Deficit Reduction Act of 2005:
Provisions Affecting Drug Benefit & Other Hot Topics

Marc Samuels
National Medicaid Congress
June 4, 2006

HILLCO PARTNERS

Current Medicaid Law Regarding Access

1. State option to cover “prescribed drugs” – same benefit for all
2. Federal matching funds to state for prescribed drugs only if manufacturer signs OBRA 90 Rebate Agreement
   - CMS has interpreted this law to permit states to use the threat of prior authorization to leverage manufacturer payment of supplemental rebates on top of federal rebate amount
3. Federal rebate statute does not apply to drugs furnished under capitated Medicaid managed care arrangements
4. State payment for prescribed drugs furnished Fee For Service—
   - Dispensing fee (filed in State Medicaid plan) to pharmacists
   - “Estimated Acquisition Cost” formula filed in State plan to pay pharmacist for the drug (subject to Federal upper limit for multiple source drugs)
   - Beneficiary co-pay, if any, must be nominal (set by regulation at no more than $0.50 generic/$1 brand)

DRA #1:
State Option to Change Medicaid Benefits

- Allows states to replace the existing Medicaid package for certain beneficiaries with coverage that is "benchmarked," or "benchmark-equivalent" to either the standard Blue Cross plan offered to federal employees, health coverage for state employees, or health coverage offered by the largest commercial HMO in the state, or a benefit package approved by the Secretary. § 6044.
  - Plus EPSDT for children
- The populations exempt from such a change include persons eligible because of disability or blindness, mandatory pregnant women, dual eligibles, people in LTC, hospice patients, foster care children and "medically frail persons with special needs" as identified by the Secretary in regulation.
  - Many of these are the "mandatory" populations that have been plaintiffs in Medicaid entitlement litigation.

Implications of DRA #1:

- Population with “traditional” Medicaid drug benefit in a given state could be much smaller
- Could be limited essentially to populations with complex, multiple medical needs if the state uses capitated managed care to implement the new benefit packages.
- Under capitated managed care state revenues from prior-authorization-induced supplemental rebates could be in jeopardy
- BUT nothing in DRA *requires* the use of capitated managed care to deliver new benefits.
  - A state could have a more restrictive, FFS benefit package.
  - If the FFS drug benefit is benchmarked to a more limited formulary used by an HMO, do manufacturers have to pay the federal rebates?
  - What happens to the principles for “negotiation” of supplemental rebates if the state piggybacks on the actual formulary used by a benchmark plan?

