In-Office Ancillary Service Exception: Current Status and Advocacy Strategy

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The Problem

- New challenges faced by physician practices
  - Decreased reimbursement
  - Increased expenses
  - Regulatory burden

THERE IS NO MONEY!

Market Response

- Two principal trends developing
  - Increased number of physicians being employed by hospitals
    - Practice acquisition
    - Direct hire from residency programs
  - Formation of large physician group practices

Advantages to Consolidation

- Economies of scale
  - Eliminate duplicated staff
  - More efficient operations
- Enhanced purchasing/negotiating ability
  - Vendors (i.e. medical supplies, EMR)
  - Third party payors
- Ability to acquire capital intensive services
  - Pathology
  - Diagnostic Imaging
  - Radiation Oncology

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Advantages to Consolidation

- Ability to assume risk
  - Medicare
    - Form Accountable Care Organizations (ACOs)
    - Contract with multiple ACO's
    - Participate in Shared Savings Programs
    - Create novel reimbursement models
      - Bundled payments
      - Case rates
  - Contract directly with third party payors

The Issue

- Historical monopolists are particularly vulnerable to market share shifts
  - Minimal patient contact
  - Rely on referrals
  - Services are increasingly becoming commoditized

The Opponents

- Alliance for Integrity in Medicine
  - American College of Radiology
  - American Clinical Laboratory Association
  - ASTRO (Radiation Oncologists)
  - American Society for Clinical Pathology

Recent Threat

- GAO Report
  - Concluded that higher use of advanced imaging by providers who self-refer cost Medicare $109M per year ($1.1B over 10 years)
  - Flawed methodology and assumptions
    - Excludes hospital referrals
    - Appropriate referral rates not studied
- Report damaging politically
- Diagnostic imaging reimbursement severely cut
  - Did NOT recommend repeal of the IOASE

Recent Threat

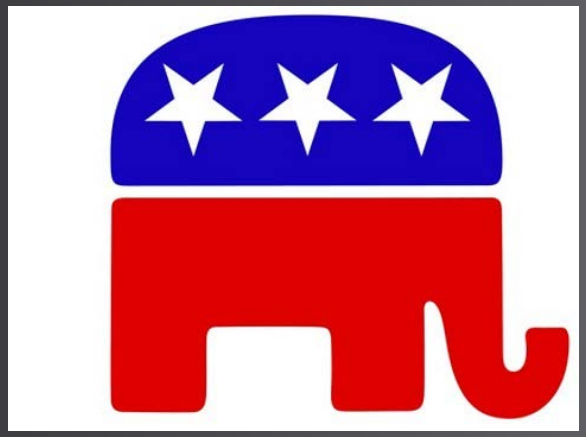
- Fiscal Cliff
  - There was an attempt to include language in the fiscal cliff bill repealing the IOASE
  - Thwarted by advocacy efforts

Upcoming Threats

- CBO Score
  - CBO charged with "scoring" potential cost savings for repeal of IOASE
- Sequestration
  - Risk that repeal of IOASE could be part of strategy to avert across the board 2% Medicare reimbursement cuts
- Problem:
  - Urology accounts for only 2.3% of Medicare expenditures
  - Risk of becoming "collateral damage"

The Case for the IOASE

Must Customize Message to the Target Audience



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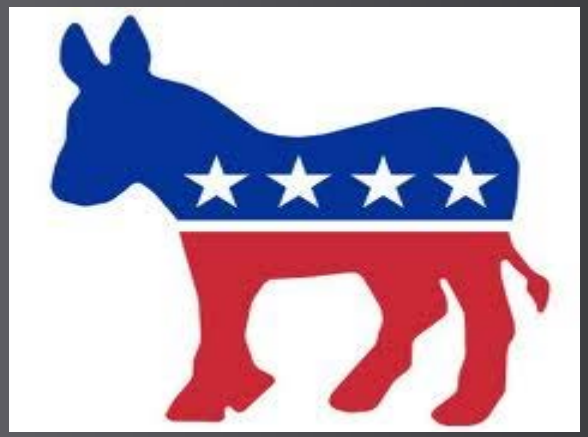

