

Compliance Tool

Through scanners, analytical software, and other equipment, digital pathology allows clinical laboratories and associates to view whole-slide images that can be interpreted by pathologists at a remote location.

The expense and complexity of these setups sometimes necessitates a network of entities cooperating to share costs. Business arrangements for digital pathology can involve entities such as labs, pathology practices, third-party service vendors, and third-party slide preparation companies.

Depending on the particular structure of these business arrangements, scenarios can arise with the potential to run afoul of self-dealing fraud and abuse laws, such as the federal Stark Law, Anti-Kickback Statute, and Eliminating Kickbacks in Recovery Act, as well as state equivalents of these laws.

Use the following checklist to monitor your organization's business arrangements as they concern digital pathology. Any "Yes" answers should lead to further discussions with attorneys or compliance consultants.

See our related story, "[Digital Pathology Business Arrangements Bring Fraud and Kickback Worries](#)," for more guidance on navigating digital pathology business arrangements.

8 Questions to Ask About Digital Pathology Business Arrangements

Question	Yes	No
Is the digital pathology vendor affiliated with a referring physician group or a performing laboratory or pathology group that could direct business to your organization?	<input type="checkbox"/>	<input type="checkbox"/>
Is the digital pathology vendor in a position to direct business to your organization?	<input type="checkbox"/>	<input type="checkbox"/>
Will your organization be billing for services that it did not perform?	<input type="checkbox"/>	<input type="checkbox"/>
If your organization is billing for the professional component (PC) and technical component (TC) of digital pathology services that didn't originate through the organization, does your organization have a more favorable commercial contract with a payer than the other party providing services? Is the situation reversed?	<input type="checkbox"/>	<input type="checkbox"/>
Do referring or performing physicians generating digital pathology work have ownership in any of the third-party digital pathology vendors involved in the arrangement?	<input type="checkbox"/>	<input type="checkbox"/>
Does the digital pathology vendor suggest you engage with a pathologist with which the vendor or an affiliated pathology group has a relationship or arrangements?	<input type="checkbox"/>	<input type="checkbox"/>
Does a digital pathology vendor bill patients for non-insurance or in-network cases instead of your organization?	<input type="checkbox"/>	<input type="checkbox"/>
Is a referring physician practice relying on expired COVID-19 public health emergency allowances to permit a pathologist to remotely read digital pathology cases on behalf of the practice?	<input type="checkbox"/>	<input type="checkbox"/>