



Practical Considerations for Medical Practices Considering Converting Their Vascular Access Centers Into Medicare-Certified Ambulatory Surgery Centers

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On November 2, 2016 the Centers for Medicare & Medicaid Services (CMS) released the 2017 Medicare Physician Fee Schedule (MPFS) Final Rule. Although the impact of the Final Rule on nephrology reimbursement is projected to be 0%, dialysis vascular access services typically provided by interventional nephrologists will experience a dramatic overall reduction in reimbursement due to CMS policy requiring services that are billed together more than 75% of the time to be bundled. As a result of this policy, the following new interventional CPT code bundles were developed resulting in reimbursement reductions for a variety of interventional services:

- 36901: Angiogram only
- 36902: Angiogram with angioplasty
- 36903: Angiogram with angioplasty and stent
- 36904: Declot only
- 36905: Declot with angioplasty
- 36906: Declot with angioplasty and stent
- 369X7-X9: Add-on codes

Despite the negative impact of reimbursement cuts for a variety of interventional services, most nephrology and dialysis industry groups and physician practices were generally pleased that the cuts were not as substantial as the overall 35-40% reimbursement cuts to interventional procedure codes originally proposed by CMS in the July 2016 MPFS proposed rule. Nonetheless, as is evident from the table below, reimbursement cuts to many commonly performed practice-based vascular access procedures remains significant:

Procedure	2016 CPT Codes	2016 FFS Reimbursement	2017 Bundled CPT Code	Office-Based 2017 FFS	Percent Change
Angiogram of access	36147	\$855	36901	\$580.70	-32%
Angiogram with angioplasty	36147, 35476, 75978	\$2052	36902	\$1234.97	-26%
Angiogram with stent	36147, 37238	\$4712	36903	\$5663.44	29%
Thrombectomy	36147, 36148, 36870	\$2567	36904	\$1800.60	-16%
Thrombectomy with angioplasty	36147, 36148, 36870, 35476, 75978	\$3222	36905	\$2304.14	-18%
Thrombectomy with stent	36147, 36148, 36870, 37238	\$5701	36906	\$6867.55	29%

These cuts, when considered in light of CMS policy to promote site-neutral payments for medical services performed across different outpatient surgical settings, have led many nephrology practices to consider the financial, operational and legal viability of converting their practice-based vascular access

centers (VAC) into Medicare-certified ambulatory surgery centers (ASC) and/or expand their service offerings to include peripheral arterial disease (PAD) and other interventional procedures consistent with a physician’s relevant training and experience. The table below highlights the approximate difference in reimbursement for certain interventional dialysis vascular access services performed in an office-based VAC as compared to the same services performed in an ASC setting:

Procedure	2017 Bundled CPT Code	Office-Based 2017 Final FFS	Approx. ASC Rate	Approx. \$ Variance	Approx. % Variance
Angiogram of access	36901	\$580.70	\$369.36	-\$211.34	-36%
Angiogram with angioplasty	36902	\$1234.97	\$3119.32	\$1884.35	153%
Angiogram with stent	36903	\$5663.44	\$6025.55	\$362.11	6%
Thrombectomy	36904	\$1800.60	\$3119.32	\$1318.72	73%
Thrombectomy with angioplasty	36905	\$2304.14	\$6025.55	\$3721.41	162%
Thrombectomy with stent	36906	\$6867.55	\$9341.79	\$2474.24	36%

The financial justification for converting a practice-based VAC is based, in part, upon a VAC’s mix of services and the costs of conversion. Practices should also be aware that as CMS continues synchronizing Medicare reimbursement rates across outpatient settings enhanced reimbursement available for providing these services in an ASC setting may not last long. In addition, legal issues in connection with a conversion also should be carefully considered before proceeding. The remainder of this article highlights certain key issues worth considering before moving forward with a conversion.

