EXHIBIT 2
DATE Tues JAN 25 2005

59th Legislative Session
Health and Human Services Appropriations Subcommittee
January 25, 2005

MMA – Part D Benefit
Impact on Medicaid and other State Programs

Friday, January 21, 2005 CMS issued the final rules implementing the new prescription drug benefit under MMA. The final regulations for Title I are 1,162 pages long! The proposed regulations were issued in August 2004 and comments were due October 4, 2004.

Attached copy of CMS Medicare fact Sheets:

- Final Rules Implementing the New Medicare Law: A New Prescription Drug Benefit for All Medicare Beneficiaries, Improvements to Medicare Health Plans and Establishing Options for Retirees.
- PRINCIPAL CHANGES IN NEW MEDICAREFROM PROPOSED RULES TO FINAL RULES *New Rules Establish New Prescription Drug benefit, Improvements to Medicare Health Plans and Options for Retirees.*

Brief review of key definitions and requirements under MMA related to Medicaid:

- Eligibility for Part D - Must be entitled to or enrolled in Part A and/or enrolled in Part B (Have Medicare Card).
- Full benefit Dual Eligible – Is a client that has both Medicaid eligibility and eligibility for Medicare under Part A and/or Part B. These clients also receive a prescription drug benefit and coverage under Medicaid.
- Medicaid clients with Medicare coverage are "deemed" to be eligible for Part D low-income subsidy. This includes:
  - Medicare/Medicaid Full Benefit Dual eligible
  - QMB, SLMB, QI-1, QI-2
- Clients that are eligible for Part D must still enroll with a PDP or MA-PD plan.
- Medicare will be the primary payer for covered Part D drugs.
  - As of 1/1/06 the Medicaid program will no longer be the primary payer for prescription drugs.
  - CMS will not provide federal Medicaid match dollars for drugs Montana provides to full benefit duals. This includes:
    - Covered Part D drugs
    - Any cost sharing for covered Part D drugs
    - Any deductibles for covered Part D drugs
- Medicaid program may provide coverage and receive FFP for non-covered Part D drugs.
- Phased-down state contribution (Clawback):

Phase-Down State Contribution

Not much clarification is provided in the January 21, 2005 final rule guidelines related to the State Phased-down state contribution (Clawback). In the Guidance for State Medicaid Agencies CMS says:

- "CMS will continue to work with states to make sure that their 2003 drug cost figures are accurate".
- "States are required to submit monthly data on dual eligibles for the calculation of the phase-down state contribution".
- "States will make their first phase-down contribution to CMS by February 25, 2006".

What is the Clawback "Phase-Down State Contribution"?

- Federal Assumption of Medicaid Drug Costs
- The clawback will be based on a State's own per-beneficiary spending for full benefit dual eligible clients.
- States are responsible for making monthly payments to Medicare for a portion of the state share of drug expenditures for full benefit dual eligible clients. (Clawback)

Will there be any savings to the State as a result of the phased down contribution at 90% in 2006 and 75% in 2015?

- Yes, according to CMS the State will no longer have to pay for drug coverage for full-benefit duals. States will only be required to pay a percentage of the state share of the per capita expenditure as determined by the Phase-down percentage identified in MMA as follows:

CY 2006	90%
CY 2007	88 1/3%
CY 2008	86 2/3%
CY 2009	85%
CY 2010	83 1/3%
CY 2011	81 2/3%
CY 2012	80%
CY 2013	78 1/3%
CY 2014	76 2/3%
CY 2015 and thereafter	75%

- CMS also recognizes that States will also incur some new administrative costs in our role with the low-income eligibility determination process. In addition, the new drug coverage and outreach are expected to increase Medicaid enrollment. All of the related administrative activities and enrollment are difficult to estimate and cost out due to the uncertainty of the impact of MMA on the State.

CMS has provided the formula and steps in the calculation so this should be easy to calculate right?

