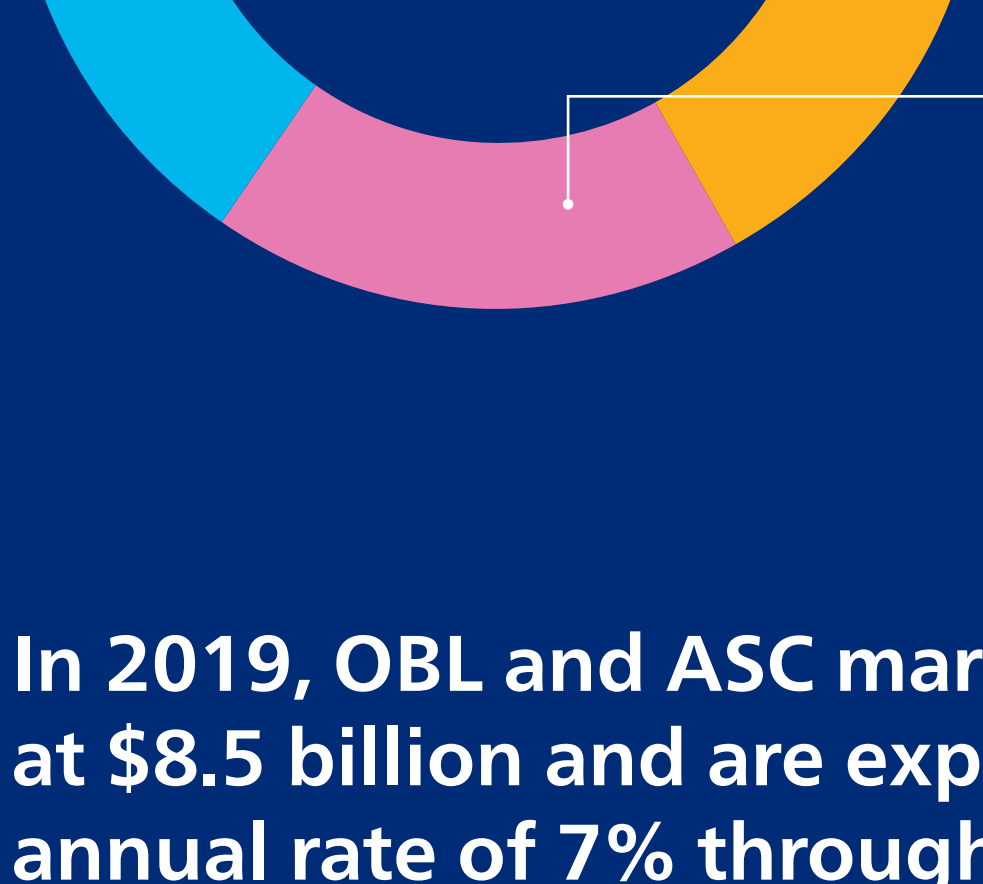


Understanding the outpatient landscape

More procedures are moving to out-of-hospital care settings such as office-based labs (OBLs), ambulatory surgery centers (ASCs) or outpatient hospital centers.

Almost 70% of surgical procedures are being performed in outpatient settings

Source: www.grandviewresearch.com/industry-analysis/office-based-labs-obl-market



Total annual surgery volume:

● 23 million ASC procedures

● 12 million OBL procedures

● 11.5 million hospital-based ambulatory procedures

● 10 million hospital inpatient (overnight stay) procedures

Source: www.ormanager.com/can-hospital-survive-growing-dominance-asc/

In 2019, OBL and ASC markets across specialties were valued at \$8.5 billion and are expected to grow at a compound annual rate of 7% through 2027, reaching \$14.5 billion.

Source: Grand View Research, U.S. Office-based Labs Market Size, Share & Trends Analysis by Modality (Single Specialty Labs, Hybrid Labs), by Service, by Specialty, and Segment Forecasts, 2020 – 2027 Report Summary, December 2020. www.grandviewresearch.com/industry-analysis/office-based-labs-obl-market, Accessed July 9, 2021.



Care setting differences

Office-based lab (OBL)

CMS place of service code: 11

“Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, state or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis and treatment of illness or injury on an ambulatory basis.”

– CMS.gov

Ownership options

Physician owned and independent of a hospital location

Specialties and procedures

Single or multi-specialty
Many interventional procedures are allowed in the OBL setting but some physicians may utilize the OBL for diagnostic procedures
Services require general anesthesia and are not invasive
Peripheral vascular, endovascular cases

Reimbursement and payments

OBLs bill a single/global fee that includes both the professional fee for the physician and the facility or practice fee related to the expense of performing the procedure in the OBL

