

# Oncology Outlook

## What to Expect in 2009

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# Overview of Issues

- Congress & the New Administration
- Legislative & Regulatory Issues
  - Medicare payments for services
  - Coverage and access
  - Imaging
  - Quality and Health Information Technology
  - Other Issues

# Major Changes in 111<sup>th</sup> Congress

- House margin significantly increased
- Senate margin still to be determined but close to veto proof
- Energy & Commerce Committee: Change in Leadership
- Ways & Means: Many new Members
- Senate Committees: No major changes

# Obama Administration

- Campaign Cancer Plan
- Double funding for cancer research
- Affordable health coverage for all
- Focus on prevention
- Strengthen Workforce
- Focus on Value
- BUT...facing economic crisis and other priorities

# 111<sup>th</sup> Congress Health Care Agenda – Must Do's

- SCHIP (Children's Health Insurance Program) likely the first thing addressed
- Medicare bill later in the year to address SGR and other payment reforms possible
- Part D
- Medicare Advantage
- Drug Price Negotiating Authority
- Extension of Therapy Cap Exceptions

# 111<sup>th</sup> Congress Health Care Agenda – Other High Priorities

- Health Care Reform
- Comparative Effectiveness
  - Baucus/Conrad Legislation
- Pay for Performance/Value Based Purchasing
- Oversight of FDA
- Drug Importation
- Health IT
  - Bipartisan Support

# Medicare Service Payments to Physicians and Hospitals

# Physician Payment Update

- CMS announced 2009 CF at \$36.0666
- Update reflects Congressional mandates:
  - 1.1% increase to avoid scheduled 15.1% cut due to SGR formula
  - Requirement that CMS apply budget neutrality adjustment to conversion factor
- Conversion factor reduction amplifies problems with physician payment formula

# Oncology-Specific Payments

- CMS estimates that oncology payments will go down 1% in 2009. This reflects:
  - Impact of budget neutrality adjustment from 5-Year Review of physician work
  - Continued transition in practice expense methodology
- ASCO has expressed serious concern with reductions and asked CMS to dampen impact of reductions to chemo admin codes while permanent solutions are discussed.

# Oncology Payments – Practice Expense

- ASCO is participating in AMA survey to collect updated practice expense data
  - CMS expected to use data to update Medicare payment calculations
  - Important for oncologists to participate
    - Any adjustments to fee schedule will be budget neutral – “zero-sum game”
    - Oncologists should have data to ensure we are not disadvantaged relative to other specialties

# Comprehensive Care Planning – Legislative Outlook

- “Capps-Davis” bill
- Seeking reintroduction in the new Congress
- Adds new Medicare benefit for comprehensive care planning services
- Payment for plan of care or revision equal to payment for Level 5 new patient consult plus home health certification (\$298 in 2006)
- Service could be provided by physician or hospital

# Anti-Markup Rules

- In 2007, CMS adopted expanded anti-markup rules to address situations where outside entities provide a service to physicians that the physicians could bill at a profit
  - E.g., “pod labs” performing anatomical pathology services
  - Applies to all diagnostic tests furnished by employee or contractor outside the “office of the billing physician”
- Rules were to have been effective January 1, 2008
- Postponed until January 1, 2009 except with respect to anatomical pathology services furnished in a different building

# Anti-Markup Rules (2)

- Effective January 1, rules do not apply if ordering and performing physicians “share a practice.”
  - Physician performing prof component or supervising tech component must perform at least 75% of his or her professional services for the billing physician.
  - If 75% test not met, service may be exempt if physician has owner, employee, or contractor arrangement with billing physician and provided in same building where full range of services are typically offered.
- Physicians consult experienced attorneys regarding application of these rules to their practice.