Illustrative Calculation of State Phased-down Monthly Contribution for 2006

	Item	Illustrative Value	Source
(1)	Gross per capita Medicaid expenditures for prescription drugs for 2003 for full-benefit dual eligibles not receiving drug coverage through a Medicaid managed care plan, excluding drugs not covered by Part D	$2,000	MSIS data
(2)	Aggregate state payments under rebate agreements for 2003	$100,000,000	CMS-64
(3)	Gross state Medicaid expenditures for prescription drugs in 2003 from CMS-64	$500,000,000	CMS-64
(4)	Rebate adjustment factor	0.2000	(2) ÷ (3)
(5)	Adjusted 2003 gross per capita Medicaid expenditures for prescription drugs for full-benefit dual eligibles not in managed care plans	$1,600	(1) x [1 - (4)]
(6)	Estimated actuarial value of prescription drug benefits under capitated managed care plans for full-benefit dual eligibles for 2003	$1,500	To be Determined
(7)	Average number of full-benefit dual eligibles in 2003 who did not receive covered outpatient drugs through Medicaid managed care plans	90,000	MSIS data
(8)	Average number of full-benefit dual eligibles in 2003 who received covered outpatient drugs through Medicaid managed care plans	10,000	MSIS data
(9)	Base year state Medicaid per capita expenditures for covered Part D drugs for full-benefit dual eligible individuals (weighted average of (5) and (6))	$1,590	[(7)x(5) + (8)x(6)]÷ [(7) + (8)]
(10)	100 minus Federal Medical Assistance Percentage (FMAP) applicable to month of state contribution (as a proportion)	0.4000	Federal Register
(11)	Applicable growth factor (cumulative increase from 2003 through 2006)	50.0%	NHE projections
(12)	Number of full-benefit dual eligibles for the month	120,000	state submitted data
(13)	Phased-down state reduction factor for the month	0.9000	specified in statute
	Phased-down state contribution for the month	$8,586,000	1/12 x (9) x (10) x [1+(11)] x (12) x (13)

Provided by CMS on March 25, 2004

What are the State's issues with this Clawback baseline calculation?

- Baseline MSIS eligibility data cleanup – Process directed by CMS
  - Started May 6, 2004
    - Reconciliation project identified and updated over 4,000 eligibility records to add Medicare coverage.
  - November 15, 2004 - CMS accepted FFY 2003 Qtrs 1, 2, and 3 files (10/02-6/03)
  - December 20, 2004 - CMS accepted FFY 2003 Qtr 4 file (7/03-9/03)
  - January 11, 2005 - CMS accepted FFY 2004 Qtr 1 file (10/03-12/03)
- Excludable baseline drugs
  - File received September 9, 2004
    - 50,667 NDC's Included Drug
    - 45,886 NDC's Excluded Part D Drug
    - 2,814 NDC's Covered Part B Drugs (Excluded)
  - Supplemental file received November 3, 2004
    - Updated more NDC's excluded Part D Drugs
- Drug Rebate Factor – Timing differences on payment of claims and rebate collections.
  - Cash basis = 20.3% (Proposed methodology used by CMS)
    - Only represents rebates collected on drug claims paid through 6/03.
    - Over half of the drug rebate collections are for drugs dispensed and paid for in 2002!
    - Does not account for increased rebate collections for over half of the drugs dispensed and paid for in 2003.
  - Adjust for timing differences = 21.3%
    - Could be significant considering this is a baseline calculation that will be inflated forward in the out years will no provision for future adjustments.
- National Health Expenditure (NHE) inflation factor
  - Inflate costs from 2003 to 2006
  - Received factor from CMS December 14, 2004
  - Factor is 38.3% - will be used by all States
  - State impact depends our growth rate above or below this factor!
    - Montana experienced growth of:
      - 12.49% 2003-2004
      - 17.38% 2004-2005 YTD
- Managed care drug cost calculations – Issue for many States but not Montana
- Full-dual eligible definitions – Issue for some State's that operate Pharmacy Plus Waivers
- Consideration and credit for drug cost containment measurers implemented since 2003 – Issue for all States!
  - Mandatory Generic
  - Step Therapy
  - Preferred Drug Lists (PDL)