1. State Certificate of Need Laws.

As a threshold matter, a number of states require a certificate of need (CON) or a CON exemption from the applicable healthcare planning commission prior to converting a practice-based VAC into an ASC. Depending upon the availability of ASCs already providing interventional nephrology and PAD services within a geographic area, it may be difficult to obtain a CON or exemption if a CON commission determines that there is limited additional need for such services. Many states also allow competitive ASCs, hospitals and other healthcare facilities to publicly object to a proposed conversion project while allowing such competitors to provide evidence regarding why additional ASC services are not needed within a relevant service area.

2. Federal and State Fraud and Abuse and Self-Referral Laws.

In many respects, a properly structured nephrologist investment in an ASC requires a similar analysis of Federal fraud and abuse risk as a nephrologist’s investment in an outpatient dialysis center. Although, as described below, the structure of a physician’s investment in an ASC may heighten the level of Federal fraud and abuse risk.

The Federal Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b(b), imposes criminal penalties on any person that knowingly and willfully solicits, receives, offers, or pays any remuneration (including

any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind, to any person, in return for or to induce such person to either: refer an individual to a person for the furnishing or arranging for the furnishing of an item or service for which payment may be made in whole or in part under a federal health care program, or purchase, lease, order, or arrange for or recommend the purchasing, leasing, or ordering of any good, facility, service, or item for which payment may be made in whole or in part under a federal health care program.

The AKS is a specific-intent statute. The U.S. Department of Health and Human Services Office of the Inspector General (OIG) and some courts have taken the position that the intent requirement is met where “one purpose” of a payment is to induce referrals for, or purchases of, an item or service covered under a federal health program. Under the “one purpose” test, the fact that the parties may have had other good intentions in paying or receiving the payment is irrelevant. However, not all interactions encompassed within the broad scope of the AKS violate the statute. There are statutory safe harbors protecting certain types of activities (such as a physician’s investment in an ASC). The safe harbors describe activities that the government will not prosecute if the elements of a safe harbor are completely satisfied because the government has determined that these activities are unlikely to be abusive. The OIG’s principal concern with ASC joint ventures is that these ventures might serve as a means to reward physicians for indirect referrals (e.g., referrals to other physicians who actually perform the services at the ASC):

In the context of an ASC, our chief concern is that a return on an investment in an ASC might be a disguised payment for referrals. Two examples illustrate the potential problem. First, primary care physicians could be offered an investment interest in an ASC for a nominal capital contribution as an incentive to refer patients to surgeon owners of the ASC. The primary care physicians would not perform any services at the ASC, but would profit from any referrals they make. Second, physicians in specialties that typically refer to one another could jointly invest in an ASC so that they are positioned to earn a profit from such referrals or so that one physician specialty provides the ASC services and the other provides the referrals. In such cases, medical decision-making may be corrupted by financial incentives offered to potential referral sources who stand to profit from services provided by another physician.

[64 Fed. Reg. 63,518, 63,536 (Nov. 19, 1999)]. To mitigate against the risk of payment for referrals, the ASC Safe Harbor sets forth both qualitative and quantitative requirements, each of which must be satisfied to fit within the ASC Safe Harbor.

Accordingly, the following qualitative requirements must be satisfied when investing in both single-specialty and multi-specialty ASCs: (a) the physician investors must disclose their ownership interests in the ASC to patients they refer to the ASC; (b) the physician investors must not discriminate against Medicare or Medicaid patients; (c) the ASC must provide physicians an equal opportunity to purchase interests in the ASC without regard to the volume or value of referrals that the physician may generate; (d) any distributions to investors must be based on ownership, among other requirements; and (e) at least one-third of each physician investor’s medical practice income from all sources for the previous fiscal year or previous 12 month period must be derived from the physician investor’s performance of ASC procedures. In addition, in multi-specialty ASCs, an additional quantitative requirement must be satisfied to meet the ASC Safe Harbor. Physician investors must perform at least one-third of their outpatient surgical procedures at the ASC in which they are investors.

