

Private Practice Checklist

Key Considerations in Providing Ancillary Services in Your Physician Practice



Many physicians and physician practices are looking for ways to expand the services they offer as a convenience to patients, as a means of delivering more comprehensive care (e.g., telehealth) as well as to provide new sources of revenue to the practice. This checklist, provided by the American Medical Association, is intended to be used when physicians are considering regulatory issues that may affect providing such “ancillary” services. The federal and state self-referral and anti-kickback laws that can apply to providing ancillary services are complicated—physicians should consult with an experienced health care attorney to review existing and proposed services compliance with federal, state, and local regulations.

Examples of in-office services

- Traditional “ancillary” services—imaging, lab, physical therapy, infusion services.
- Office-based surgical procedures
- Additional services (e.g., integrated mental health services)
- Telehealth modalities

Basic legal and operational considerations

- How are the services regulated in your state? Does the provision of a service require an additional license or permits?
 - Some states do not allow physician practices to provide services with other kinds of licensed professionals. For example, some states do not allow ophthalmologists and optometrists to practice within the same group, and a few states prohibit physician practices from employing physical therapists. Check with your state medical association for the latest information on such state specific regulations.
 - Some services will require distinct or additional licenses, permits, or accreditation.
 - Some services trigger more stringent legal requirements (for example, more restrictive privacy rules apply to records of some behavioral health services).
- Compliance with Stark Law, Anti-Kickback Statute, and state fraud and abuse laws.
 - How will any revenue from the new services be distributed?

- What investments will be needed to provide the service safely and effectively? For example, if you are planning to offer x-ray or CT services, have you considered the construction cost for radiation shielding? Will the practice self-fund the purchase or obtain a bank loan? If a loan, how will it be guaranteed (e.g., existing assets, personal guarantees)?
- Who will operate the new service—practice staff or an outside partner?
 - If an outside manager is involved, how will the parties share governance, investment in the service, and division of revenues?

Stark Law—Basic limit on (some) in-office services

For a more detailed explanation of these laws, see Prohibition on referring certain “**designated health services**” (DHS)—as defined below—if a physician or immediate family member has a financial relationship with an entity (**including his or her own practice**).

- What are DHS? The following as defined at 42 CFR 411.351:
 - Clinical laboratory services.
 - Physical therapy, occupational therapy, and outpatient speech-language pathology services.
 - Radiology and certain other imaging services.
 - Radiation therapy services and supplies.
 - Durable medical equipment and supplies.
 - Parenteral and enteral nutrients, equipment, and supplies.
 - Prosthetics, orthotics, and prosthetic devices and supplies.
 - Home health services.
 - Outpatient prescription drugs.
 - Inpatient and outpatient hospital services.

- What services are not DHS?
 - Professional services not described above
 - Services included in a composite rate (e.g., SNF Part A, ASC facility fee)
 - Services not payable by Medicare
- **Some states have laws similar to Stark that may apply to other/different kinds of services, and may apply across all payers, not just Medicare or Medicaid.**
- If the Stark Law applies, a physician's referrals may still fit an exception. One example is below, but practices should obtain legal guidance before proceeding.

- Are the services performed or supervised by the ordering physician or another physician in the group practice?
- Are the services performed in:
 - A "centralized building" (a space occupied by a group practice at all times without any occupancy by any other party) or
 - The "same building" used by the group practice for other non-DHS patient care services (as defined in the Stark rules)?

Reminder: CMS issued several waivers of Stark requirements for the duration of the COVID-19 Public Health Emergency. These waivers include some relaxation of the location requirements under the In-Office Ancillary Services Exception, **but only until the expiration of the Public Health Emergency, which has been extended into 2022.** For more information, please see apma-assn.org/system/files/2020-12/stark-waiver-guide.pdf.

The in-office ancillary services exception

An exception that physician practices commonly utilize is the in-office ancillary services exception, which allows physicians who are part of "Group Practices" (as that term is defined under the Stark Law and Regulations) to order DHS from their Group Practices. However, before a practice can use the in-office ancillary services exception, it must confirm that it meets all of the requirements to qualify as a "Group Practice."

- In order for your practice to qualify as a "**Group Practice**" under the Stark Law, you will need to be able to answer yes to the following questions (obtaining assistance from an experienced health care attorney in evaluating these questions is strongly recommended):
 - Does your practice qualify as a "**single legal entity**"?
 - Does the practice have at least two "members" (physician owners and/or employees)?
 - Do the practice's Members (owners and employed physicians (not independent contractors) provide at least 75% of their patient care services (in the aggregate) through the practice?
 - Are the overhead expenses and income of the practice distributed according to methods determined before the receipt of funds?
 - Is the practice a unified business with centralized decision-making by a representative body that maintains effective control over the practice's assets and liabilities (including budget, compensation, and salaries) and consolidated billing, accounting, and financial reporting?
 - Do members personally conduct at least 75% of the practice's physician-patient encounters?
 - Physician compensation cannot be based directly or indirectly on DHS referrals except:
 - Shares of **overall** DHS profits or DHS profits attributable to a component of **5 or more physicians**
 - Productivity bonus based on **personally performed and "incident to"** services
- Do the services qualify for the **in-office ancillary services exception**? This is an exception designed specifically to allow solo practitioners and group practices to provide ancillary services within the group practice, but only if the services meet the following conditions:
 - Are the services billed through a physician or the physician's "group practice" (as defined above)?

The anti-kickback statute

Criminal law prohibiting the knowing and willful offering, payment, solicitation, or receipt of anything of value (e.g., cash, free rent, expensive hotel stays and meals, excessive compensation) with intent to induce or reward patient referrals or the generation of business involving any item or service payable by the Federal health care programs.

- Arrangements that meet all of the criteria of a regulatory **safe harbor**, are protected from prosecution under the anti-kickback statute, but failure to comply with a safe harbor does not make an arrangement per se illegal (For a detailed discussion of the anti-kickback statute and its safe harbor regulations, see ama-assn.org/system/files/2020-12/stark-law-aks-summary-final-rules.pdf).
- One safe harbor that physician practices commonly use protects "investment interests in a 'group practice'":
 - All ownership interests are held by professionals who practice through group.
 - The ownership interests apply to the whole practice and not a subset or subdivision.
 - Revenues from any ancillary services must fit the in-office ancillary services exception.
 - A group practice must meet the requirements of the Stark Law definition and must have a compensation/profit distribution system that is not based on satellite offices operating substantially as if they were separate enterprises or profit centers.
- The Anti-Kickback Statute applies more broadly than the Stark Law, including to relationships with outside managers, providers, and non-physician professionals. Any exchange of value should be analyzed to assess compliance with the law.
- Some states also have statutes similar to the federal Anti-Kickback Statute that apply with respect to services paid by all payors. Any exchange of value should also be carefully reviewed under applicable state laws.