The Case for the IOASE: Common

- Compliance & convenience
- Quality & coordinated care
- Cost & outcomes

Compliance and Convenience

- Improves adherence to treatment plans and outcomes
  - Elimination of duplicate paperwork
  - Minimizing travel issues
  - Easing insurance referral process
  - Simplifying issues for patients

Quality and Outcomes

- Allows for better coordination of care between physicians
- Allows for the development of disease specific expertise
  - Recent publication: contamination rate of biopsy specimines significantly lower in pathology labs operated by urology practices significantly lower than in other sites of service*

*Pfeifer JD, Liu J. Rate of occult specimen provenance complications in routine clinical practice. *Am J Clin Path*. 2013;139(1):93-100

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Cost

- Utilization rates similar regardless of site of service
- Patients will simply seek services at alternative site of service
- Physician office is far less expensive than hospital
  - By law, under the Deficit Reduction Act all imaging services performed by physicians must be reimbursed at equal or less than the hospital rate

Pathology Utilization

- Jean Mitchell Health Affairs Study
  - Study funded by American Clinical Lab Association and College of American Pathologists
  - Concluded that physician owned labs took twice as many samples as control groups
    - Only a handful of urology groups in 11 arbitrarily selected counties
    - Groups were taking 12 rather than 6 cores
  - positive biopsy rates of between 21 percent to 27 percent
    - 14% lower cancer detection than her control group
    - Used unproven and clearly flawed methodology to determine positive biopsy rate

Pathology Utilization: LUGPA*

- Collaborated with Bostwick Laboratories
- Obtained positive biopsy rate and vials/specimen directly from practice and patient source data
  - Did not rely on arbitrary claims data methodology
- LUGPA analyzed data from 2005-2011
- Compared utilization data between urologists that used their own labs vs. those that sent specimens to a national reference lab

Olsson CA, Kapoor DA, Mendrinos SE et al. Utilization and cancer detection by U.S. prostate biopsies (2005-2011). J Clin Oncol 31, 2013 (suppl 6; abstr 107)

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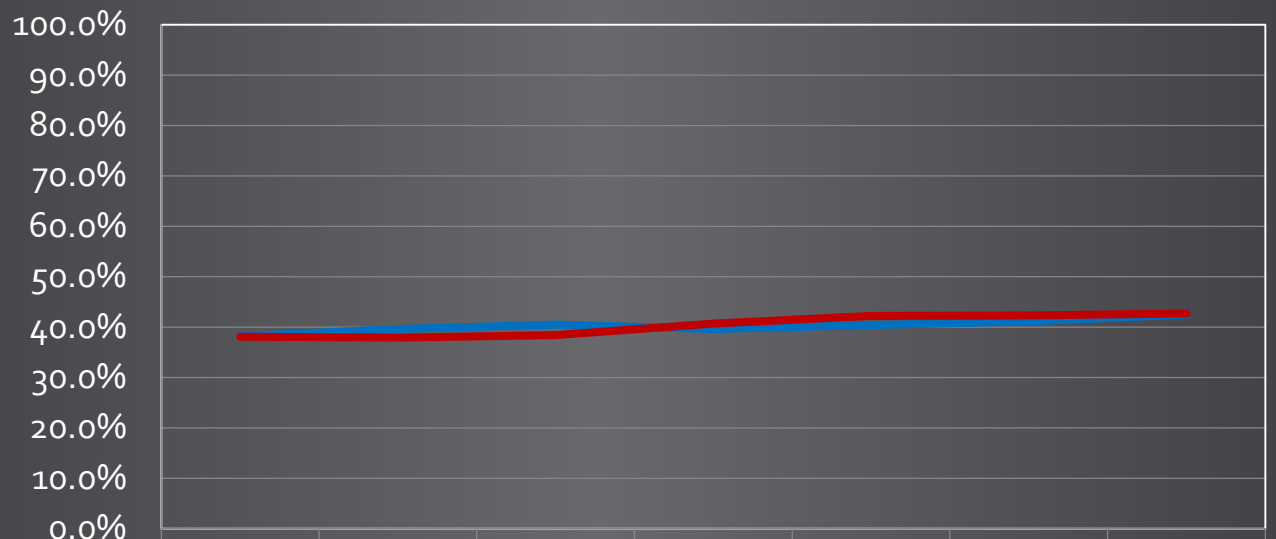
Pathology Utilization: LUGPA

