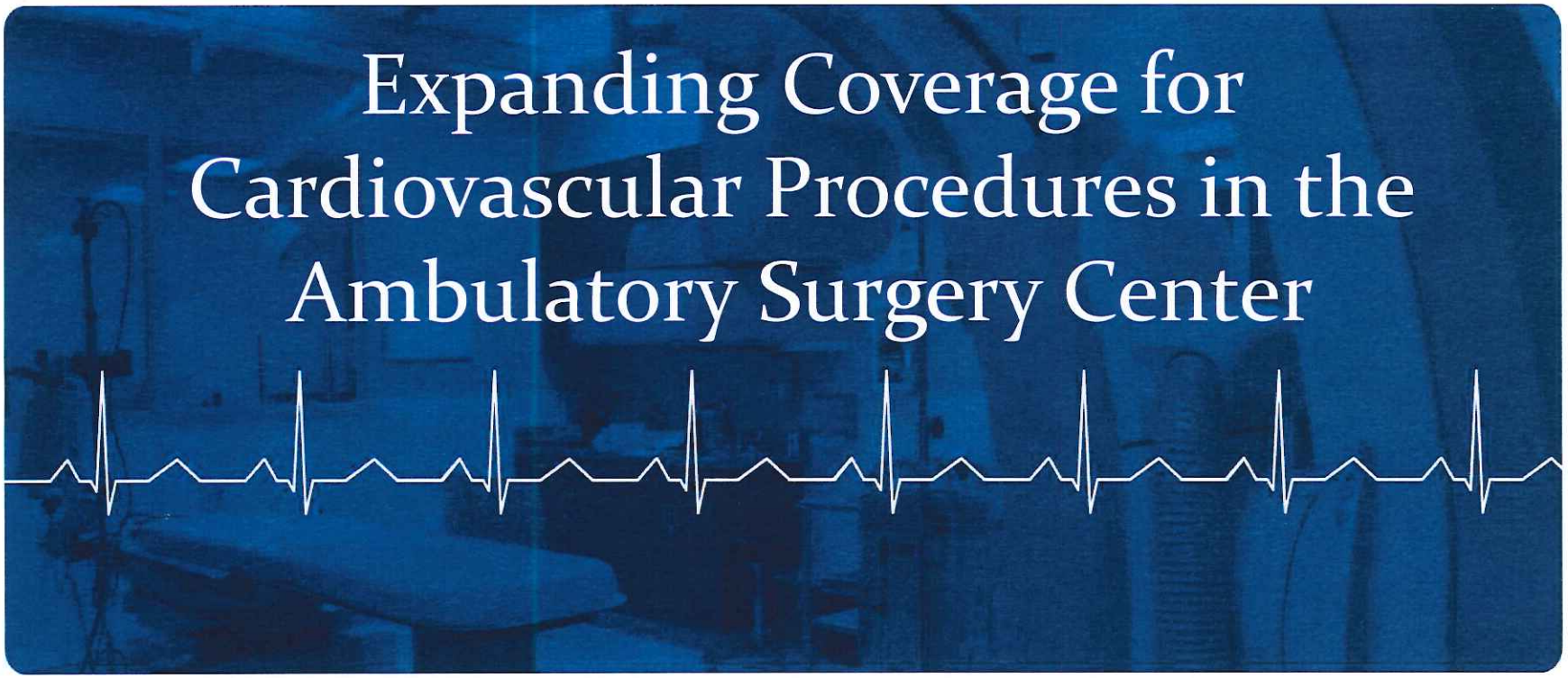

Expanding Coverage for Cardiovascular Procedures in the Ambulatory Surgery Center

Modernizing ASC Policy

Participants

On behalf of NCP:

- **Brian Gauger**, CEO, National Cardiovascular Partners
- **Cam Lynch,** SVP, Fresenius Medical Care North America
- **Dr. Neil Marwah,** SVP, Fresenius Medical Care North America
- **Stacey Fahrner**, Vice President, Fresenius Medical Care North America
- **Christopher Young,** The Moran Company

Our Mission:

To provide superior quality healthcare services that: ***PATIENTS*** *recommend to families and friends,* ***PHYSICIANS*** *prefer for their patients, and* ***EMPLOYEES*** *take pride in.*

About Us:

- National Cardiovascular Partners creates, sustains and grows **independent, outpatient cardiac catheterization and vascular labs** in unique business partnerships with physicians.
- NCP has partnered with over 250 physicians in 22 outpatient cardiac catheterization & vascular labs in Texas, Arizona, California, Louisiana and Kansas, with expansion into numerous additional states to take place in the coming years.