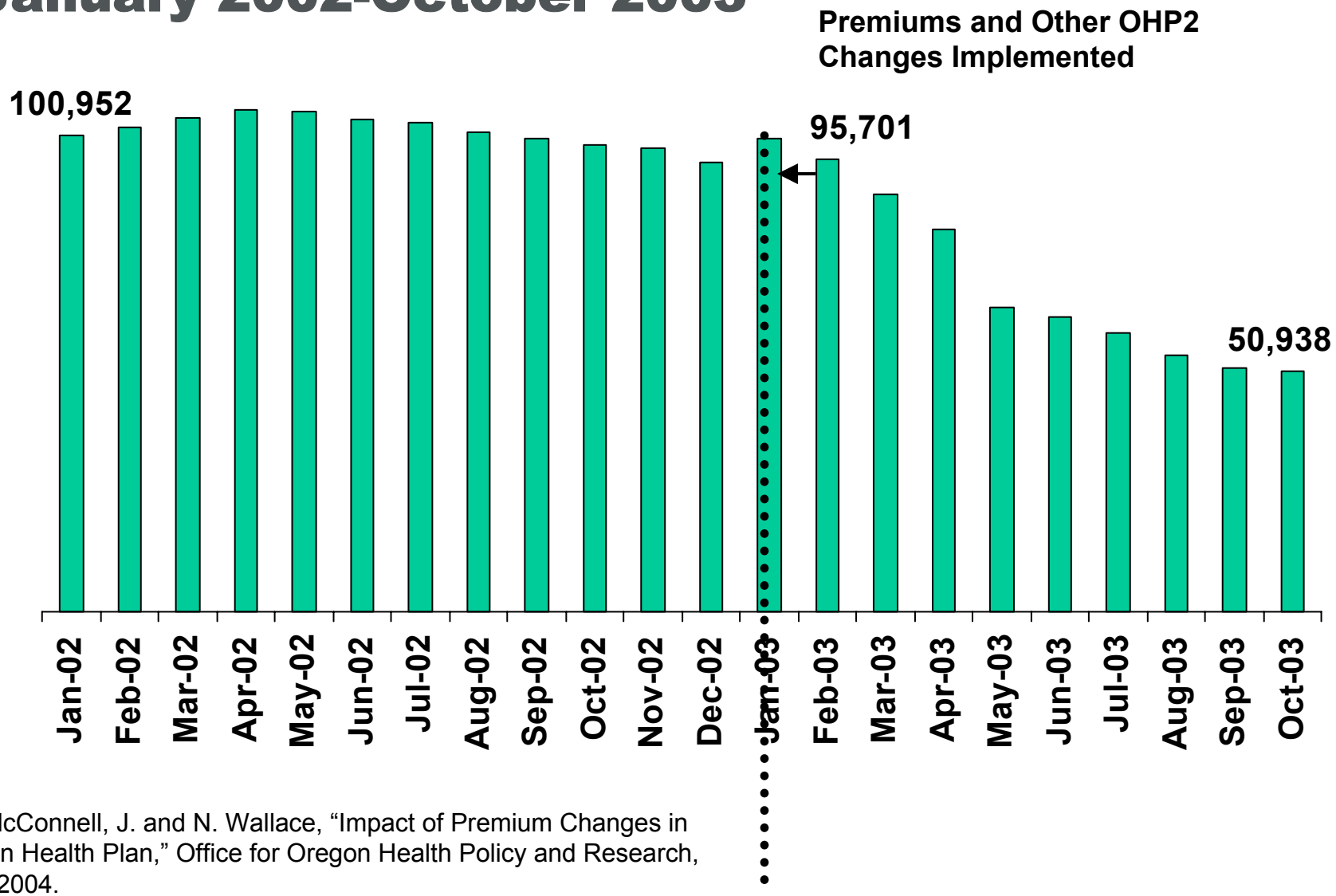
DRA #2: State Option to Charge Premiums

- Allows states to condition Medicaid coverage on beneficiary payment of premiums. § 6041(a).
  - After 60 days of non-payment of premium, state may terminate eligibility of individual
- Premiums limited by federal law:
  - Between 100-150% (FPL), (and apparently all groups under 100% FPL) the state may impose no premiums)
  - Above 150% FPL, the state may charge premiums, and the total for a family of premiums plus cost-sharing for an individual item or service cannot exceed 5% of income.
  - Certain vulnerable groups are exempted from premiums and states may exempt additional groups. § 6041(a).

Implications of DRA #2

- Some individuals and families with incomes at or above 150% FPL may lose Medicaid eligibility as a result of non-payment of premiums.
- The number of uninsured individuals in a state may increase, if the Oregon Health Plan experience is any guide.
- Will this increase the number of people seeking pharmaceuticals through PAPs and SPAPs?

OHP Standard Enrollment
January 2002-October 2003



Source: McConnell, J. and N. Wallace, "Impact of Premium Changes in the Oregon Health Plan," Office for Oregon Health Policy and Research, February 2004.

DRA #3: State option to permit providers to require a beneficiary to pay cost-sharing as a condition of receiving care. § 6041(a).

- Three cost-sharing groups, including cost-sharing for any item or service (drugs have different limits)
  - Certain vulnerable groups are exempted from cost sharing, and states may exempt additional groups. § 6041(a).
  - Between 100-150% (FPL), cost-sharing may not exceed 10% of the cost of the item or service.
    - The total of cost-sharing plus premiums (including drug co-pays) for a family cannot exceed 5% of income.
  - Above 150% FPL, cost-sharing for an individual item or service cannot exceed 20%.
    - The total cost-sharing plus premiums (including drug coinsurance) imposed on a family cannot exceed 5% of income.

