Issue Brief: Stark Reform

Background:

- **The Ethics in Patient Referrals Act, also known as the “Stark Act” or “Self-Referral Law”**
  - Preserves the integrity of the Medicare Program: Prohibits clinicians from referring Medicare patients to entities in which they have a financial interest.
  - Protects against distorted medical decision-making: Seeks to ensure that medical decisions are made in the best interest of the patient on the basis of quality, diagnostic capability, turnaround time, and cost without consideration of any financial gain that could be realized through self-referral.

- **The In-Office Ancillary Services (IOAS) Exception to the Stark Law**
  - Legislative Statute: Certain ancillary services are included under the IOAS exception and are therefore exempt from the Stark law.
  - Practical Application: Clinicians are allowed to self-refer for the specified ancillary services that are included under the IOAS exception.
  - Original Congressional Intent: Congress intended for the IOAS exception to apply only to ancillary services that are capable of being provided, with results read, during the clinician office visit. This would allow clinicians to self-refer for these services (to in-office laboratories) in order to enable quick turnaround time of results while enhancing patient access and convenience.

Issue:

- **Inappropriate Inclusion of Complex Ancillary Services under the IOAS Exception:** Certain services, such as anatomic pathology services, have been inappropriately included under the IOAS exception based on the false premise that these services could be furnished, with results read, during the clinician office visit.

- **Diluted ‘IOAS Exception’ Objectives:**
  - Does NOT Enhance Patient Convenience: If a service is too complex to be furnished, with results read, during the clinician office visit, then the patient must schedule a separate visit to receive it.
  - Does NOT Enhance Patient Access: When a clinician self-refers for a service, he/she limits patient access by guiding the patient to receive the service at a specific entity in which he/she has financial interest.
  - Does NOT Improve Care Coordination: The IOAS exception enables self-referral of services that are not always provided alongside the clinician within the walls or service hours of the clinician office. Moreover, in-office services are typically provided by a single provider that is unable to leverage the multi-provider consensus and breadth of (sub)specialty expertise present at fully staffed, non-affiliated entities.

- **Negative Byproducts of Inappropriate Self-Referrals:** Evidence shows that self-referral leads to increased utilization of ancillary services that may not be medically necessary, poses a potential risk of harm to patients, and costs the health care system millions of dollars each year.
  - MedPAC Report to Congress, June 2010: The ability to self-refer creates incentives to increase volume under Medicare’s current FFS payment system, increasing financial burden on taxpayers/beneficiaries
  - Health Affairs Study, April 2012: The cancer detection rate in 2007 was 12 percentage points higher for men treated by urologists who did not self-refer, suggesting the ability to self-refer creates financial incentive to perform prostate biopsies on men unlikely to have prostate cancer
  - GAO Report, September 2012: Self-referring providers referred over 918,000 more anatomic pathology services than non-self-referring providers, costing Medicare approximately $69 million in 2010

Solution:

- **Passage of H.R. 2914, the “Promoting Integrity in Medicare Act:”** Introduced on August 1, 2013 by Congresswoman Jackie Speier [D-Calif.]; Eliminates anatomic pathology, diagnostic imaging, radiation therapy, and physical services from the list of service types for which the IOAS exception applies – resulting in the prohibition of self-referral of these service types.

- **SGR Repeal Legislation “Pay-For:”** The current Sustainable Growth Rate (SGR) repeal legislation is priced at $126 billion. In the FY 2015 President’s Budget, The Office of Management and Budget estimated the cost-savings associated with Stark reform at more than $6 billion – which could be allocated to help fund SGR repeal.