- Urology practices
  - 29 urology practices representing 805 urologists nationwide
  - 179,681 patients with 1,866,775 specimens
- National reference laboratory
  - 919 practices with 1513 urologists nationwide
  - 258,256 patients and 2,363,354 specimens
- Combined total of 2318 urologists (over 25% of all urologists in the US)
  - Total of 437,937 patients with 4,230,129 specimens

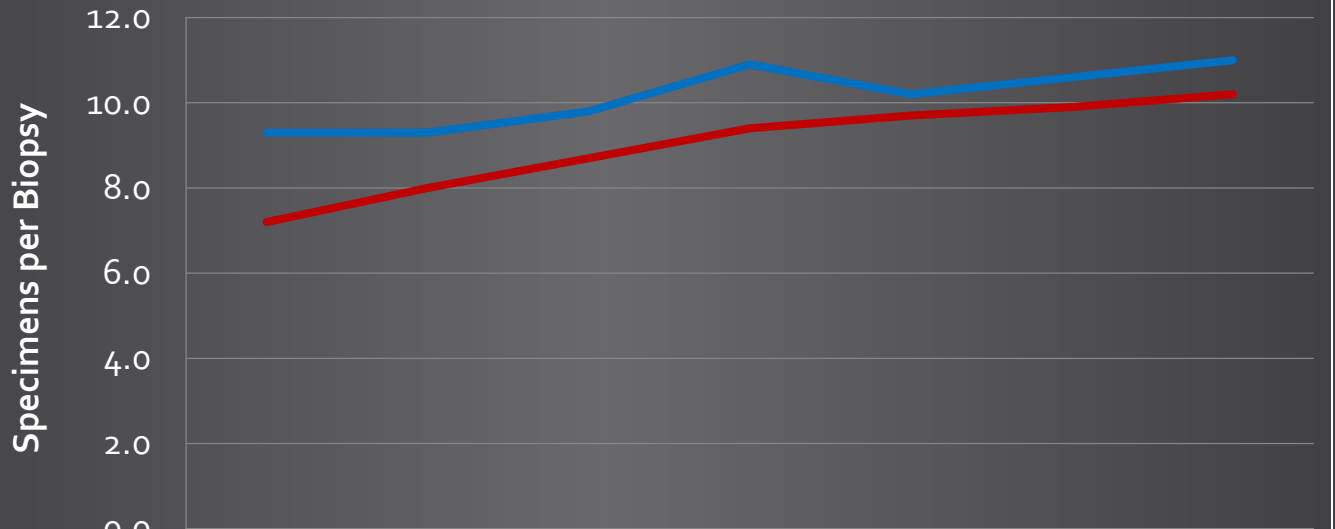
Pathology Utilization: LUGPA



	2005	2006	2007	2008	2009	2010	2011
LUGPA	38.2%	39.6%	40.5%	39.6%	40.4%	41.1%	42.5%
Reference Lab	38.1%	37.9%	38.4%	40.7%	42.2%	42.3%	42.7%

- Average positive biopsy rate for LUGPA: 40.3%
- Average positive biopsy rate for reference lab: 40.3%
- These values are mathematically and statistically identical

Pathology Utilization: LUGPA



	2005	2006	2007	2008	2009	2010	2011
LUGPA	9.3	9.3	9.8	10.9	10.2	10.6	11.0
Reference Lab	7.2	8	8.7	9.4	9.7	9.9	10.2

- From 2005-11, average difference in vials per biopsy between LUGPA and reference lab was only 1.2 vials per biopsy
- From 2009-11, the difference of 0.6 vials/biopsy was not significant

