

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 1st.
- 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

4th 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