L3-4

growth 4-6 ASCs per year

60% Med FFS/MA

CMS should expand access to ASCs for Medicare beneficiaries needing certain cardiac procedures

Objective: Expanding the range of endovascular cardiology procedures that are covered and paid in the ASC to create a seamless site of service for diagnosis and treatment consistent with care for many commercially insured patients.

private insurance allows stent in ASC Medicare does not. need to be transferred. CMS interaction. Jan mtg updated data set March

Why? Expanded access is good for patients:

- Procedures performed in an ASC are less expensive
- A single point of service is more convenient for patients
- Modernizing the coverage and payment rules will bring Medicare up to date with commercial payers
- Clinical guidelines support performing most procedures in an ASC-like (non-hospital) setting*

Current Medicare coverage by setting	HOPD	ASC	Physician office
Cardiac Dx	✓	×	✓
Coronary Tx	✓	×	×
Pacemakers/AICD	✓	✓	×

33% of procedures done w/out bypass backup, either in inpatient or outpatient. NO change in mortality may need transfers

How? NCP recommendations include:

- Minor changes in ASC methodology to align with OPPS
- Adding a number of diagnostic and interventional procedures to the ASC payment list (based on data analysis by The Moran Company)
  - Many procedures are already performed in the physician office setting
- Updating regulations to reflect clinical guidelines and advancements

*SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Interventions Without On-Site Surgical Backup on Cardiac Catheterization Laboratory Standards Update

2 others — Tenant & Optent. — only ASC focused on cardiology

Clinical Evidence

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Randomized controlled clinical trials show that Percutaneous Coronary Intervention (PCI) outcomes at sites without surgical backup are the same

Two randomized clinical trials support the safety of non-emergent procedures in ASC-like settings (sites without onsite surgical backup)

CPORT-E: N Engl J Med 2012; 366: 1792-1802

18,867 patients with stable CAD or ACS underwent non-emergency PCI at a hospital with (n = 4,718) or without (n = 14,149) on-site cardiac surgery from April 2006 to March 2011.

Findings: Elective percutaneous coronary intervention (PCI) performed at hospitals without on-site cardiac surgery is non-inferior to similar procedures performed at hospitals with surgical capabilities.

9 Month Outcomes

	No on-site surgery (n= 14,149)	On-site surgery (n=4,718)	*P* value
Death	3.2%	3.2%	
TVR	6.5%	5.4%	0.01 (for superiority)
MI	3.1%	3.1%	
MACE	12.1%	11.2%	0.01 (for non-inferiority)

Summary of randomized controlled studies cont.

MASS COMM: N Engl J Med 2013; 368: 1498-1508

3,691 patients who presented for elective PCI at hospitals in Massachusetts without on-site surgery capabilities between July 7, 2006, and September 29, 2011. The patients were randomized in a 3:1 fashion to undergo PCI at the initial hospital (n = 2,774) or be transferred to another with on-site surgical back-up (n = 917).

Findings: Patients undergoing non-emergency percutaneous coronary intervention (PCI) experience similar outcomes whether they are treated at hospitals that possess on-site cardiac surgery capabilities or do not offer such services.