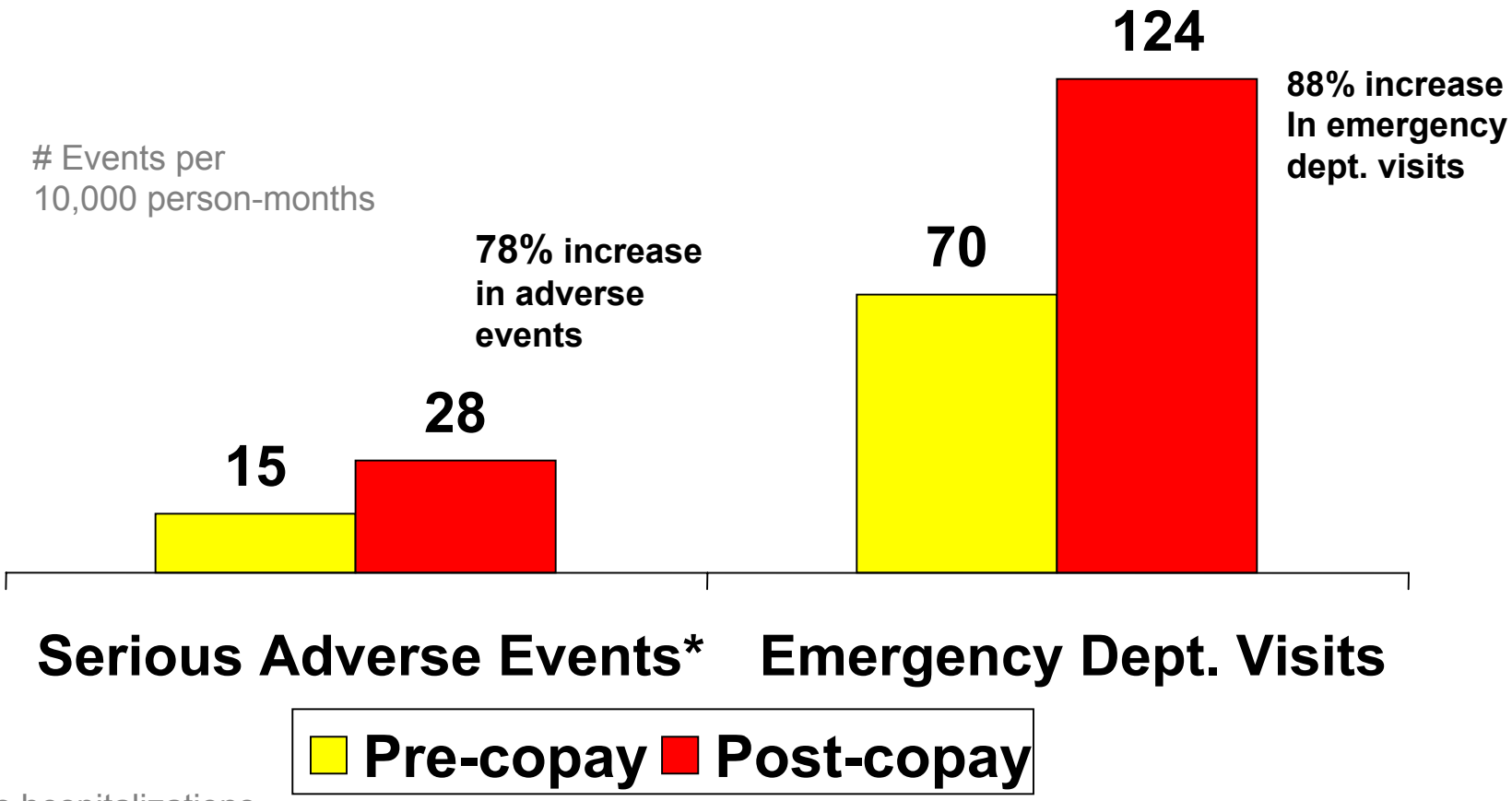
DRA #3, continued, Changes To Drug Copayments

