Monthly Network Call
October 17, 2019
Agenda

- Drug Pricing Legislative Update
- Radiation Oncology Model
- Learnings from OCM PP4
Speakers

Tyler Hanson
Associate Director, Congressional Affairs
ASCO Policy & Advocacy

Anne Hubbard
Director of Health Policy
ASTRO

Margarita Valdez
Assistant Director Government Relations
ASTRO

Brian Bourbeau
Director, Business Metrics and Analysis
ASCO Clinical Affairs
Drug Pricing Legislative Update

Tyler Hanson, JD
Associate Director, Congressional Affairs
ASCO

PracticeNET
October 17, 2019
Drug Pricing – Executive Branch

“One of my greatest priorities is to reduce the price of prescription drugs.”

PRESIDENT DONALD J. TRUMP

Drug Pricing Blueprint

HHS has identified four key strategies for reform:

1. Competition
   Lower drug prices and increase innovation through more competition

2. Seniors
   Give Medicare Part D plans tools to negotiate lower prices for seniors

3. Incentives
   Develop incentives for drug makers to lower their list prices

4. More Options
   Offer more drug options, which will lower out-of-pocket spending

HHS.GOV/DrugPricing

ASCO
Administrative Action on Drug Pricing

Done
- Gag Clauses
- Speeding Generic Approvals

Proposed
- International Pricing Index
- Drug Importation

Not Moving Forward
- List Price in DTC Advertising
- Rebate Rule
- Part D Six Protected Classes
Drug Pricing Action on Capitol Hill

- House Ways and Means Committee STAR Act
- House Energy and Commerce Committee FAIR Drug Pricing Act
- Senate HELP Committee Lower Health Care Costs Act
Senate: Prescription Drug Pricing Reduction Act

- Senate Finance Committee passed the Prescription Drug Pricing Reduction Act (PDPRA) of 2019 July 25
- Wide ranging reforms to Medicare Part D, Part B and Medicaid
  - Includes value of coupons in ASP determination
  - Sets maximum add-on payment for Part B drugs
  - Creates inflation rebate for Medicare Part B and D drugs
  - Redesigns Medicare Part D benefit
House: Lower Drug Costs Now Act

- House Speaker Nancy Pelosi and committee chairs released *HR 3*, the *Lower Drug Costs Now Act*, September 19
- HR 3 includes:
  - Drug price negotiation
  - Inflationary caps on Medicare Part B & D drug price increases
  - A variation on the international price index
  - Medicare Part D benefit redesign
What ASCO Has Supported

- **Price Transparency**: Allowing greater transparency on all aspects of drug pricing
- **Pay for delay/evergreening/product hopping**: Preventing manufacturers from participating in anti-competitive behaviors
- **Reducing Market Exclusivity**: Reducing the time it takes before a generic/biosimilar can enter the market
- **Patient Out of Pocket Maximums in Part D**
Where ASCO Has Raised Concerns

- Policy changes that could negatively impact cancer patients and Medicare Part B drug reimbursement:
  - Including value of coupons in the determination of Average Sales Price
  - Establishing a Maximum Add-on Payment for Part B drugs
Drug Pricing: What Will Get to the Finish Line?

• Unclear what Congress can accomplish on drug pricing this year
  • Low hanging fruit?
  • More robust reforms?
Radiation Oncology Model

Anne Hubbard, Director of Health Policy
Margarita Valdez, Assistant Director Government Relations
Agenda

• Model Overview and Identification of Key Issues

• Hill Strategy & Stakeholder Engagement

• What’s Next?
Agenda

• Model Overview and Identification of Key Issues

• Hill Strategy & Stakeholder Engagement

• What’s Next?
RO Model released on July 10th as “Notice of Proposed Rule Making”

A proposed rule, or Notice of Proposed Rule Making (NPRM), is the official document that announces and explains the Agency’s plan to address a problem or accomplish a goal. All proposed rules must be published in the Federal Register to notify the public and to give them an opportunity to submit comments. The proposed rule and the public comments received on it for the basis of a final rule.

Comment period deadline: September 16, 2019
Who’s in, who’s out...

• What does CMS want to achieve:
  • CMS’ goal is to achieve 3% in Medicare savings from the RO Model ($250-$260 million)

• What that means:
  • Potentially 40% of all RO episodes in eligible geographic areas will be included in the model.

• CMS will identify CBSAs required to participate in the model in the final rule
Who’s in, who’s out...