30 Day Outcomes

	No on-site surgery (n= 2,774)	On-site surgery (n=917)	*P* value
MACE	9.5%	9.4%	<0.001 (for non-inferiority)
DEATH	0.7%	0.3%	0.39
MI	6.5%	6.5%	1.00
Repeat revascularization	2.7%	3.5%	0.25
Stroke	0.4%	0.1%	0.21

1 Year Outcomes

	No on-site surgery (n= 2,774)	On-site surgery (n=917)	*P* value
MACE	17.3%	17.8%	<0.001 (for non-inferiority)
DEATH	2.3%	2.4%	0.89
MI	8.6%	7.8%	0.55
Repeat revascularization	8.5%	9.9%	0.24
Stroke	1.0%	0.8%	0.83

Recent observational study findings support PCI at facilities without on-site surgery for all indications

Outcomes and Temporal Trends of Inpatient Percutaneous Coronary Intervention at Centers With and Without On-site Cardiac Surgery in the United States (Kashish Goel, MD1; Tanush Gupta, MD2,3; Dhaval Kolte, MD, PhD4; et al JAMA Cardiol. 2017;2(1):25-33. doi:10.1001/jamacardio.2016.4188)

A national inpatient sample (N = 6,912,232) was used to identify patients who underwent inpatient PCI in the United States from January 1, 2003, to December 31, 2012. Of these PCIs, 396,741 (5.7%) were conducted at centers without on-site cardiac surgery.

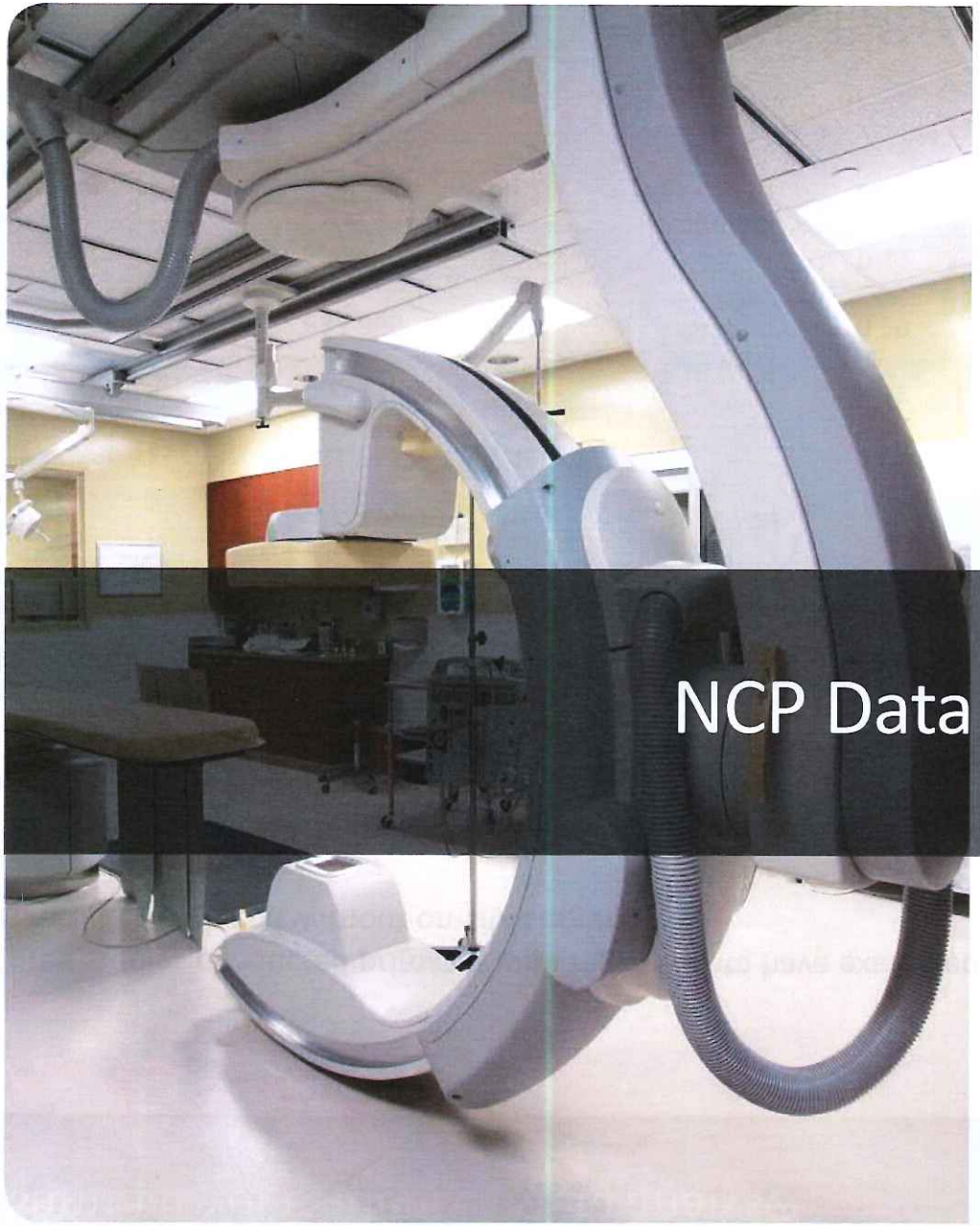
Findings: There was a 7-fold increase in the proportion of PCIs at centers without on-site cardiac surgery from 2003 to 2012 in the United States, with the adjusted in-hospital mortality after inpatient PCI being similar at centers with and without on-site cardiac surgery. ***These data provide evidence that PCI at centers without on-site cardiac surgery may be safe in the modern era***.