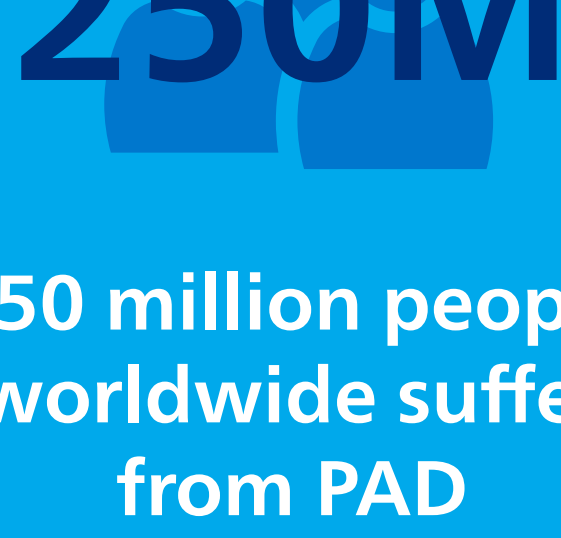
Considerations

General life-safety and building codes apply (OSHA, state, city)



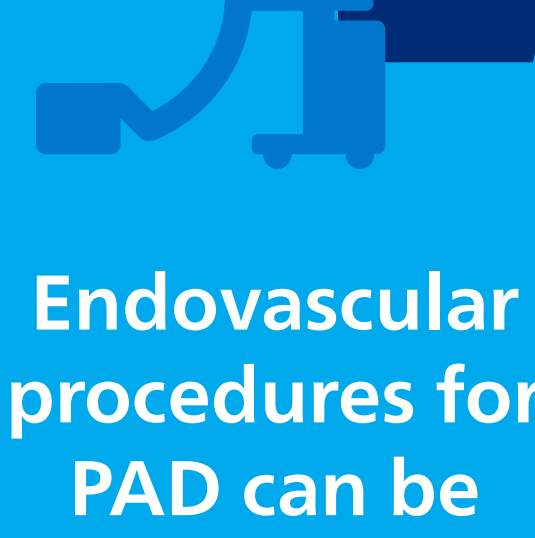
Every 30 seconds a diabetic patient somewhere in the world has a limb amputated

Source: Teraa M, et al. J Am Heart Assoc. 2016 Feb 23;5(2): pii: e002938.



250 million people worldwide suffer from PAD

Source: Fowkes FG, et al. Lancet. 2013 Oct 19;382(9901):1329-40.



Endovascular procedures for PAD can be performed safely in a rural outpatient setting with low complication rates

Source: <https://journals.sagepub.com/doi/full/10.1177/1753944720948651>

Ambulatory surgery center (ASC)

CMS place of service code: 24

“A freestanding facility, other than a physician’s office, where surgical and diagnostic services are provided on an ambulatory basis.”

– CMS.gov

Ownership options

Physician owned and independent of a hospital location
Joint venture or partnership between physician(s) and hospital
Hospital owned

Specialties and procedures

Single or multi-specialty
Limited to entities that provide surgical services to patients who do not require hospitalization and expected duration of care would not exceed 24 hours from registration
Range of procedures: cardiovascular, orthopedics, spine, endoscopy, ophthalmology, etc.

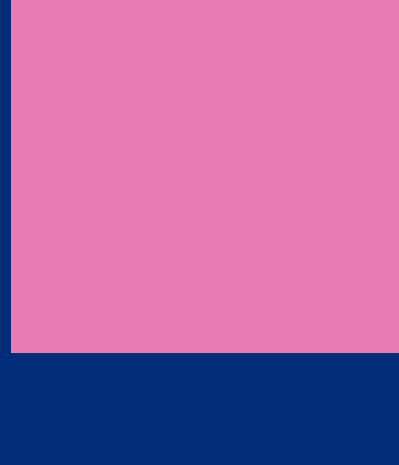
Reimbursement and payments

Center bills insurance company or patient directly for charges related to the use of the center, while the physicians using the facility separately bill for their professional services rendered

Considerations

ASC operation/licensing requirements vary by states; many require a certificate of need (CON)
Specific and stringent building requirements
Cardiovascular procedures only allowed in certain states
Separate from a hospital campus (>250 yards from hospital or built after 2015)
Can’t share space with a hospital outpatient department or Medicare-participating independent diagnostic testing facility (IDTF)

7.1% Growth in new ASCs



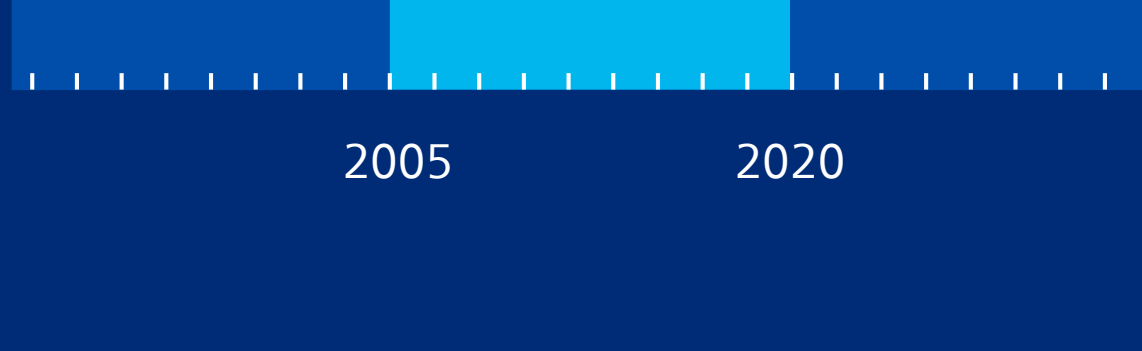
0.97% Growth in hospital development

From 2016 to 2020, there was a 7.1% growth in new ASCs versus a 0.97% growth in hospital development over the same period.

