2007 State Perspectives Medicaid Pharmacy Policies and Practices
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Over the last decade, states implemented aggressive and creative strategies for mitigating the double digit rate of growth in Medicaid pharmacy programs. Introduction of Preferred Drug Lists, particularly in combination with negotiating supplemental rebates from manufacturers, was perhaps the most successful tool used by many states to moderate the rate of growth. These strategies leveraged the significant volume of prescriptions purchased by Medicaid to obtain more favorable net pricing for brand name drugs.

In recent years, however, states have seen a dramatic drop in the size of directly-administered Medicaid pharmacy programs. The Medicare Modernization Act of 2003 created Medicare Part D, which established pharmacy coverage for all Medicare beneficiaries, including dual eligibles, effective January 1, 2006. Transitioning dual eligibles away from full pharmacy coverage under Medicaid to Part D has resulted in many states reporting a significant decline in the number of prescriptions filled under the Medicaid program. In addition, states continue to increase their reliance on Medicaid-contracting managed care organizations, often including the cost of drugs in the capitation rates to managed care organizations. While total state funds spent in Medicaid for pharmacy services has not declined in most states, the portion of the pharmacy program directly managed by Medicaid in many states has been reduced, creating potential challenges to the volume-based pricing strategies employed with Preferred Drug Lists.

At the same time, federal reforms are placing new requirements on Medicaid pharmacy programs. In the U.S. Troop Readiness, Veterans’ Health Care, Katrina Recovery & Iraq Accountability Appropriation Act of 2007, Congress mandated that Medicaid programs require the use of tamper-resistant pads for written prescriptions (now expected to be implemented April 1, 2008). In the Deficit Reduction Act of 2005 (DRA), Congress adopted new provisions that were intended to improve the accuracy of pharmacy reimbursement. Reforms included defining Average Manufacturer Price (AMP), making AMP information publicly available, establishing new Federal Upper Limits for generic drugs, and requiring states to collect federal rebates for physician-administered drugs. The DRA also included provisions intended to enhance state flexibility in the design of pharmacy programs.

As a result, the last two years have been a challenging time for state pharmacy programs. While continuing to assist in the transition of vulnerable populations into a still unfamiliar Medicare pharmacy program, states must also find alternative strategies to offset declining purchasing power in the marketplace and implement or otherwise respond to new federal requirements and options.
Acknowledgements

This report is the second annual pharmacy report in a series published by the National Association of State Medicaid Directors (NASMD). Its purpose is to provide a better understanding of federal and state pharmacy initiatives faced by Medicaid pharmacy administrators.

Our report findings are based on survey responses received from states across the nation, the District of Columbia, and Puerto Rico. NASMD would like to thank the many Medicaid officials who completed the survey and responded to follow-up questions used to draft this report. We recognize that the survey required a coordinated response from various individuals within each Medicaid agency and appreciate the time and effort that was devoted to providing thoughtful and detailed information.

Deep appreciation is conveyed to the members of the NASMD and Centers for Medicare and Medicaid Services (CMS) Pharmacy Technical Advisory Group. The guidance from the group’s members was invaluable in the development of the survey instrument as well as the publication of this report.

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NASMD would like to thank its staff who worked on this project, including a former employee Andrea Maresca, who developed the survey questionnaire and Gregory Hunt, who sought clarification on state responses. Appreciation is extended to Health Management Associates for their assistance analyzing survey data and drafting this report.

In Appreciation,

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Executive Summary

The National Association of State Medicaid Directors (NASMD) surveyed pharmacy administrators from August through October 2007. Health Management Associates was commissioned to analyze survey data and draft a report to present at the annual fall NASMD meeting. This report is based on 50 responses received from states and the District of Columbia. Puerto Rico also responded to the survey, but its responses were limited to issues on tamper-resistant prescription pads. Following are key themes and findings of the 2007 pharmacy survey.

Key Themes & Findings

Medicare Part D Coordination

1. Despite Congressional expectations, most states continue to report the transition of dual eligibles to the Medicare Part D prescription drug program and the implementation of the Phased-Down State Contribution (the Clawback) have not resulted in significant state savings. Only ten states reported that they are paying less in 2007 for prescription drugs for dual eligibles than when the state provided drugs directly to this population.