# Coverage and Access

# Drug Payments in Office

- Payments for drugs made at 106% of ASP
- “Underwater” drugs continue to be a significant problem
  - Some drugs not available to some physicians at Medicare rate
  - Prompt pay discounts included in calculation but not passed on to physician
  - No exceptions process for particular drugs.
  - 2-quarter delay in adjusting payments to reflect price increases

# Underwater Drugs – Legislative Outlook

- Previously the “Towns bill”
- Seeking reintroduction in the new Congress
- Bill addresses “underwater” drugs:
  - Would establish a floor on Medicare payment for Part B drugs at WAMP
  - WAMP is defined in current law as the price that a prudent physician would pay for the drug
  - CMS would increase payment above 106% of ASP as necessary to reach WAMP

# Drugs In Hospital Outpatient Department

- Separately billable drugs now paid at ASP+4% in hospital outpatient department
- CMS has reduced payments over last two years and could reduce further.
- ASCO has advocated for revisiting reduction based on problems with charge compression, in line with other stakeholders

# Drugs in Hospital Outpatient Department (2)

- Medicare will continue paying separately for drugs costing more than \$60 per day; drugs costing less than \$60 are not reimbursed separately
- Anti-emetics continue to be reimbursed separately regardless of their daily cost

# Off-Label Coverage

- CMS recognizes off-label uses published in specified compendia for Medicare Parts B, D:
  - Thomson DrugDex
  - NCCN Drugs & Biologics Compendium
  - AHFS Drug Information
  - Clinical Pharmacology
- In 2008, CMS implemented annual process to consider requests to change this list

# Off-Label Coverage (2)

- Medicare contractors also cover uses supported by evidence published in one or more of 26 specified peer-reviewed journals
- Issues on the horizon:
  - Increased scrutiny of conflicts of interest
    - MIPPA provision requires compendia transparency around conflicts of interest by January 2010
    - AHRQ has drafted paper on compendia and conflicts

# Leucovorin Shortage

- ASCO issued clinical alert on current shortage
  - Levoleucovorin has been used off-label for treatment of malignancies as substitute for leucovorin
  - Cost of levoleucovorin may be higher
  - Check with Medicare contractors and private health plans on coverage
    - Palmetto and Noridian have approved temp coverage

# ESAs

- FDA has issued limited additional guidance on ESA label changes and medication guides
- ASCO seeks clarification on distribution requirement for medication guides in office versus pharmacy.
- FDA expected to issue additional requirements in form of Risk Evaluation and Mitigation Strategies (REMS)

# IVIIG

- For 2009, CMS has eliminated the pre-administration fee for IVIG in both hospital outpatient department and physician office
- CMS states that problems with acquisition have subsided and market is more stable

# Competitive Acquisition Program

- Medicare CAP program for drugs and biologicals is on hold for 2009
- CMS does not have a vendor
  - Previous vendor BioScrip has not reapplied
- CMS is accepting public comment on how to reform the CAP program.

# Local/Regional Coverage

- CMS has awarded MAC contracts for all regions.
- Recently announced on January 7:

Jurisdiction	Company	States
6	Noridian	IL, MN, WI
8	NGS	IN, MI
10	Cahaba	AL, GA, TN
11	Palmetto	NC, SC, VA, WV
15	Highmark	KY, OH

# Clinical Trials Coverage

- ASCO continues advocacy on insurance coverage for routine costs associated with clinical trials
  - Ensuring coverage for phase I trials under the existing Medicare NCD
  - Appropriate carve-outs for Medicare Advantage enrollees
  - Establishing coverage standard for federal employees

# Kennedy-Hutchison Legislation

- 21<sup>st</sup> Century ALERT (Access to Life-Saving Early detection, Research and Treatment) Act
- National Cancer Program to facilitate coordination between agencies
- Centralized IRB
- Prevention and Early Detection Programs
- Promotion of Biomarker Development
- Mandated Coverage of Routine Patient Care Costs in Clinical Trials
- Patient Navigator Programs
- Demonstration on Treatment Planning

# Access to Care Background

- 40% of all new cancer cases are diagnosed among the non-elderly (<65 yr) – 11% of these individuals are uninsured.
- Uninsured cancer patients incur about half of the health care expenditures of those who have insurance.
- Lack of insurance and reduced health care spending for the uninsured may largely explain poor outcomes for African Americans and Hispanics with cancer, compared to the outcomes for whites.
- Cancer care outcomes can be improved for minority populations, underserved populations, and others by removing financial barriers to care.