ASTRO has long supported a voluntary model, and we are very concerned about launching a model that requires mandatory participation from such a large number of radiation oncology practices at the outset. Given the significant change and rapid implementation of the model, forcing some unready practices to participate while at the same time prohibiting others that are well-prepared is problematic. **ASTRO will urge CMS to reconsider pursuing a mandatory model, or at least consider requiring fewer practices to participate.**
## Estimated Reduction in Payment

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<tr>
<th>CMS VERSION</th>
<th>2020</th>
<th>2021</th>
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<th>2024</th>
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<td>-$69</td>
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</table>
Participation Requirements

• RO Participants
  - Professional Participant = Medicare enrolled physician group practices (PGPs), identified by a single TIN, that delivery only the professional component of radiation therapy services at either a freestanding or Hospital Outpatient Department (HOPD)
  - Technical Participant = Medicare enrolled HOPD or freestanding center, identified by a single CCN or TIN, which delivers only the technical component of radiation therapy services.
  - Dual Participant = A RO participant, identified by a single TIN, that delivers both the professional and technical radiation therapy services through a freestanding radiation therapy center.
Participation Requirements

• Medicare FFS Beneficiaries
  • Any Medicare FFS beneficiary receiving radiation therapy for at least one identified cancer type.
  • Medicare FFS beneficiaries participating in clinical trials for radiation therapy services.
  • Professional and Dual participants must notify Medicare beneficiaries that they are participating in the RO Model by providing a written notice.
    • Beneficiaries can refuse data sharing component. In those cases the participant must notify CMS.

• Model Exemptions
  • No hardship exemption
  • Centers in MD, VT, US Territories, ASCs, CAHS, PPS-Exempt Cancer Hospitals and Penn Rural Health Model Participants are exempt
Cancer Types, Episode Length and Trigger

- Anal Cancer
- Bladder Cancer
- Bone Metastases
- Brain Metastases
- Breast Cancer
- Cervical Cancer
- CNS Tumors
- Colorectal Cancer
- Head and Neck Cancer
- Kidney Cancer
- Liver Cancer
- Lung Cancer
- Lymphoma
- Pancreatic Cancer
- Prostate Cancer
- Upper GI Cancer
- Uterine Cancer
Cancer Types, Episode Length and Trigger

90-Day Episode of Care

Trigger Criteria: 1) Initial Treatment Planning Service (77261-263) delivered by a Professional Participant or a Dual Participant and 2) at least one radiation treatment delivery service delivered by a Technical Participant or a Dual Participant within 28 days

28 Day Clean Period
## Included Services & Modalities

<table>
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<th>Services</th>
<th>Modalities</th>
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<td>• Consultation Treatment planning</td>
<td>• 3-D Conformal Radiotherapy</td>
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<td>• Dose planning</td>
<td>• IMRT</td>
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<td>• Radiation physics and dosimetry</td>
<td>• SRS</td>
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<td>• Treatment devices</td>
<td>• SBRT</td>
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<td>• Special services</td>
<td>• PBT</td>
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<td>• Treatment delivery</td>
<td>• IORT</td>
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<td>• Treatment management</td>
<td>• IGRT</td>
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<td></td>
<td>• Brachytherapy</td>
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Site Neutral Test

CMS proposes a common payment amount for services regardless of where they are furnished.

- More certainty regarding pricing for services
- Removes incentives to deliver services in one site over another
- Only applicable in RO-Model

ASTRO appreciates the Agency’s desire to establish a site neutral test, however it must be done through the application of appropriately determined National Base Rates for each disease site.
Payment Methodology

The RO Model Payment Methodology has 8 steps:
1. National Case Rates based on HOPPS historical payments
2. Application of a Trend Factor
3. Case Mix, Historical Experience & Efficiency Adjustments
4. Discount Factor (-4% for PC and -5% for TC)
5. Withholds for Payment Issues and Quality Measures Performance
   2% for payment issues and 2% for PC quality measures and 1% for TC quality measures
6. Geographic Adjustments
7. Co-Insurance
8. Sequestration (-2%)
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<thead>
<tr>
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<th>TECHNICAL COMPONENT</th>
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<tr>
<td>Anal Cancer</td>
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<td>Bone Metastases</td>
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<td>CNS Tumor</td>
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<td>Head and Neck Cancer</td>
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<td>Kidney Cancer</td>
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<td>Lung Cancer</td>
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<td>Lymphoma</td>
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<td>Pancreatic Cancer</td>
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<td>Prostate Cancer</td>
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<td>$3,777</td>
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<td>Upper GI Cancer</td>
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<td>Uterine Cancer</td>
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<tr>
<td>Cancer Symptom Palliation, Not Otherwise Specified</td>
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<td>$1,147</td>
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*Historical Base Rate is adjusted for case mix and efficiency
Case Mix, Historical Experience and Efficiency Factor

Case Mix Adjustment = \frac{(predicted payment – expected payment)}{expected payment}

Historical experience adjustment = \frac{(Winsorized payments – predicted payments)}{expected payments}

Efficiency Factor:
Winsorized episode payments > predicted payments = 0.90 (PY1), 0.85 (PY2), 0.80 (PY3), 0.75 (PY4), 0.70 (PY5)

Winsorized episode payments ≤ predicted payments = 0.90 (PY1-PY5)
**EFFICIENCY FACTOR ANALYSIS**

**EFFICIENCY FACTOR ANALYSIS PY1**

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<th>Efficient Practice</th>
<th>Inefficient Practice</th>
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<td>PY1 Efficiency Factor</td>
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<tr>
<td>Combined Adjustments</td>
<td>0.95</td>
<td>1.16</td>
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</table>
| Subtotal                             | $3,219.93          | $3,921.54            | $701.61 | 21.8%
The RO Model Payment Methodology has 8 steps:

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Apply adjustments based on quality performance and incomplete episodes to future years, similar to MIPS
Payment Methodology

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4. Discount Factor (-3% for PC and -3% for TC)
5. Withholds for Payment Issues & Quality Measures Performance
   2% for payment issues and 2% for PC quality measures and 1% for TC quality measures
6. Geographic Adjustments
7. Co-Insurance – HOLD PATIENTS HARMLESS FROM HIGHER CO-PAYS
8. Sequestration (-2%)
Added Service Lines & Equipment Upgrades
• Rate review *mechanism for practices that would allow them to apply for new rates based on adoption of new service lines or equipment replacement/upgrade needs*

New Technology and Innovation
• FFS payment for new technologies
Advanced APM and MIPS APM

• CMS is designated the RO Model as an Advanced APM and MIPS APM
• The Agency proposes to limit the 5% bonus to the PC component only, rather than both the PC and TC components as prescribed in MACRA. CMS is seeking a waiver for the one-sided application.
  • Concern about shifts in site of service, from hospital to freestanding, should both components receive the 5% bonus.

ASTRO believes that the RO Model meets the MACRA defined requirements of a capitated payment model and should be deemed an Advanced APM for all participants.
# Revised Payment Reductions

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<tr>
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<th>2020</th>
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<th>2024</th>
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<td>$1</td>
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<td>$12</td>
<td>$10</td>
<td>$7</td>
<td>$5</td>
<td>$48</td>
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Compliance Burden

- Quality Measures
  - Plan of care for pain
  - Screening for Depression
  - Advanced Care Plan
  - Treatment Summary
- CAHPS Cancer Care Survey
- Clinical Data Elements

- Monitoring Requirements
  - Discuss goals of care
  - Use of Clinical guidelines
  - TNM Status
  - Performance Status
  - Treatment Summary
  - Cost sharing discussion
  - Peer Review
## Compliance Burden

### Quality Measures
- Plan of care for pain
- Screening for depression
- Advanced care planning
- Treatment summary
- CHAPS Cancer Care Survey
- Clinical Data Elements

### Monitoring Requirements
- Discuss goals of care
- Use of Clinical guidelines
- TNM Status
- Performance Status
- Treatment Summary
- Cost sharing discussion
- Peer Review
Agenda

• Model Overview and Identification of Key Issues

• Hill Strategy & Stakeholder Engagement

• What’s Next?
Hill Engagement

• Shared ASTRO RO Model proposed rule summary and one pager on model with Capitol Hill Champions
• Met with individual offices to share concerns and respond to questions
• Met with staff from House Ways and Means, and Energy and Commerce, as well as Senate Finance to provide overview of RO Model and address key concerns (Committee's of Jurisdiction)
• Developed sign-on letter supporting ASTRO’s position on the RO Model to be submitted to CMS
Stakeholder Engagement

- Weekly ASTRO Payment Reform Work Group Calls
- Weekly Industry and Patient Advocacy Stakeholder Calls and One-on-One Calls
  - Radiation Oncology Vendors
  - ABS, AAPM, AADM, SROA
  - Patient Advocacy Groups
  - AHA, AAMC, and Hospital Systems
- Circulated draft ASTRO comments one week in advance of comment deadline
Agenda

• Model Overview and Identification of Key Issues

• Hill Strategy

• What’s Next?
Timeline

**Proposed Rule**
- Model the model
- Analyze impact on different practice types
- Provide constructive feedback by 9/16 deadline

**Final Rule**
- Assess impact on different practice types
- Develop tools for successful implementation

**Implementation**
- Evaluate and provide feedback on implementation to CMS
- Engage Agency on future model revisions

- **July 10, 2019**
- **November 2019**
- **January or April 2020**
Learnings from Oncology Care Model Performance Period 4
Savings percentage > target (positive = savings)

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<tr>
<td>Breast Cancer</td>
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<tr>
<td>Chronic Leukemia</td>
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<td>Head and Neck</td>
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<td>Lung Cancer</td>
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<td>Lymphoma</td>
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<td>Malignant Melanoma</td>
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<td>Multiple Myeloma</td>
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<td>Prostate Cancer</td>
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<td>Small Intestine / Colorectal</td>
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Representing 46% of all OCM cases, breast and prostate cancers dominate prediction modeling, leaving other cancers to be poorly calculated.

Practices treating a significant portion of blood cancers have found themselves negatively impacted by this issue, while those specializing in certain solid tumors are positively impacted.
Failure to account for differences amongst diseases

The OCM Prediction Model fails to account for key differences amongst disease types. This leads to significant variation in performance due to common case mix changes each period.

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<th>w/o Part D Coverage</th>
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Improved / Worsened performance, or just case mix variation?

The presented simulation was performed by resampling an OCM practice's actual episodes 100,000 times.

As the median practice has accomplished savings in only 1-2 of 4 periods, can we confidently say that their performance has improved, worsened, or is it just case mix variation?

Our calculated confidence intervals (90% CI) for a practice with 1,000 episodes per period is ~ +/- 3%. At 250 episodes, +/- 6.5%.
PracticeNET Calls

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