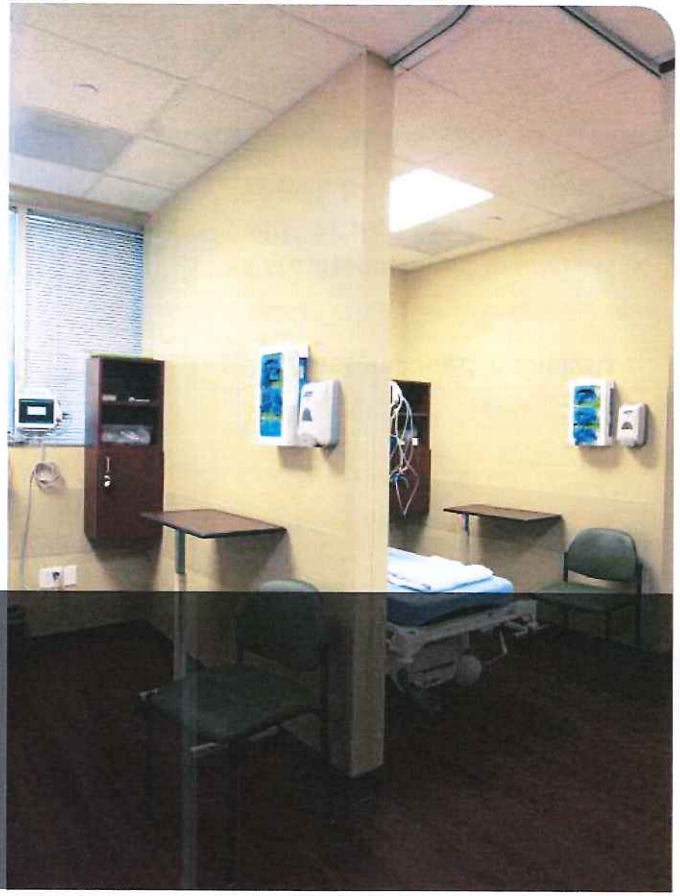
Summary of evidence: Meta analyses

Three studies conducted primarily with registry data have examined the use of non-emergent (non-primary) PCI at facilities with and without on-site surgery.

Findings: Overall, mortality and the need for emergency CABG surgery did not differ between hospitals with and without on-site surgery.

