Meeting Attendees

- MDMA
  - Dan Waldmann, EVP, Health Policy & Reimbursement
  - Clayton Hall, EVP, Government Affairs
  - Elliott Warren, VP, Outreach & Engagement
- Teleflex
  - Kevin Hardage, President and General Manager
  - Ann Decker, VP, Reimbursement & Health Policy
  - Jennifer Ditlow, Sr. Dir., Strategic Reimbursement & Market Access
- Boston Scientific
  - Jenifer Levinson, VP, Global Health Economics and Market Access
  - Kristen Hedstrom, VP, Payer Relations & Global Policy
  - Christopher Timmerman, Dir., Government Affairs and Health Policy
- Medical Technology Partners
  - Jerry Stringham, President

About MDMA

- Founded in 1992 to provide a dedicated policy and advocacy voice for the entrepreneurial sector of the medical device industry
- Today MDMA represents over 300 member companies, ranging from small innovators to the largest companies in the world
- MDMA's mission is to promote patient access to safe & effective medical technologies that improve health outcomes
- We value collaboration with other stakeholders and key government agencies on policies that support innovation and effective use of healthcare resources

Summary

- CMS has proposed to update the non-physician clinical labor cost data used to calculate direct practice expense (PE). This data was last updated in 2002.
- The substantial and wide-ranging reductions in non-facility payment rates resulting from CMS's proposed methodology will reduce access for Medicare beneficiaries.
- The reductions are due to CMS administrative policy of applying budget neutrality within the direct practice expense pool.
    - Under this policy, an increase in reimbursement for clinical labor costs must be offset by decreasing reimbursement for the other two components of direct practice expense—medical supplies and equipment.
    - If implemented as proposed, **at least 142 codes will have national non-facility PFS rates that are 10% or more *below* the physician's direct supply and equipment costs.** That is *more than 20 times* the number in CY 2021.[1]
- Non-facility payment rates that are less than what it costs a physician to provide a service in the office setting would shift a significant amount of procedural volume to hospital outpatient departments and ambulatory surgery centers, possibly creating barriers to access for some Medicare beneficiaries.

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[1] Source: MCDA/Medical Technology Partners. (Analysis limited to codes with at least $100 in direct supply and equipment cost.)

52441	*Cystourethroscopy, with insertion of permanent adjustable transprostatic implant, single implant*
52442	*Each additional permanent adjustable transprostatic implant (x3)*

Prostatic Urethral Lift Using The UroLift® System

- Over 40 million men in the US have Benign Prostatic Hyperplasia (BPH) pathology[1] of whom ~12M are actively managed[2]
- The UroLift System provides rapid, significant[3,4] and durable relief of LUTS symptoms[5] with improvement in quality of life and low morbidity[3,6]

Insertion of UroLift® device into the urethra

Transprostatic implants firmly grasp the prostatic capsule

Glandular tissue is compressed opening the prostatic fossa

Additional implants are delivered as required

Code	Non-Facility		
	2021 Payment	2022 Payment	% Change
52441	$1,433	$1,155	-19.4%
52442	$1,021	$796	-22.0%

The proposed CY 2022 payment for a typical four-implant Urolift procedure is $3,543. The total cost of just the implants is $3,500. The remaining $43 is inadequate to cover the cost of other supplies ($220.05), 150.5 minutes of RN labor, equipment costs, malpractice costs, indirect costs, plus the physician's 7.03 RVUs of work.

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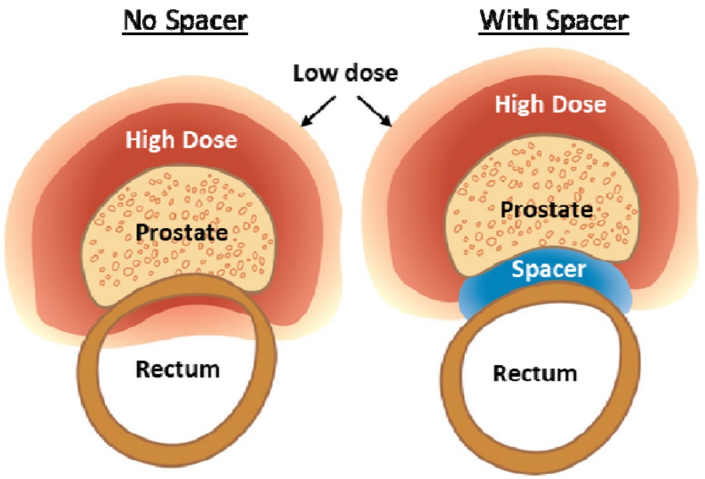
1. Based on Berry, et al., J Urol 1984; 132: 474-479 and US Census population estimates; 2. Based on Roehrborn, Prostate Cancer and Prost Dis 2006; 9: 30-34 and US Census population estimates; 3. Roehrborn, J Urology 2013 LIFT Study; 4. Shore Can J Urol 2014; 5. Roehrborn, 2015 Can J Urol, 5 yr results of PUL LIFT study; 6. Roehrborn, et al. Can J Urol 2017

55874 *Transperineal placement of biodegradable material, peri-prostate, single or multiple injection(s), including image guidance, when performed.*

Due to the proximity of the two organs, radiation therapy of the prostate can unintentionally cause damage to the rectum, which can lead to issues with bowel function.

A ***rectal spacer*** is an injectable, biodegradable material that increases the space between the prostate and rectum, reducing the often-debilitating side effects and potentially chronic complications associated with rectal damage.

Direct Practice Expense Inputs versus Proposed Practice Expense Reimbursement	
Device	$2,965
Other Supplies	$128
Total Supply Inputs	**$3,093**
Equipment	$16
Non-Physician Labor	$37
Total*	**$3,146**
CY 2022 Proposed Practice Expense Reimbursement	$2,454



CMS has proposed a non-facility payment for CY 2022 of $2,566, which includes $2,454 in direct practice expense reimbursement. With a device cost of $2,965, an office-based physician would incur a $399 loss on the device alone, *before* accounting for the cost of other necessary supplies, 62 minutes of RN labor, equipment, malpractice, and indirect costs. The physician would also incur 3.03 RVUs of work that would not be compensated.

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- ***CMS should defer the proposed update to clinical labor data until the agency and stakeholders have an opportunity to consider and comment on alternative approaches to mitigate the negative impact on office-based specialists and on beneficiary access to device-intensive procedures.***
- A phase-in of the reductions is not sufficient to resolve the problem.
- Other benefits of a delay:
  - Can align timing with other, potentially interdependent updates to the practice expense methodology already in process
  - Can incorporate updates to BLSA data and methodology that will be implemented in 2022
  - Allows Congress time to consider appropriate statutory changes or other legislative action aimed at maintaining the viability of device-intensive procedures in the office setting
  - Avoids further disruption and financial strain for physician practices during the ongoing COVID-19 public health emergency