- Consideration of TPL recoveries – Cost avoidance and collections will not be considered.
- CMS has not provided States the exact processes and steps they are using to match up data!
    - January 11, 2005 Denver meeting with CMS
        - First time CMS outlined the process of matching MSIS Quarterly eligibility information with monthly MSIS drug claims.
        - First time CMS identified they were excluding Family Planning drug claims and Indian Health Services drug claims from the calculation.
        - Requested the detail step-by-step logic that will be used by CMS in this calculation. Still waiting!
- CMS due date for the calculations is October 15, 2005
- CMS indicated that MMA does not provide for adjustments related to the issues identified by the States and they envision this as a Cash payment / receipt process and not based upon an accrual basis.

Can we appeal the CMS calculation of the clawback?

- This question was asked at a January meeting in Denver with CMS representatives and the answer was NO! There is no provision for an appeal due to the tight timelines between October 2005 and implementation in 2006.

Are there any other issues related to the Clawback and how it is paid to the feds? Yes, there are a couple issues that are of concern!

- Retroactive Clawback Payments
    - The payment will be made on a monthly basis based upon the baseline calculation and the number of full-benefit duals reported monthly by the State.
    - The department is required to notify CMS all clients determined eligible for Medicaid on a retroactive basis and pay retroactive clawback payments.
    - This includes anyone we have Medicaid eligible that we discover has retro eligibility for Medicare.
        - Possible that we paid drug claims under Medicaid and will also be required to pay the clawback. Duplicate payments & cost to the GF! *(Remember for full benefit duals, Medicaid cannot claim FFP for covered drugs under Part D. If we paid drug claims for a client when they were Medicaid only and later find out they were covered under Medicare Part D (retroactive), and we are required to pay the clawback, then we have paid twice for the service! Once for the claims and once under the clawback!)*
        - Questions to CMS – Asked January 11, 2005 (no answer to date)
            - If the state is required to make retroactive payments on the State Phasedown Contribution (Clawback) how will the

state recover our costs for drugs we paid for under Medicaid? Since we cannot recover the payment from the pharmacies, will CMS require PDP plans to pay the full cost of the drugs to State Medicaid programs to reimburse us for the cost of the drugs? If not, why not?

- Will CMS set up a process to allow State Medicaid program to bill PDP plans for these drugs? If not, why not?
- If not, how will CMS reimburse States the general fund share of the cost of the drugs paid under the Medicaid program? *It is unacceptable to expect states to cover the general fund cost of the drugs and also pay retroactive general fund dollars under the clawback!*

- Growth Factor
  - The applicable growth factor for 2004, 2005, and 2006 is the average annual percent change as determined by National Health Expenditure projections (38.3%).
  - In subsequent years, <u>the growth factor is the annual percentage increase average per capita expenditures under Part D</u>. *We have no control over the growth factors used to inflate the baseline clawback calculation after 2006!*

Low-Income Subsidy Activities – State Responsibilities (1/21/05 CMS Fact Sheet)
Including comments regarding impact to Montana.

- States are required to take and process applications for the low-income subsidy program.
  - States are strongly encouraged to use the Social Security Administration's SSA) application and eligibility determination process for the low-income subsidy unless an individual requires that the state make the low-income subsidy eligibility determination. If an individual demands to have a state determination, or refuses to use the SSA application, the state must take and process the application, which must be consistent with the CMS final rule, using the state's own eligibility determination process. The state is responsible for appeals and redeterminations associated with state eligibility determinations.
    - System changes for eligibility
    - Increase in Administrative workload for:
      - Develop State application for the low-income subsidy?
      - Eligibility determination under the Low-Income Subsidy determination.
      - Appeals process related to eligibility determinations and redeterminations.
      - Outreach and training related to the implementation of MMA.

  - As part of making an eligibility determination, states are required to screen applicants for the Medicare Savings Program and offer enrollment if the individual meets that state's Medicare Savings Program requirements.

Information on people found to be eligible for the low-income subsidy through SSA will be shared with the States for use in MSP determinations. (Woodwork effect)!