- Beginning in 2006, requires HHS to update the amounts established as "nominal" cost-sharing each year in accord with the medical component of the CPI-U. § 6041(b).
- Allows states to impose higher cost-sharing for non-preferred prescription drugs. § 6042.
  - For beneficiaries below 150% of federal poverty level and for eligibility *groups that have been exempt* from cost-sharing, cost sharing for non-preferred drugs cannot exceed nominal amounts (as updated).
  - For beneficiaries above 150% FPL, cost sharing cannot exceed 20% of the cost of the drug.
  - If physician determines that the preferred drug would be ineffective or have negative side effects, the state may impose no more than the cost-sharing amount for a preferred product.
  - The State has flexibility to exclude specified drugs or classes of drugs from these cost-sharing rules.
- Allows states to permit pharmacy to refuse service for non-payment of copay

Implications of DRA #3

- If the state chooses, patients at all income levels may be exposed to drug copayments for *non-preferred* drugs.
  - There is no requirement that copayments be imposed on “preferred drugs”
  - There is no guideline on what preferred copayments may be (except for annual household limit)
  - There is no requirement that a state use any particular criterion for deciding which drugs are “preferred.”
- If the state permits pharmacies to refuse to dispense the drug for non-payment of the copay, more patients may go without prescriptions.
  - Where the coinsurance is 10% or 20% of a costly drug, will these denials put further pressure on manufacturer PAPs?
  - Where pharmacies choose to take a loss on the copay, will they pressure manufacturers – notwithstanding the fraud and abuse laws?
- Assuming that these copayments are imposed within the FFS drug benefit, manufacturers will still be obligated by federal law to pay the federal rebate when a drug is dispensed; supplemental rebates also will be required as negotiated by individual manufacturers.

Drug Copayments Reduced Use of Essential Medications



*Includes hospitalizations, institutionalizations, and deaths

Source: R. Tarnblyn et al. JAMA 285(4):421-9, 2001.

DRA #4
Mandatory Changes to Drug Payment

- Applies a new federal upper limit (FUL) formula to multiple source drugs equal to 250% of the average manufacturer price (AMP) of the least expensive therapeutic equivalent. DRA § 6001(a).
- Changes the definition of multiple source drug to include drugs with only one therapeutic equivalent; provides for more timely updating and monthly transmission of FUL list to the states. § 6001(a), (b)

DRA #5:
State Option to Use New Information in Setting Medicaid Drug "EAC" Payment

- Requires HHS to publish manufacturer-reported AMPs on a public website; requires monthly reporting of AMPs to the states beginning July 1, 2006. § 6001(b)
- Allows HHS to hire an outside contractor to survey retail prices for covered outpatient drugs on a monthly basis *and* to notify HHS when a generic is generally available on the market. § 6001(e).
- Requires HHS to disclose such retail survey data to the states on a monthly basis. § 6003
- Requires states to report annually on payment rates for drugs, dispensing fees, and utilization rates for non-innovator multiple source drugs. § 6001(e)
- Requires the Secretary to annually report on the top 50 drugs the national retail sales price and the payment rates established by the States. § 6001(e)

Implications of DRA #4 and #5

- State payment changes may cause pharmacy reimbursement for single source drugs to decline
- Unclear whether new payment for multiple source drugs may increase reimbursement to pharmacies for generics.
- Unclear whether “grandfathering” language will permit states to continue to establish their own MAC limits on payment for generics.

Medicaid Quotation from 2007 Budget

"Building on the HIFA initiative and the approaches adopted by innovative States such as Florida, the Administration will develop a new waiver initiative that emphasizes market-driven approaches to health care. In conjunction with the DRA, this approach allows States to emphasize expanding needed coverage to uninsured individuals and to promote greater continuity of coverage. This new model will stress consumer-driven approaches to health care with access to affordable coverage while giving States more tools to offer better health coverage to some current beneficiaries, as well as to individuals who are currently uninsured. By broadening choices and encouraging competition in the private market, Medicaid can continue to modernize through State-level reforms. The result will be more seamless access to coverage for low-income families and children in Medicaid, as well as to other uninsured persons with limited incomes."