	On-site surgery	No. of Patients	Mortality Incidence	Mortality OR (95% CI)	Emergency CABG Incidence	Emergency CABG OR (95% CI)	Comments
Zia (2011)	No	28,552	1.6%	1.03 (0.64-1.66)	1.0	1.38 (0.65-2.95)	6 studies included in analysis
	Yes	881,261	2.1%		0.9		
Singh M (2011)	No	30,423	0.9%	1.15 (0.93-1.41)	0.17	1.21 (0.52-2.85)	9 studies included in analysis
	Yes	883,865	0.8%		0.29		
Singh PP (2011)	No	1,812	0.17%	2.3 (0.60-12.97)	0.11	0.47 (0.07-3.19)	4 studies included in analysis (2 with data on mortality and CABG); RR calculated rather than OR
	Yes	4,039	0.72%		0.02		





NCP Data

BUILD SOMETHING

NCP 2016 clinical outcomes show cardiac catheterization and PCI in the ASC is safe for patients

NCP promotes a culture of safety and excellence. The data below reflects outcomes and complications for over 33,000 cases across our 22 facilities.

Variance	Cath Labs 2015	2015 Results	Cath Labs Jan-June 2016	Jan-June 2016 Results		ASC 2015	2015 Results	ASC Jan-June 2016	2016 Jan-June Results
Sentinel Events:	**8**	**0.07%**	**2**	**0.03%**		**3**	**0.03%**	**0**	**0%**
Death	4	0.04%	2	0.03%		0	0.00%	0	0%
Wrong	1	0.01%	0	0%		3	0.03%	0	0%
Loss of Limb	0	0.00%	0	0%		0	0.00%	0	0%
Loss of function	2	0.02%	0	0%		0	0.00%	0	0%
Retained Foreign Body	1	0.01%	0	0%		0	0.00%	0	0%
Transfers:	**36**	**0.32%**	**24**	**0.35%**		**17**	**0.19%**	**14**	**0.22%**
Falls	**3**	**0.03%**	**2**	**0.03%**		**1**	**0.01%**	**0**	**0**
Infections	**5**	**0.04%**	**1**	**0.01%**		**0**	**0**	**3**	**0.05%**
Complications	**68**	**0.60%**	**43**	**0.64%**		**13**	**0.14%**	**8**	**0.13%**
Return to Surgery/Lab	25	0.22%	28	0.41%		6	0.07%	3	0.05%
RP Hematoma	20	0.18%	5	0.07%		0	0%	0	0%
MI	0	0.00%	1	0.01%		0	0%	0	0%
Stroke	4	0.04%	2	0.03%		0	0%	0	0%
Other	19	0.17%	7	0.10%		7	0.08%	5	0.08%

*Cath Labs: 11,250 Cases performed in 2015; 6767 Cases performed in Jan-June 2016
*ASC: 9048 Cases performed in 2015; 6286 Cases performed in Jan-June 2016

NCP's PCI experience is consistent with published studies

Adverse event and complication rates are low, and PCI in an ASC setting is safe and convenient for patients.

	2013	2014	2015	Jan-June 2016	Total
Left Heart Cath (LHC) Procedures Performed	5775	5930	6071	3930	21,706
Percutaneous Coronary Intervention (PCI) Procedures Performed	643	728	650	354	2375
% of PCI Procedures	11.1%	12.28%	10.7%	9.0%	10.9%
Complication Rate	0.3%	0.8%	0.9%	0.9%	0.7%

While clinical outcomes are consistent with hospital facilities, patient satisfaction surveys suggests patients prefer the ASC setting

2015 Patient Satisfaction		
	Cath Labs	HCAHPS
Overall Satisfaction	97.9%	71%
Patient Would Recommend	98.6%	71%
Return Rate	61.0%	31%