2. States experienced a considerable drop in the number of prescription drug claims covered by Medicaid as a result of Part D coverage for dual eligibles; 17 percent of states report a reduction in the supplemental rebate arrangements between Medicaid and manufacturers since Part D implementation.

3. Most states have not implemented wrap-around Medicaid coverage for Part D cost sharing amounts for low-income subsidy beneficiaries, but do allow retroactive billing by nursing home pharmacies up to the date of Part D enrollment.

Impact of DRA ’05 Medicaid Reforms

4. Impacts of Federal Upper Limits (FUL) based on Average Manufacturer Prices (AMP) cannot be fully assessed until after the first release of new FULs in December 2007. Twelve states reported that they may increase the pharmacy dispensing fees paid in response to the provisions in the Deficit Reduction Act of 2005 (DRA) and the new federal regulations.

5. Over 75 percent of the states report that they are not actively considering adoption of AMP-based reimbursement for brand name drugs.

6. 26 states’ claims processing systems now collect National Drug Codes for physician-administered drugs—up from the seventeen reported in 2006. This is necessary to support billing manufacturer rebates for multiple-source drugs, as required by the DRA. Another 19 states reported working on system upgrades to allow National Drug Code collection.
Medicaid Managed Care and Pharmacy

7. Most states continue to allow managed care organizations considerable flexibility developing drug formularies and managing prescription drug benefits for Medicaid enrollees.

8. 11 states reported carving out all classes of drugs from managed care arrangements, up from nine in 2006, which may in part reflect the financial value of full federal and supplemental rebates otherwise lost or dramatically reduced when drug costs are included in capitation rates paid to managed care organizations. Nine states reported carving out some drugs, most often drugs for treatment of mental illness and HIV/AIDS.

Prescription Drug Purchasing Pools

9. The number of states participating in a multi-state purchasing pool has increased to 24, compared to 17 in 2006, with participating states reporting increased savings in terms of manufacturer rebates.

Pharmacy Management Strategies and Policy Decision-Making

10. 29 states have implemented (or plan to) steps to contain costs for mental health drugs. Actions include preferred drug list approaches for atypical antipsychotics, antidepressants, and attention deficit hyperactivity disorder drugs.

11. Only three of 43 states reported implementing new or increased cost-sharing for brand name drugs in 2007; nine of 50 states reported having enforceable cost-sharing for drugs, while 21 states reported giving pharmacists the discretion to waive cost-sharing.

12. Overall, states reported relying on evidence-based research (e.g., Comparative Effectiveness Reviews, research from peer reviewed journals, etc.) more heavily than on supplemental rebate information when establishing coverage policy.

Tamper-Resistant Prescription Pads

13. The six month implementation delay for Medicaid tamper-resistant prescription pads is welcomed. However, additional guidance on “industry-recognized” tamper-resistant features and acceptable vendors is needed.

14. State officials question the rationale for having tamper-resistant policies for Medicaid that differ from those of other payers (particularly Medicare). Also, states note that having different Medicaid policies from state-to-state could be problematic for healthcare providers who serve patients in multiple states.

15. Some states predict that monitoring pharmacies for prescriber compliance will be difficult and that some prescribers with low Medicaid volumes may discontinue program participation as a result of this new Medicaid-specific requirement.

For additional information, please see:
Appendix A—Survey Design and Methodology
Appendix B—Glossary
Appendix C—State-By-State Data Charts
Snapshot of Medicaid Pharmacy Programs

**Medicaid Demographics**
At the end of 2006, there were nearly 45.2 million Medicaid beneficiaries. Approximately 41 percent were enrolled in capitated managed care plans rather than a traditional fee-for-service or primary care case management (PCCM) model. Nearly 17 percent (7.7 million) of Medicaid beneficiaries are dual eligibles who receive full or partial Medicaid benefits along with Medicare coverages.

**Medicaid Spending on Prescription Drugs**
Medicaid provided 19 percent of the total national prescription drug spending in 2005. On January 1, 2006, most prescription drug coverage for dual eligibles shifted from Medicaid to Medicare Part D.