The italicized requirements are sometimes referred to as the “one-third tests.” Compliance with all of the requirements of the ASC Safe Harbor provides an absolute defense against prosecution under the AKS. However, many physician investors may find it difficult to satisfy all of the elements of the ASC Safe Harbor, particularly the one-third tests, and arrangements that do not meet every requirement of the ASC Safe Harbor or any other applicable safe harbor may nevertheless be lawful under the AKS so long as other prophylactic measures are implemented to ensure that referring physicians are not otherwise rewarded for making indirect referrals to other physicians or the ASC. In addition, the AKS provides for a safe harbor for a group practice investment and thus an ownership of an ASC within a group practice may also provide safe harbor protection if structured properly.

Finally, like in the dialysis context, the prohibitions contained Section 1877 of the Social Security Act (the Stark Law) preventing physicians from referring Medicare patients for certain designated health services (DHS) to an entity in which a physician or a member of a physician’s immediate family has a direct or indirect financial relationship, generally do not apply to a physician’s investment in an ASC. The government has stated that services that would otherwise constitute DHS, but that are paid by Medicare as part of a composite payment for a group of services as a separate benefit (e.g., ASC or dialysis services) are not DHS for purposes of the Stark Law. As a result, the Stark Law’s restrictions will only apply if there is a referral to an ASC from a physician with a financial interest in the ASC for DHS that is separately reimbursable outside of the ASC’s composite rate. It is therefore advisable to work with experienced legal counsel to evaluate whether the services to be provided at the ASC (e.g., many types of imaging services) qualify as separately-reimbursable DHS and, if so, to develop a strategy for providing those services in a practice-based setting.

3. State ASC Licensure Laws.

Most states do not require VACs operated as an extension-of-practice to be licensed; however almost all states require licensure of ASCs. As a result of a variety of recent high-profile patient adverse events, ASC licensure requirements have become increasingly stringent in many states. At a minimum, many states require strict engineering and design specifications and minimum patient parking requirements that may require practices to make costly renovations. It is also important to evaluate what other state licenses may be required to operate a licensed ASC, including pharmacy and drug dispensing licenses, CLIA laboratory permits or exemptions, hazardous waste permits, radiology and x-ray licenses and other municipal permits.

4. Federal ASC Medicare Conditions for Coverage.

Medicare-certified ASCs are required to satisfy Medicare Conditions for Coverage for ASCs. Thus, ASCs need to comply with applicable Federal fire and life safety codes applicable to ASCs, hospital transfer procedures, anesthesia administration standards, and must also adhere to certain requirements that limit the ASC’s ability to use the space for other purposes among other conditions. ASCs must also maintain an independent waiting room and recovery room, and may not have concurrent overlapping hours of operation with a physician practice using the same space as might be the case in a VAC.

5. Tax Considerations.

Finally, some conversions could involve the contribution of the value of a practice's depreciated assets and goodwill related to its vascular access service line to a newly organized limited liability company, professional limited liability company or S-corporation that will operate as the Medicare-certified ASC, while others may continue to operate the ASC as a part of their practice. It is therefore critical for a practice to involve its accountant or tax advisors when considering whether such a conversion may be accomplished on a tax-free or tax-advantaged basis. Depending upon a practice's organizational structure, other special tax issues, such as built-in gains (BIG) tax should also be considered if a sale of the ASC is contemplated within a period of time after the conversion. The BIG tax is an entity-level tax on an S corporation that was formerly a C corporation or received assets from a C corporation, and later disposes of the assets that had built-in gain when owned by the C corporation in a taxable sale or exchange during a 10-year period beginning when a C corporation converts to an S corporation, or when an S corporation receives assets from a C corporation. The built-in gains tax is imposed at the highest corporate rate.

In light of the likelihood that CMS's site-neutral payments policies are likely to create a more level financial playing field in coming years, regardless of the setting in which dialysis vascular access services are offered, providers may wish to consider whether converting a practice-based VAC into an ASC can be accomplished in a way that achieves the dual goals of enhancing patient choice, value and safety, while ensuring that such a conversion may be accomplished in a timely and cost-effective manner in compliance with applicable laws.

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