

# Prescription Drug and Medicare Advantage Compliance Conference

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# Change in the Definition of a Medically Accepted Indication

- MIPPA revised the definition of medically accepted indication (MAI) for Part D drugs used in anti-cancer regimens, effective January 1, 2009.
- In addition to the existing Part D compendia, the update included the use of the NCCN Drugs and Biologics Compendium, Clinical Pharmacology, and peer-reviewed medical literature when evaluating off-label uses.
- An HPMS memo issued on December 9, 2008, provides details regarding this change.

# Transition Audit Findings

CMS has identified a number of Part D sponsors who were not in compliance with Part D transition requirements



# Transition Requirements

Part D sponsors must provide for an appropriate transition process for new enrollees and current enrollees prescribed Part D drugs that are not on its formulary.



# Transition Requirements

- Specifically, a sponsor must provide for an appropriate transition process with respect to:
  - The transition of new enrollees into prescription drug plans following the annual coordinated election period;
  - The transition of newly eligible Medicare beneficiaries from other coverage;
  - The transition of individuals who switch from one plan to another after the start of the contract year;
  - Enrollees residing in LTC facilities; and,
  - In some cases, current enrollees affected by formulary changes from one contract year to the next.

# Transition Requirements

Also, sponsors should consider how to expedite transitions to formulary drugs for enrollees who change treatment settings due to changes in level of care.



# Transition Audit Findings

Majority of compliance actions involved current enrollees affected by changes to their plans formulary

- Sponsor intended to prospectively transition all members who were subject to a formulary change prior to January 1<sup>st</sup>.
- Improperly relied on Annual Notice of Change (ANOC) to effectuate the transition
- Processed transition fills for only some drugs subject to a cross-contract year formulary change, or coding errors on processor's part when implementing new formulary

# Transition Audit Findings

- Sponsor denied claims with “hard edit”



- Denied beneficiary access to transition fills as a result of errors in enrollment dates

# Preparing for Next Year

- Part D sponsors required to enforce transition policy
- Sponsors should re-examine their adjudication for point of sale
- This transition allows for:
  - Immediate need of enrollee to be met
  - Gives beneficiary time to work with prescriber



# Preparing for Next Year

- Sponsor using “hard edit” approach are at most risk for non-compliance
- Conduct Quality and Assurance checks on adjudication system prior to the start of the plan year

# 2011 Readiness Checklist

## 4<sup>th</sup> Annual Readiness Checklist

- Released via HPMS in early September
- Covers Parts C & D
- Reiterates existing guidance only
- Important topics for 2011 preparedness
- Includes reference sources
- New Benefits, Compliance, and Operations sections

# 2011 Readiness Checklist

## Next steps for Sponsors

- September - Review the checklist
- October - Respond to immediate action items
- November - Respond to survey for each readiness checklist item
- Expect calls from CMS if you're a PDP expecting LIS Re-Assignments

# Example of a Compliance Plan We Should Never See and You Should Never Use

## ACME HEALTH PLAN

### COMPLIANCE PROGRAM & PART D COMPLIANCE PLAN

Instructions: Replace “ACME” with Plan Name. Use the Find & Replace Function. Please review committee structure, titles, and committee membership in detail. This is a general template document designed to meet all of the CMS requirements; however, your organization may have slight variances in structure and operation.

# What's On the Horizon?

- Stepped up oversight – more rigorous, proactive, data-driven, targeted monitoring
- High Risk Program areas:
  - Marketing remains an area of concern
  - Compliance program audits
  - Enrollment, appeals, access to providers and benefits, vulnerable beneficiaries, transition
  - Administration of Medicare plans as if they were commercial plans

