Regulatory Concerns and How We Reduce Risks

Anti-Kickback Statute ("AKS") and Suspect Contractual Joint Ventures

The AKS prohibits individual and entities from offering, soliciting, paying or receiving any form of remuneration in exchange for referrals or the arranging of referrals of items and services reimbursable in whole or in part by a federal health care program (e.g., Medicare, Medicaid, Tricare, etc.).

However, Proximity not only provides management services, but also a range of other services, such as inventory, office and personnel, billing support, and space. While Proximity essentially operates the Lab, the billing of insurers and patients is done in the name of the physician. Finally, the aggregate payments for Proximity's services will vary with the volume or value of business generated.

Under the proposed arrangement, Proximity does not make any referrals to the physician or the physician's lab and does not perform any marketing on behalf of those entities in exchange for the fees it receives for providing the management and equipment services.

The physician should have more financial and human capital exposure. For instance, the physician should purchase sufficient inventory and supplies and directly employ certain clinical staff. This ensures that the physician has "skin in the game" and the manager is not taking all the risk.

The physician should have exclusive control (during certain days and times) over the space where his/her lab will be operated. agreements should be modified to reflect the exact location (square footage), days and times the space will be utilized by the physician or a separate block lease agreement should be considered.

The management fee should not be contingent upon reimbursement or vary based on the volume of tests performed. Instead, a fixed or hourly fee that is fair market value for the management services actually provided, regardless of whether or not the physician is reimbursed for the tests performed, would further reduce the risk under the AKS.

Pass-Through Billing (Commercial) and Reference Lab Limits (Medicare)

Many commercial payors have policies that prohibit the practice commonly referred to as "Pass-Through Billing" ("PTB"). PTB occurs when a provider, such as a laboratory, performs a covered service for a beneficiary, but the laboratory is not "in-network" with the payor, and instead of billing directly for the service as an out-of-network ("OON") provider, the OON provider enters into an arrangement with an in-network provider to essentially utilize their payor contracts. In exchange for the ability to bill under the in-network provider's contract, the OON provider offers to perform the test at a rate lower than the reimbursable amount, thereby allowing the billing provider to retain the difference.

Due to the level of services provided by Proximity under the proposed arrangement and the lack of bona fide business risk to the physician (if the fee was based on percentage of reimbursement, no fixed fee for equipment, no fixed space rental fee, all personnel, staff, supplies, etc., provided by manager), a payor could take the position that Proximity is actually the provider performing the tests that are being billed under the physician's contracts.

Medicare rules prohibit an enrolled lab from referring more than 30% of its overall tests to an outside lab (also known as a reference lab). As mentioned above, Medicare may take the position that Proximity is actually the lab providing the services under the proposed arrangement due to the lack of involvement and risk associated with the enrolled physician that is billing for the lab services. If that is the case, then 100% of the lab services billed by the physician would be referrals to another provider and would violate Medicare's 30% reference limit, which could result in an assessment of an overpayment to the physician and possible exclusion from the Medicare program.

To mitigate the risks: We suggest the same course of action as described above. Taking these steps should clearly delineate that the physician is the provider and Proximity is merely performing managerial services, space and equipment, regardless of reimbursement rates or volume of business generated.

CLIA Shared Location Guidance

CMS clarified its position on what it previously referred to as "shared laboratories" in the attached 2018 memorandum to agency directors. In it, CMS clarified that if multiple labs were to be sharing the same physical location, equipment, and personnel, the following conditions must be met:

- All records (e.g., quality control, procedure manuals, personnel competency) must be kept separate and distinct for each lab and must clearly show that each lab is operating independently.
- The hours of operation must be specified for each lab. The hours of operation for each lab must be separate and distinct (the times of testing cannot overlap and cannot be simultaneous).

To mitigate the risks: We suggest the same course of action as described above. Specifically, the physician should have exclusive control (during certain days and times) over the space where his/her lab will be operated. Agreements should be modified to reflect the exact location (square footage), days and times the space will be utilized by the physician, or a separate block lease agreement should be considered.

Taking these steps should clearly delineate that the physician is the actual provider operating in the space for CLIA purposes.

Stark Law – In-Office Ancillary Services Exception

Stark law prohibits physicians from referring Medicare or Medicaid beneficiaries for items of DHS to entities with which they have a financial relationship unless an exception is satisfied. Unlike the AKS, the Stark law is a strict liability statute, which does not require intent to violate. This means that if Stark is triggered, every element of an applicable exception must be satisfied to escape liability. Substantial compliance with an exception will not be sufficient.

Assuming the physician will refer Medicare/Medicaid patients to the lab, the proposed arrangement will implicate the Stark law. The applicable exception would be the "In-Office Ancillary Service" exception ("IOAS"). Among other things, the IOAS exception requires the location where the services are performed be "a centralized building that is used by the group practice for the provision of some or all of the group practice's clinical laboratory services."

To mitigate the risks: We suggest the same course of action as described above. Specifically, the physician should have exclusive control (during certain days and times) over the space where his/her lab will be operated. Arrangements should explicitly discuss exclusive rental of the space. Either the existing agreements should be modified to reflect the exact location (square footage), days and times the space will be utilized by the physician, or a separate block lease agreement should be considered.

Proximity Lab Services LLC utilizes Munsch Hardt Kopf & Harr, P.C. as our legal advisors. Last Legal Review was performed November 2023 after Stark 3 rules were released.

To fully comply with the advice of our legal advisors the following actions are put into our contracts and service offerings:

- Proximity Lab Services LLC, has no physician ownership and does not own, control or partially own a reference laboratory, MSO, marketing company or medical practice.
- The practice is responsible for hiring qualified staff to perform specimen collection and phlebotomy
- The practice is responsible for purchasing supplies to perform the collection and preparation of specimens, including vacutainer tubes, fecal specimen cups, urine cups and test tubes, blood collection sets and swabs. Additional supplies may be required depending on the lab services requested by the practice.
- The practice is responsible for purchasing the required centrifuges to perform blood spins based on the requested testing.
- All fees are fixed amounts and do not vary based on insurances accepted by the provider or patient populations.
- The lab suite is specific to the practice and is available for the practice to access 24 hours a day, 7 days a week. Door access is electronically controlled and will be given to the designated representative of the practice.
- The practice pays all associated licensing and proficiency fees. These fees are usually to CLIA for licensure and CAP for proficiency. Depending on the state, some state fees may be required for licensure.
- All testing performed under the contract with the practice is performed exclusively within the suite contracted for services.
- None of the testing performed requires interpretation by a pathologist or another medical professional that requires licensure by a state medical board.
- All testing performed is either an FDA approved, FDA exempt or validated Laboratory Developed Test where a valid and credentialed Lab Director has reviewed and signed off on the methods and procedures.
- All personnel performing the testing have been reviewed, approved and signed off by the assigned Lab Director.