

**Medicare Comments Working Group
Medicare Modernization Act Proposed Regulations
Overview of Select Issues for Comment
September 15, 2004**

This outlines some of the topics that will be more fully addressed in a final comment letter. Given the length and complexity of the proposed regulations, this document does not enumerate all of the issues that will be addressed in that letter or covered in the discussion today, but highlights some key points.

The items noted are grouped by subject matter in the order they will be discussed today, rather than in order of the proposed regulations. For each topic area, the relevant subparts of the proposed regulations are noted in parentheses. All relate to Title I unless otherwise noted.

General Observations

- Pro-consumer provisions discussed in preamble should be included in the final regulations; many are missing from the proposed regulations.
- Notice of Proposed Rulemaking leaves much unanswered; a second notice/comment round needed.
- Simplicity, as well as additional support for information and counseling, needed to ensure beneficiaries are reached.

Low Income Issues

Low-Income Eligibility and Enrollment (Subpart P)

- Definition of "Assets" appears well-intended, but needs tightening.
- Support proposed definition of family members.
- Automatic subsidy eligibility for Medicare Savings Program beneficiaries is a positive step, but will need refinement.

Premiums and Cost-Sharing Subsidies for Low-Income Individuals (Subpart P)

- Ensure equitable enrollment for all MSP-eligible beneficiaries.
- Require Deeming and Notice for full subsidy-eligible individuals.

- Inadequate provisions for administration of low-income subsidy payments to plans.
- Require notification of beneficiaries no more than 30 days after application filed
- Make redetermination simple.

Special Rules For States—Eligibility Determinations for Subsidies and General Payment Provisions (Subpart S)

- Inadequate time and processes to ensure continuity of coverage as dual eligibles are automatically enrolled in Part D plan (*this is in Subpart B*).
- Inadequate provisions regarding states' obligations to screen subsidy applicants and offer them enrollment in MSPs.
- Could states be required to screen and enroll individuals for full Medicaid benefits?

General Eligibility, Enrollment, Plan Marketing Materials and Marketing Practices

Enrollment, Late Enrollment Penalties, Disenrollment (Subpart B)

- Need to address enrollment, outreach, and education issues for special populations.
- Provisions on “required disenrollment” could result in serious disruptions in care/access.
- Inadequate beneficiary protections in provisions allowing disenrollment for “disruptive or threatening” behavior.
- Need appeals process for late-enrollment penalties; coordination with special enrollment periods and disenrollment.

Information about Part D; Marketing Materials (Subpart B)

- Ensure beneficiaries have sufficient information on price and formularies to make an informed plan selection.
- Inadvisable to allow plans to offer other services or allow single PBM-affiliated pharmacies to conduct enrollment; do not allow telemarketing.
- Guarantee beneficiary notification on “creditable” status of existing coverage.
- Require plans to provide 24/7 customer support.
- Strengthen privacy protections.

Formularies, Quality Assurance, Quality Improvement and Utilization Review

Formulary Policies (Subpart C)

- Issues regarding Pharmacy & Therapeutics Committee (P&T) process integrity, i.e., composition, independence, operating standards.
- Need adequate processes to allow for coverage of clinically appropriate off-label uses.
- Strengthen processes to ensure non-discrimination by plans.
- Add formulary exception/protections for populations with special medication needs.
- Establish limits on tiered cost sharing.
- Improve out-of-network access standards to ensure emergency access.

Dissemination of Benefits Information (Subpart C)

- Ensure adequate access to formulary information.
- Provide for routine, easily understood Explanation of Benefits.

Cost Control and Quality Improvement (Subpart D)

- Limit use of Cost-Containment Tools such as dispensing limits; additional protections to prohibit use of “unacceptable” cost containment approaches.
- Greater, and timely, public information on error rates, outcomes, and quality.
- Require P&T oversight of plans’ Utilization Management.

Appeals, Grievances, Benefits Structure

Appeals and Grievances (Subpart M)

- Inadequate coverage determination notice requirements.
- Inadequate consumer protections to guarantee continuous access to necessary medications.
- Need more specificity regarding processes for physician, SPAP, etc. input in appeals process; ensure appropriate medical specialty involvement.
- Improve consumer protections at least to standards for Medicare Advantage plans (specifically for appeals to an Independent Review Entity).

- More specificity in setting threshold for right to an ALJ hearing and standard process for hearing request.
- Unacceptably long time frame for plans to implement IRE or ALJ coverage determination reversal.

Benefits Structure/Qualified Prescription Drug Coverage (Subpart C)

- Need to ensure beneficiaries can truly compare plans given variations in benefit structure based on definition of “actuarial equivalence.”

Retiree Coverage

Payments to Sponsors and Calculation of True Out-of-Pocket Spending (Subpart R)

- Ensure Medicare payments for retiree coverage do not provide a windfall to employers’ plans.

Other Coverage

MA Provisions (Various Subparts in Title I; Title II)

- Issues for separate comment letter on Title II: Opposition to weakening disenrollment/quality standard and reports; concern whether payment increases will be passed along to enrollees in benefit improvements; support specialized (disease group) MA plans.

Medigap Policies (Subpart S)

- Simplified notice; guaranteed delivery regarding changes in creditable coverage.

Care in Other Settings (Long Term Care Issues)

Special Issues for Long-Term Care Facilities (Various Subparts in Title I)

- Special needs of and issues related to long term care residents not adequately considered.
- Need provisions to ensure adequate access for long term care residents.