Source: “Provider of Services files,” CMS, December 2020.

The cost of elective OR time is less than \$15 per minute in an ASC versus \$40 a minute in a hospital OR.

Source: www.ormanager.com/can-hospital-survive-growing-dominance-asc/.



60% of outpatient surgeries were performed in ASCs in 2020 versus 41% in 2005.

Source: www.advisory.com/en/daily-briefing/2019/03/05/asc-shift

Lower costs and favorable outcomes are driving estimates that ASCs will account for 30-35% of all cardiac procedures by the mid-2020s.

Source: <https://www.bain.com/insights/ambulatory-surgery-center-growth-accelerates-is-medtech-ready/>



Hybrid lab

CMS place of service code: 24 or 11

“A site of service that combines an OBL facility and an ASC facility to provide a broader range of cardiovascular or other specialty services.”

– Philips

Ownership options

Physician owned and independent of a hospital location

Specialties and procedures

Same outline for specialties and procedures for both ASCs and OBLs
Operates as an OBL on certain days and an ASC on others – or some other form of temporal separation

Reimbursement and payments

Both reimbursement and payment rules as outlined for ASCs and OBLs

Considerations

Both considerations as outlined for ASCs and OBLs
Only allowed in certain states
Must have medical records for both the OBL and ASC stored separately
Must have separate tax IDs and operate as separate entities on separate days



“OBL/ASC ownership gives cardiologists more autonomy, as well as the potential to be compensated for facility fees.”

Source: www.beckersasc.com/cardiology/the-hybrid-asc-office-based-lab-model-for-cardiology-6-pros-cons.html

Outpatient hospital

Off-campus

CMS place of service code: 19

“A portion of an off-campus hospital provider-based department which provides diagnostic, interventional, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.”

– CMS.gov

On-campus

CMS place of service code: 22

“A portion of a hospital’s main campus which provides diagnostic, interventional, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization”

– CMS.gov

Ownership options

Hospital owned

Specialties and procedures

Diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization

Reimbursement and payments

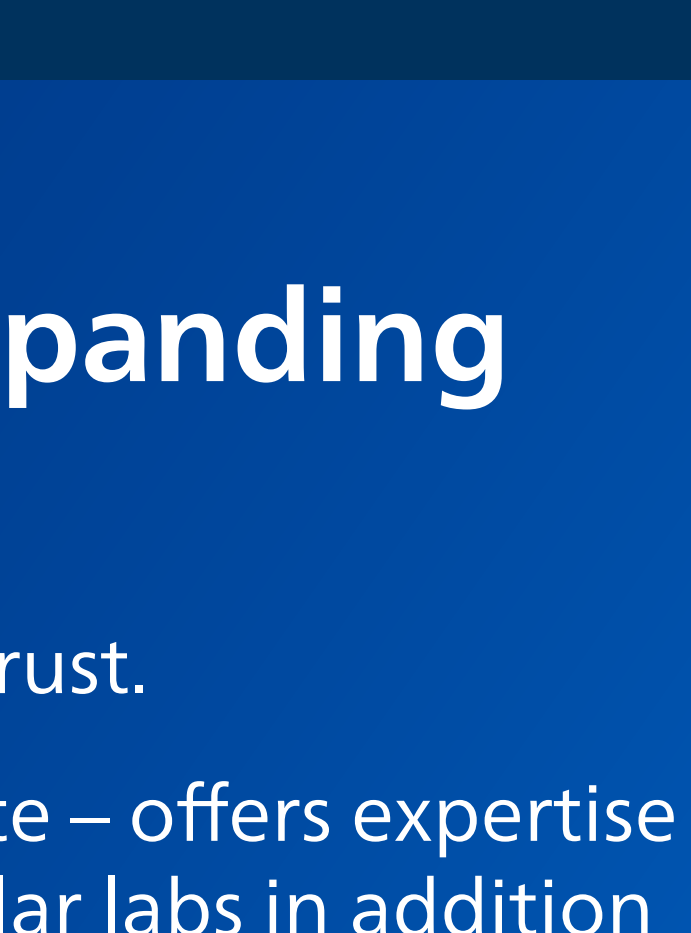
Paid at the facility rate under the Medicare PFS-physician fee schedule

Considerations

Off-campus: More than 250 feet away from a hospital
On-campus: Located within 250 yards of main building that are not contiguous to the main building; determined on individual case basis by CMS regional office to be part of provider campus

“Center for Medicare and Medicaid services implemented place of service 19 and place of service 22 to gather statistics of on-campus outpatient hospital and off-campus outpatient hospital.”

Source: <https://bulletin.facs.org/2015/12/cms-creates-new-place-of-service-code-for-outpatient-care-at-hospitals/>



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