- This change was estimated to reduce Medicaid prescription drug spending by 45 percent across the nation. Included is the reduction in federal funding that matched state Medicaid pharmacy spending on dual eligibles prior to Part D.
- States must help finance Part D costs for the dual eligibles through the Phased-Down State Contribution (commonly called the Clawback).
- Part D excluded drug classes (if covered for non-dual populations) and cost sharing amounts on Part B drugs remain Medicaid coverages.

**Medicaid Pharmacy Benefit Design**
All Medicaid programs reimburse for prescription drugs. Each has flexibility to adopt its own policies for preferred drug lists, supplemental manufacturer rebates, utilization controls, patient copayments, etc. as illustrated below.

- Preferred Drug Lists—44 states have implemented their own preferred drug lists to encourage the use of clinical and cost effective drugs.
- Patient Copayments—42 states had implemented patient cost sharing on prescription drugs as of October 2006.

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2. Medicaid Managed Care Penetration Rate & Expansion Enrollment by State (as of December 31, 2006) available at [www.hhs.cms.gov](http://www.hhs.cms.gov)
4. Ibid.
Impact on Dual Eligibles

- 29 of 46 states reported that from ten to 20 percent of the state’s total Medicaid population transitioned to receive prescription drug coverage through Medicare Part D; seven states reported less than ten percent of the Medicaid population transitioned, while others reported percentages from 21–60 percent. Some states noted the higher percentages represented the percentage of the state’s remaining Medicaid fee-for-service population moving to Part D.
- Table 1 in Appendix C lists states providing Medicaid coverage for Part D cost sharing.
- Eight of 47 states require nursing home residents who are enrolled in a Part D plan that is above the benchmark premium at the time they become eligible for Medicaid to enroll in a benchmark plan instead; nine states allow Long-Term Care facilities to deduct payments for Medicaid enrollees whose Part D premiums are above the benchmark prescription drug plan (PDP).
- 18 of 48 states reported that nursing home residents covered by Part D experience difficulty in accessing subsidized medication under Part D occasionally or frequently; 20 states reported that they did not know if this was a problem.
- 57.1 percent of 49 responding states allow retroactive billing for Medicaid long term care beneficiaries, up to the date of Part D enrollment.

Cost of Part D for State Medicaid Programs

- 14 of 48 states reported they are paying about the same for prescription drugs under Part D as when the state provided coverage directly through Medicaid; 11 states report they are paying more, while ten states report paying less. (Figure 1)
- States reported a significant decrease in the number of prescriptions paid by Medicaid since the Part D implementation. 13 of 48 states reported that, overall, the number of prescriptions decreased by 40–55 percent or more. Six states reported decreases of 25–39 percent. States often reported a larger reduction in the number of brand name prescriptions in comparison to generic prescriptions.
- Ten of 41 states reported a change in the state’s supplemental rebate percentage that is due to the fact that dual eligibles no longer are covered under the Medicaid drug benefit. Overall, 20 states reported that supplemental rebates are unchanged or increased since July 2006, with seven states reporting a decrease in rebates.
- Nine of 49 states reported that Part D implementation has impacted the calculation of budget neutrality under a Medicaid waiver.
- 17 of 49 states reported that nursing home pharmacies submit bills to Medicaid “occasionally” or “frequently” that should have been paid under Medicare Part B or Part D; 18 did not know if this was a problem.

Quality and Care Management

- 98 percent of 49 responding states reported not lifting utilization management controls even though many chronic care patients have transitioned to Part D.
- Only three of 49 states do (or plan to) work with Medicare Advantage or PDP Medication Therapy Management programs to coordinate Part D.

Medicare’s Part D Prescription Drug Benefit

The Medicare Part D drug benefit became the primary pharmacy coverage program for over 6.2 million dually eligible Medicaid beneficiaries on January 1, 2006. Prior to 2006, these individuals received drug coverage from state Medicaid programs. Individuals who are dually eligible automatically qualify for financial assistance under Part D, assuring that they have no monthly premiums (up to a benchmark level) and do not experience the gap in coverage otherwise known as the “doughnut hole.” However, non-institutionalized dual eligibles are still responsible for reduced drug copayments.
Key State Issues with Part D

State issues regarding Part D implementation and its operation involve three major areas. The first is the impact on individuals who must now rely on Medicare for most drug coverage rather than Medicaid, especially the impact of copayments and access to the drugs that are excluded from coverage under Part D.