# Access to Care Legislative Proposal

- Developed in 2008 by ASCO Access to Care Task Force
- Expands access to cancer care through Medicare for people who are diagnosed with cancer who are uninsured
- Eligibility: Less than 65 years old, received a diagnosis of cancer, no health insurance coverage

# Imaging

# Imaging – Regulatory Issues

## Physician Office

- CMS proposed but did not finalize plans to require physician offices who furnish diagnostic services to meet IDTF standards.

## Hospital Outpatient Department

- CMS has finalized a proposal to provide a single payment when two or more imaging procedures using same modality are conducted in one session.

# Imaging – Legislative Outlook

- Recently passed Medicare bill requires physicians and other suppliers that furnish advanced diagnostic imaging services like MRI, CT, and PET to meet Medicare accreditation criteria by 2012
- GAO report recommends prior authorization to control spending
- ASCO member of Access to Medical Imaging Coalition

# Proposed NCD on FDG-PET

- CMS has issued proposed NCD on coverage of PET for cancer
  - National Oncologic PET Registry asked CMS to remove Coverage with Evidence Development (CED) requirements for PET scans in previously non-covered indications
  - CMS proposes to remove CED requirement for initial scan but maintain reporting for subsequent scans
- CMS will review comments before finalizing

# Quality & Health Information Technology

# Medicare E-Prescribing

- New incentive program for physicians who e-prescribe beginning January 1, 2009:
  - 2% payment increase in 2009-2010
  - 1% payment increase in 2011-2012
  - 0.5% payment increase in 2013
  - Penalties will be assessed for non-participating physicians after 2013.
- Successful reporting defined as reporting for at least 50% of eligible patients

# Medicare E-Prescribing (2)

- **Challenges**
  - eRx is voluntary for pharmacies
  - Estimated cost of \$3000/physician to adopt eRx
- **E-prescribing for controlled substances**
  - DEA has proposed new regulations to allow eRx for controlled substances listed on schedules III-V.
    - DEA would require an intricate system of checks and cross-checks, both human and programmed
    - DEA might require 2 different workflows, one for controlled substances and one for other drugs.

# PQRI – Medicare Quality Reporting in 2009

- PQRI Incentive for 2009 & 2010: ~2%
- CMS to adopt several new cancer specific measures:
  - Plan of care for pain
  - Pain intensity quantified
  - Radiation dose limits to normal tissues
  - Recording of clinical stage for esophageal & lung cancer
- Measures to be deleted :
  - #73: Chemotherapy planning
  - #74: Radiation recommended for invasive breast cancer
  - #104: Review of options for prostate cancer

# PQRI (2)

- Looking ahead
  - Registry-based reporting is now an alternative way for physicians to participate in PQRI
  - Some specialties are moving towards registry-based reporting
  - ASCO is developing plans to facilitate registry-reporting to PQRI that is coordinated with the Quality Oncology Practice Initiative (QOPI)

# Funding for the National Institutes of Health



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# Funding for NIH

- Congress has passed a Continuing Resolution (CR) through March 6 to keep government running at 2008 levels.
- Congress will have to pass appropriations bills or another CR by March 6.
- May pass omnibus bill.
- ASCO and others in the biomedical community advocating for additional funding for NIH in the economic stimulus

# Other Issues

# Recovery Audit Contractors

- CMS Recovery Audit Contractors (RACs) will soon operate nationwide
- Drugs and services subject to review
- CMS to make program less onerous during full rollout based on complaints from medical community
- 2 of 4 new RAC contracts are being protested; new outreach on hold

# Workforce Supply/Demand: ASCO Analysis & Plan

- Demand for oncology visits outstripping supply
- Expanding need due to increased survivorship & incidence in an aging population
- Coordinated, multi-faceted approach required
- ASCO Strategic Plan Goals:
  - Identify ways to improve practice efficiency
  - Adapt/expand training
  - Collect, assess, and report real-time data
- Physician Investigator Project

# Workforce Supply/Demand: ASCO Plan

- Competitive grants to study innovative practice arrangements
- Pilot projects to test innovative practice models
- Partnerships with other health professionals
- Number and funding for training slots and recommendations for expansion
- Exposure to outpatient oncology during training
- Workforce information database and health of the workforce report

# Questions?

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