- Reconciliation and verification of eligibility for Medicare Part A, Part B and Part D.
- Increases in Medicaid eligibility as a result of outreach efforts under MMA. This will impact payment for:
  - Covered services under Medicaid that are not covered under Medicare
  - Payment of coinsurance and deductibles
  - Payment of Part B Buy-in for certain individuals

- States are required to submit monthly data on dual eligibles and those eligible under Medicare Savings Programs (QMB, SLMB and QIs). CMS will use this data to deem these beneficiaries eligible for the low-income subsidy, for auto-enrollment of full-benefit dual eligible individuals, and the state phase-down contribution (see below). CMS expects to use these data to start the auto-enrollment and deeming processes for Medicaid beneficiaries eligible for the low-income subsidy in the spring of 2005.
  - System changes for data exchanges between CMS and the State
    - MSIS – Required changes to be implemented December 2005
    - Subsidy and Deeming file – Required to be completed and operational July 2005
    - Medicare Enrollment Database Match – New process to identify Medicare eligibles.
- States may inform beneficiaries when they lose Medicaid benefits that they must reapply for the Part D low-income subsidy in the next year.
  - ? What this means
  - Impact on Medically Needy clients with spenddowns?
- States may perform outreach and education related to the Part D drug benefit and low-income subsidy. CMS will provide outreach, coordination, and support services for these state activities, as part of its overall outreach and education campaign on the drug benefit. SSA, in coordination with CMS, will also provide outreach and education on how to apply for the low-income subsidy. Examples of Medicare beneficiaries, who live in states that are likely to help them take advantage of the low-income subsidy, include seniors and people with disabilities who participate in other state-sponsored low-income programs or who have recently lost Medicaid benefits. Working with the States and others, CMS hopes to identify and enroll as many of these beneficiaries as possible in the low-income subsidy program by the fall of 2005.
- States may receive administrative matching funds for these administrative activities. (50/50)
  - Possibility of enhanced match for system changes at 75/25 or 90/10.

Other State Impacts

- States may continue to cover the drugs in §1927(d)(2) of the Social Security Act (except smoking cessation drugs, which will be covered by Part D) and receive Federal Financial Participation.
    - System changes for processing claims
        - Deny claims 1/1/06 for clients with Medicare Part D coverage
        - Assess impact of any Coordination of Benefits with PDP plan?
        - Identify what if any of these non-covered drugs Medicaid will continue to cover.
    - Appeals process related to claim denials.
    - Address complaints and inquiries regarding Part D coverage and coordinate with CMS and PDP plans.

- In the MMA statute, Medicaid agencies are identified as entities that are required to notify Part D eligible individuals regarding the drug coverage they provide, and whether or not it is creditable prescription drug coverage—meaning the drug coverage is at least as good as Medicare Part D drug coverage. CMS is working with state organizations to develop guidance regarding creditable prescription drug coverage disclosure notices, including the form and manner of providing these notices. Our intent is to reduce as much as possible the administrative burden on the States. For example, CMS notification to full benefit dual eligibles through our deeming process for the Low Income subsidy could be used to provide notice of creditable coverage.

- As Medicare takes over the costs of providing prescription drugs in LTC pharmacies, some states may need to modify their payments to LTC facilities if they have bundled payments for drugs into other Medicaid payments, e.g., per diem payments or other services associated with dispensing drugs. CMS will work with states to provide guidance on how to modify these LTC financing arrangements to reflect the new Medicare drug payments.

PDP Plan Formularies and drug coverage for Full Benefit Duals

Coverage under the PDP formulary has been a great concern with Medicaid programs related to the full benefit duals. We expected that the coverage under Part D should be as comprehensive as that provided under Medicaid. This concern was expressed by several states.

The final regulations outline principle changes from the proposed rules relating to drug coverage under the Medicare prescription drug benefit. See the Medicare Fact Sheet – Principle Changes in New Medicare From Proposed Rules to Final Rules.

- The effectiveness of these changes regarding coverage for full benefit duals will be critical on January 1, 2006.
- Remember, on this date Medicare is the primary payer. If PDP plans deny coverage for drugs that Medicaid used to cover – WE WILL HEAR ABOUT IT!