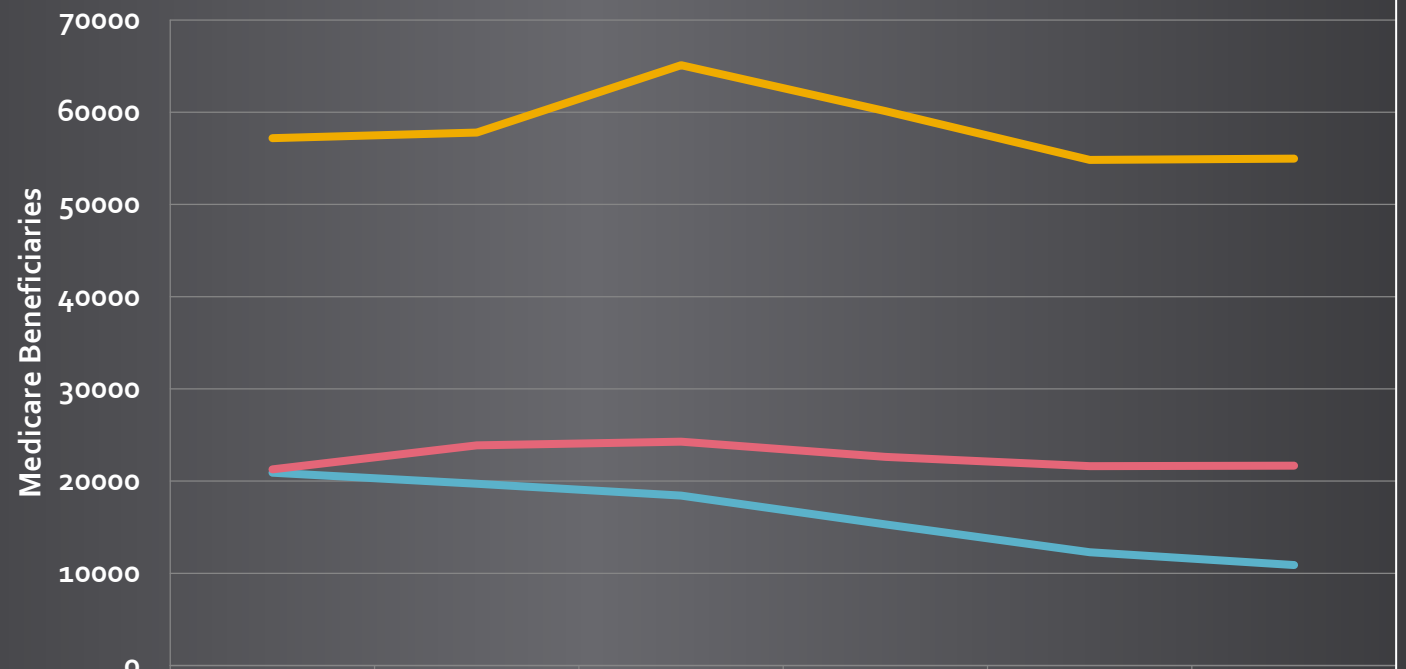
Pathology Utilization: LUGPA

- There is no difference in either number of cores, positive biopsy rate or utilization trends between physician operated and reference labs
- No evidence of inappropriate incentive to biopsy based on site of service
- There can be no cost savings with elimination of physician operated pathology laboratories as these services will simply be performed elsewhere

