urology practices that performed and billed the anatomic pathology services utilizing the in-office ancillary services exception.⁸ The studies compared the utilization of services when the physician was able to bill for the services performed by outsourced laboratories, with the utilization of physicians who did not have such an arrangement. It found that the lowest utilization increase in the three audits was 26%. One urology group increased utilization by 699% and the three groups ordered from

⁷ In some instances, these services may also be marketed to pathologists, however, such arrangements do not the same issues as those involving urologists and similar primary care physicians. Unlike urologists, pathologists do not trigger the initial referral. Rather, the pathologist must be sent the specimen from an outside physician who is seeking a pathology consultation on biopsied tissue. The pathologist may seek additional information, and then request a FISH test; however, he cannot initiate the original referral. Further, unlike the urologist or similar physician, the pathologist is trained to review and interpret the information received from the laboratory and to render a diagnosis based on that information. That is not true with regard to the urologist.

⁸ HHS, OIG, Office of Audit Services, *Audit of Pathology Lab Services Claimed by Florida Urology P.A. for the Period September through December 2004*, A-04-05-03005 (June 2007); HHS, OIG, Office of Audit Services, *Audit of Pathology Lab Services Claimed by Atlantic Urological Association, P.A. for Calendar Year 2004*, A-04-05-03002 (June 2007); HHS, OIG, Office of Audit Services, *Audit of Pathology Lab Services Claimed by Urology Tyler P.A., Tyler, Texas, from May through December 2004*, A-05-05-0037 (June 2007).

58% to 124% more prostate biopsies than other providers in the same carrier jurisdiction. Thus, it is reasonable to conclude that if these physicians can bill for, and profit from, these PC services, then their utilization of these services will also increase.

Regardless of whether the physician does the PC himself, or uses a contract pathologist, he can still earn a profit from his own referrals. The ability to earn a profit in this way gives the physician an incentive for overutilization and results in increased costs to Medicare. The revised anti-markup rules announced in the 2009 Physician Fee Schedule Rule appear unlikely to prevent this abuse, as the service will usually meet the “site of service” requirement, which is the second prong of the analysis under the anti-markup rule.⁹

These arrangements are occurring with greater and greater frequency and require even stronger action from Medicare. ACLA believes, for example, that a urologist or similar physician should not be permitted to bill for pathology services, as ancillary to his own practice, any more than he could bill for cardiology services or surgery services performed by another physician. As a result, to deal most effectively with this situation, the federal government should act to prevent physicians from utilizing the In Office Ancillary Services exception to the Stark law to shield their ability to bill for these services.

Conclusion

It is imperative that the appropriate agencies takes steps to stem the growth of these “TC plus” arrangements, by enforcing the fraud and abuse laws, including the anti-kickback, Stark, and anti-markup requirements to services that are marketed in this way. In addition, it should also make clear that even if the services are marketed legitimately, which does not appear to be the case in many instances, the PC of the service must be performed in a CLIA certified space. Failure to abide by all of these requirements should be subject to enforcement action by the appropriate federal authorities.

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See 42 C.F.R. §414.50 (as set out at 73 Fed. Reg. at 69935 (Nov. 19, 2008)).