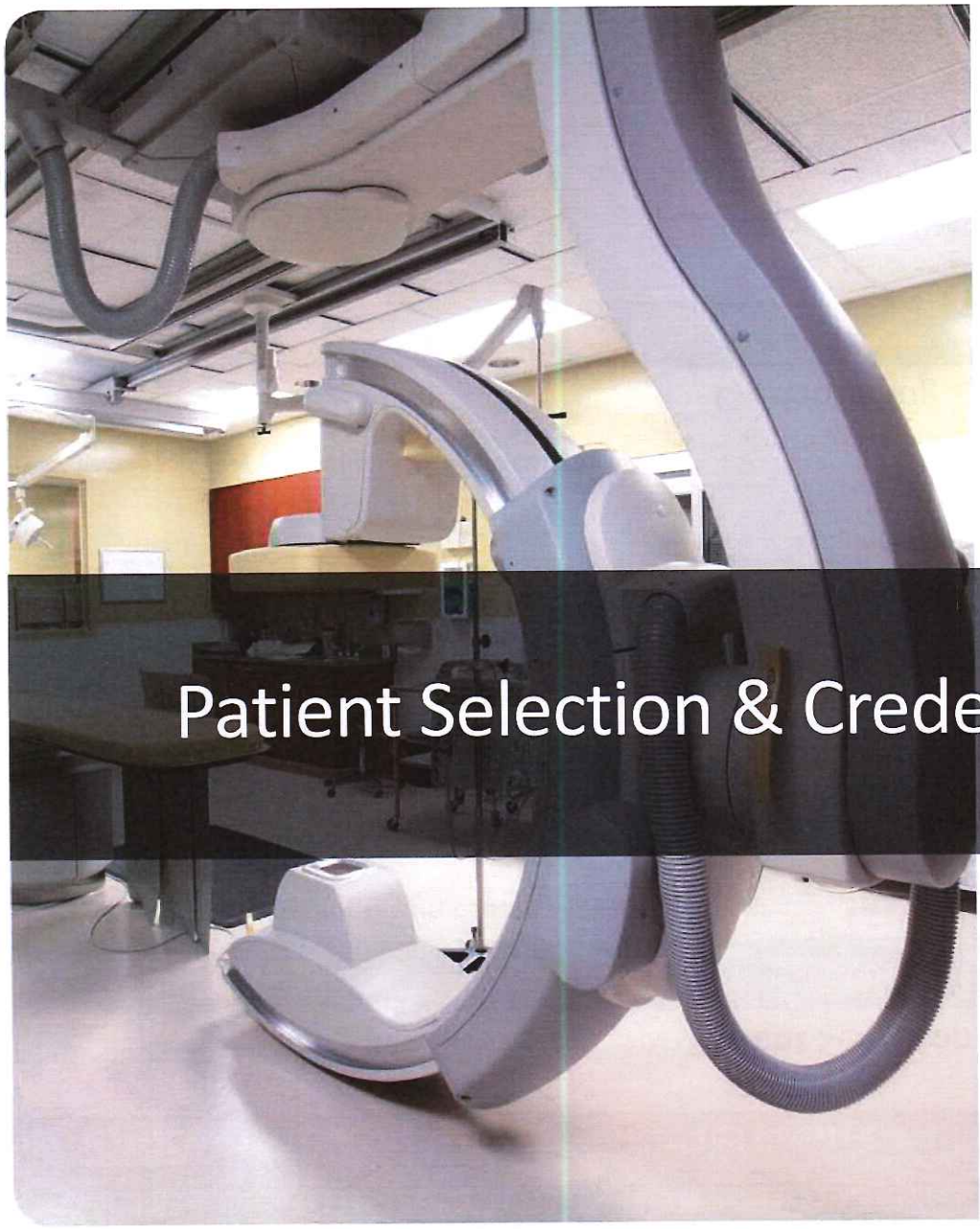
NCP recommendations for ASC coverage and payment