IMRT Utilization

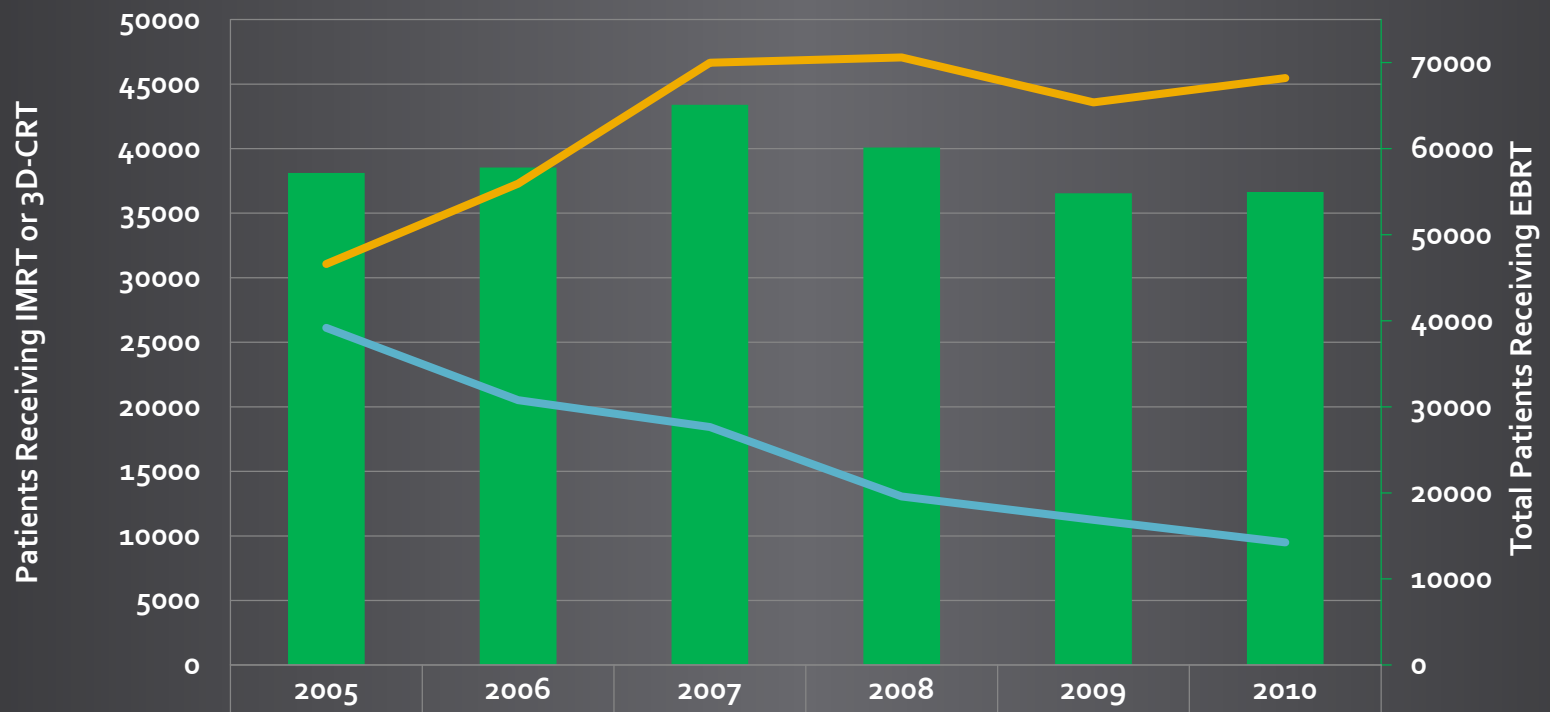
- Opponents of incorporation of radiation oncology services allege over-use of these services, particularly IMRT
- Cite increase number of IMRT cases done by integrated urology groups
- Absolutely NO objective data to support these claims