CBO's 3.3.06 Preliminary Analysis of President's Budget

Figures are federal outlays by fiscal year, in millions of dollars. Please refer to the notes at the bottom for additional information.

	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2006-11	2006-16
Prescription drug proposals													
Reduce FUL to 150% of lowest AMP	0	-275	-425	-475	-550	-600	-675	-750	-825	-900	-975	-2,325	-6,450
Allow states to have closed formularies	0	-10	-25	-40	-60	-65	-75	-80	-90	-100	-110	-200	-655
Replace best price with flat rebate	0	0	0	0	0	0	0	0	0	0	0	0	0
Subtotal	0	-285	-450	-515	-610	-665	-750	-830	-915	-1,000	-1,085	-2,525	-7,105

Implications

- Waivers have the potential to further limit access and benefits
- The precedent set by the “HIFA” waivers is to scale back benefits in order to expand eligibility
  - The zero budget baseline for the *federal* government is a new twist on an old guideline
- The Administration’s willingness to permit “hard limits” on the number of prescriptions is troubling for the industry

DRA#6: Fraud and Abuse

- **Encouraging the Enactment of State False Claims Acts**. Section 6032. effective January 1, 2007, provides financial encouragement to states to have in effect a law dealing with false or fraudulent claims that meets certain federal requirements. If states have such a law in place, when recoveries are made for Medicaid funds improperly paid, the share owed to the federal government will be decreased by 10 percentage points.
- **Employee Education About False Claims Recovery**. Section 6033, effective January 1, 2007, requires states to ensure that any entity receiving Medicaid payments of at least $5 million per year must establish written policies with information about the federal False Claims Act; state laws regarding civil or criminal penalties for false claims and statements; and whistleblower protections. **Section 6035: Medicaid Integrity Program**
- **Enhancing Third Party Identification and Payment**. Section 6036 would require states to determine if third party liability exists (in order to avoid the use of Medicaid funds) for additional entities: self-insured health plans; pharmacy benefit managers; and other parties legally liable by statute, contract, or agreement for payment of a health care claim or services. These organizations would be prohibited from taking an individual's Medicaid status into account in enrollment or making payments.
- **Improved Enforcement of Documentation Requirements** requires individuals to present documentation of citizenship or nationality when they apply for Medicaid benefits. Failure to present such documentation will make them ineligible for Medicaid services.

DRA#6: Emergency Room Co-payments for Non-Emergency Care

- Section 6043 creates another state option permitting states to submit a state plan amendment allowing hospitals to impose cost sharing for non-emergency services (defined as "any care or service furnished in the emergency department of a hospital that the physician determines does not constitute an appropriate medical screening examination or stabilizing examination and treatment required to be provided by the hospital") provided in hospital emergency rooms, if they follow strict notice requirements. This provision requires that the beneficiary receive a medical screening (as defined in Medicare law) and a determination by the emergency room that the beneficiary does not have an emergency medical condition. Before non-emergency care is provided, the beneficiary must be told that:
  - the hospital can require a co-pay before the non-emergency service is provided;
  - the name and location of an alternate non-emergency provider (that is available and accessible) that may charge a lower co-pay;
  - the alternate non-emergency provider can provide the services with a lower or no co-pay;
- Alternate non-emergency providers include physicians' offices, health care clinics, community health centers, and hospital outpatient departments. Such providers must be able to diagnose or treat a condition "contemporaneously" - i.e. within the same amount of time as a hospital emergency room would have taken to provide the non-emergency services.
- Co-pays for non-emergency services in an emergency room for beneficiaries under 100% FPL cannot be more than twice the nominal amount (i.e. currently $6.00 – twice the nominal $3.00 limit).