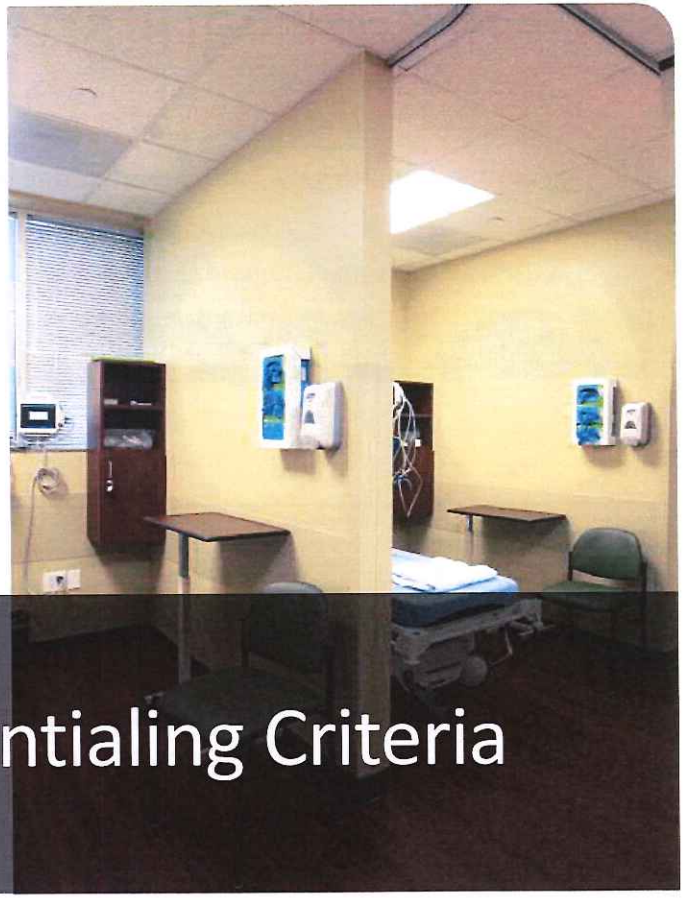
Coverage and payment for the codes identified in the attached spreadsheet would provide a more seamless point of service for diagnosis and treatment of certain cardiac conditions, would reflect recent clinical advancements, and would better align Medicare with commercial payers.

NCP recommends:

1. Coverage for procedures allowed in the physician office, but most often performed in the OPPS.
   - Payment based on OPPS weights reduced according to ASC policy
2. Coverage for procedures allowed in both the OPPS and physician office, but are performed a majority of the time in the physician office.
   - Payment based on the MPFS rate
3. Creating a "conditional packaging" policy for ASCs consistent with the current OPPS policy to allow for reimbursement for procedures that are performed more than half the time without another major procedure.
   - Separate payment for procedures packaged in the ASC, but separately payable in both the physician office and OPPS (conditionally packaged). Claims analysis suggests these procedures are performed more than half the time in the OPPS without another major procedure.
4. Coverage of codes that are "safe" when performed in the OPPS. Claims analysis shows little evidence of hospital admission, emergency room visit, or death. Recent clinical guidelines support provision of these services in non hospital settings for appropriate patients.
5. Align ASC payment policy with recent OPPS comprehensive APC methodology to recognize particularly complex procedures.

Patient Selection & Credentialing Criteria





BUILD
SOMETHING

NCP has established admission criteria and a screening process that promotes safe and effective patient care in the outpatient setting

Patient Selection

Admission Criteria	Contraindications
• Physician's order for the procedure with a provisional diagnosis • History and Physical performed within the last 30 days • Patient must be 18 years of age or older • Diagnostic test results, as required. (Must be within 30 days of procedure) • ASA Classification documented. (ASA 1, 2 or 3) * • Patient must demonstrate ability to use judgement and follow instructions • A responsible adult must be available to accompany patient	• Creatinine > 2.0 (unless on Dialysis) • Potassium > 5.8 (unless on Dialysis) • Weight > 450 lbs • Hemoglobin < 8.0 (unless chronic anemia) • INR > 1.8 • Active, untreated infection • Hx of Anaphylactic shock with Iodine exposure • Unable to lie flat due to Hypoxia • Type C Lesions • Unprotected Left Main • Acute Coronary Syndrome

**American Society of Anesthesiologists Patient Classification*

Credentialing

Procedure	Required documentation for initial appointment
Diagnostic Cardiac	Must have an appointment/privileges for Cardiac Cath in good standing at a hospital
Interventional Cardiac	Must have an appointment/privileges for intervention in good standing at a hospital

Discussion

- **How can NCP help?**
- **What additional data or information do you need?**