Trends in Prostate Cancer Therapy



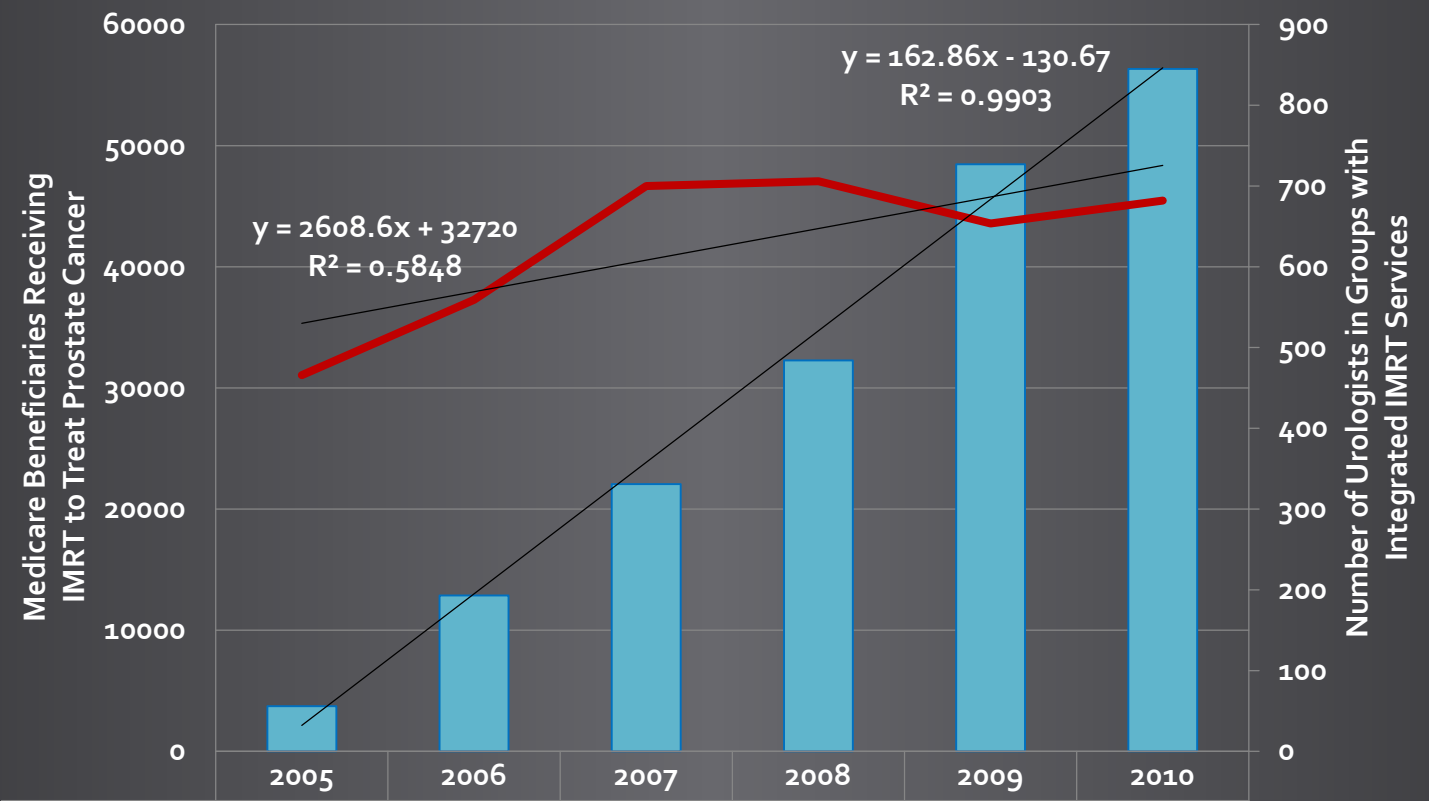
	2005	2006	2007	2008	2009	2010
EBRT	57180	57800	65100	60120	54820	54960
Brachytherapy	20911	19705	18423	15300	12289	10900
RP	21275	23883	24277	22630	21615	21667

