



The Stark Law and the In-Office Ancillary Service Exception (IOASE):

Allowing independent practices to thrive under MACRA

What is the Stark Law?

“Stark Law” corresponds to Section 1877 of the Social Security Act (42 U.S.C. 1395nn). Also known as the physician self-referral law, the Stark Law governs physician self-referral for Medicare and Medicaid patients.

This law is broken down into three provisions:

- 1** Prohibits physicians from making referrals for certain designated health services (DHS) payable by Medicare to an entity in which he or she (or an immediate family member) has a financial relationship (ownership, investment, or compensation), unless an exception applies.
- 2** Prohibits the entity from presenting claims to Medicare (or billing another individual, entity, or third party payer) for those referred services.
- 3** Establishes several specific exceptions and grants the Secretary of Health and Human Services the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse.

Though CMS has published a number of regulations interpreting the physician self-referral statute over the years, the most recent rules were finalized in three phases between 2001 and 2007. CMS annually publishes an updated list of codes for the relevant DHS in the Physician Fee Schedule final rule.

***The Stark Law is related to, but not the same as, the federal anti-kickback law.*

What are Designated Health Services (DHS)?*



1. Clinical laboratory services
2. Physical therapy services
3. Occupational therapy services
4. Outpatient speech-language pathology services
5. Radiology and certain other imaging services
6. Radiation therapy services and supplies
7. Durable medical equipment and supplies
8. Parenteral and enteral nutrients, equipment, and supplies
9. Prosthetics, orthotics, and prosthetic divides and supplies
10. Home health services
11. Outpatient prescription drugs
12. Inpatient and outpatient hospital services

*Current as of March, 2017

Why does the Stark Law Matter to LUGPA members?

Within the Stark Law lies the in-office ancillary services exception (IOASE), which permits referring physicians who are members of a physician group practice to refer a patient for imaging services or other DHS, without violating the Stark Law. The IOASE is the main way that referring physician practices are able to provide supplementary ancillary services reimbursed by Medicare. Without this exception, the Stark Law would generally prohibit referring practices, other than practices located in rural areas, from billing Medicare for these essential services.

In more than 25 years since its passage, the law has become one of the most significant sources of regulatory burden on physicians and, ultimately, for Medicare beneficiaries. These restrictions make it more difficult for independent physician practices to coordinate care, creating a competitive advantage for large hospital systems. Given that the system is rapidly transitioning away from fee-for-service payment, the law is outdated.

Current State of the Stark Law and the IOASE

Over the last several years, there have been attempts to curb the ability for independent physician practices to offer clinically appropriate ancillary services to their patients. These attempts have focused on curbing or eliminating the IOASE. Thanks in large part to LUGPA's leadership role, data illustrating that ancillary service utilization in the independent physician setting is driven by competitive market forces was developed. This data helped rally the broader physician community: more than 30 physician specialty organizations supported sign-on letters on to Congress demanding that the IOASE be preserved to promote competition and help deliver superior, targeted care. At present, no support exists at the Federal level for stand-alone legislation to modify the IOASE.

As we move to value-based paradigms, the ability to provide ancillary services is integral to LUGPA's member practices' ability to serve patients, provide integrated and comprehensive care, and compete with large hospital systems. Furthermore, ancillary services performed at physicians' offices are far more cost effective than when done at the facility setting, greatly reducing expense to both patients and third-party payors. As such, LUGPA is leading efforts to modernize Stark law to reflect changes instituted in MACRA. These changes will help level the playing field in the development of alternative payment models, ensuring that patients will continue to have access to high quality integrated health care at the site of service of their choosing.



LUGPA is a trade Association that represents independent urology group practices in the U.S., with more than 2,200 physicians who make up more than 25 percent of the nation's practicing urologists, and provide more than 30 percent of the total urologic care in the U.S. The association is committed to providing the best resources and information for its member practices through advocacy, research, data collection and benchmarking efforts. LUGPA advocates for independent urology practices by promoting quality clinical outcomes, fostering new opportunities and improving advocacy in the legislative and regulatory arenas. For more information, visit lugpa.org.