EBRT: IMRT increasing, 3DCRT decreaseing



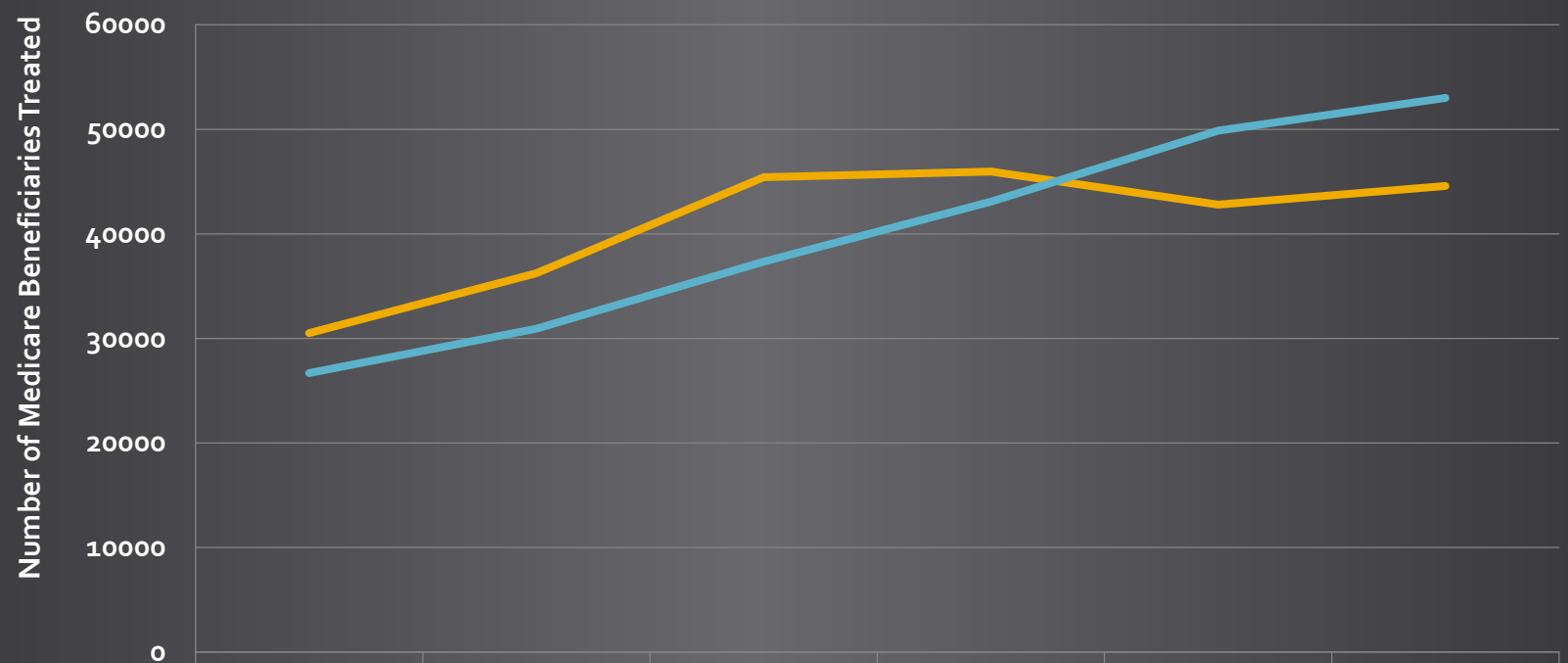
	2005	2006	2007	2008	2009	2010
EBRT	57180	57800	65100	60120	54820	54960
IMRT	31060	37280	46660	47060	43580	45460
3D	26120	20520	18440	13060	11240	9500

IMRT Utilization: No correlation to number of urologists providing service



	2005	2006	2007	2008	2009	2010
Urologists	56	193	331	484	727	845
IMRT	31060	37280	46660	47060	43580	45460

IMRT Utilization: Prostate vs. Non-Prostate



	2005	2006	2007	2008	2009	2010
Prostate	30500	36240	45420	45960	42800	44580
Non-Prostate	26680	30920	37340	43080	49880	53000

Radiation Oncology Summary

- Increased utilization of IMRT reflects changing clinical standards and is occurring in treating other disease states as well as prostate cancer;
- The trend towards increased utilization of IMRT in the treatment of prostate cancer occurred prior to 2007, and thus predated the formation of integrated urology groups;
- Trends in IMRT utilization to treat prostate cancer are similar regardless of whether the service is provided in the hospital or physician office setting;
- There is absolutely no correlation between utilization of IMRT to treat prostate cancer and the number of urology practices offering these services

The Case for the IOASE: Targeted

- Inappropriate interference with doctor-patient relationship and the practice of medicine
- Ability to develop alternative strategies to traditional fee for service medicine

Summary

- The IOASE is not a loophole, it is a provision deliberately inserted to improve access and enhance quality of services
- Utilization patterns of GU services provided under the IOASE reflect changing clinical patterns and do not correlate with physician ownership
- Legislative modifications in this arena would produce little or no cost savings and could adversely affect access to care

Questions?

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