The second area of concern relates to cost implications for state Medicaid programs. Cost impacts include the state payments to Medicare to cover a share of the Part D costs for dual eligibles (the Clawback payments), any impact that the shift in pharmacy spending away from Medicaid might have on state supplemental rebate programs, and the cost of any wrap-around coverages that states may choose to provide to the population.

The third area of concern relates to the impact on quality and care management, regarding both state loss of control over low-income Medicare beneficiaries’ prescription drug use and also any collaboration that might develop between state programs and a federally required Part D plan Medication Therapy Management Program (MTMP).

Figure 1: Dual Rx Costs—Estimated State Cost Impact After Part D

Legend:
- More
- About the Same
- Less
- Unknown or Preferred Not to Answer

Source: NASMD 2007 Rx Survey
For decades, the Centers for Medicare and Medicaid Services has set rates on multiple-source generic drugs called Federal Upper Limits (FULs). States have the option to use the FULs or their own Maximum Allowable Costs (MACs)—as long as payments for multi-source generic drugs do not exceed FULs, in aggregate. DRA changed the FUL calculation process. Another DRA provision revised the definition for Average Manufacturer Price (AMP) used in the new FUL calculation and made the previously confidential AMPs publicly available on all drugs. The first new FULs under DRA provisions will be published December 30, 2007, and monthly thereafter. After the monthly FUL distribution, states have 30 days to implement needed changes or risk losing federal funding. On July 17, 2007, CMS issued final regulations on AMPs, FULs, and other DRA pharmacy require-

<table>
<thead>
<tr>
<th>Changes</th>
<th>Pre-DRA</th>
<th>Post-DRA</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>FUL Calculation</td>
<td>Average Wholesale Price (AWP) + 150 percent of least costly therapeutic equivalent</td>
<td>Average Manufacturer Price (AMP) + 250 percent of least costly, widely available therapeutic equivalent</td>
<td>Unknown, until first release of new FULs on Dec 30, 2007</td>
</tr>
<tr>
<td></td>
<td>Uses the smallest package size commonly purchased (e.g. bottles of 100 versus 1000 tablets)</td>
<td>• Uses weighted average price for all packages</td>
<td>Pharmacies are asking many Medicaid programs for higher dispensing fee rates to cover presumed lower generic payments resulting from the DRA changes</td>
</tr>
<tr>
<td>FUL Drugs</td>
<td>Three or more sources available (Innovator Brand + two Generics)</td>
<td>Two or more sources available (Innovator Brand + one Generic)</td>
<td>FULs on more multi-source drugs</td>
</tr>
<tr>
<td>FUL Updates</td>
<td>Quarterly (but usually less frequent)</td>
<td>Monthly</td>
<td>More frequent FUL price updates</td>
</tr>
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**Impact of DRA Medicaid Rx Reforms**

Federal Upper Limits & Average Manufacturer Prices
ments. Interestingly, CMS allowed another comment period on the AMP and FUL provisions in the final regulations. This second comment period ends January 2, 2008. See Appendix C, Table 2 for details of state level processes required to implement selected pharmacy changes under the DRA.

FUL Changes for Multiple-Source Generic Drugs

Although DRA changes the FUL calculation, federal regulations still allow states to adjust multiple-source generic drug prices—as long as, in aggregate, FULs are not exceeded. Many states believe it is too early to fully understand the impact of reforms prior to the anticipated release of the first new AMP file in December 2007. However, one state expressed concern that decreased reimbursement could result in rural pharmacies going out of business. Another doubted whether the current AMP data from CMS could be relied upon to estimate new FUL rates. Another state was concerned that states face an administrative burden under the new standards if they cannot accurately project what aggregate utilization will be.

Some states reported that they believe their current MAC programs are more aggressively priced than the expected revised FULs.

General Accounting Office (GAO) 2006 Findings

One state noted the “GAO report indicated that this [the FUL changes] may have a negative impact because pharmacies may be reimbursed less than actual acquisition cost.” From a sample of 77 most frequently used drugs, the GAO found that DRA’s AMP-based FULs were 36 percent lower than average retail pharmacy acquisitions costs. CMS commented the GAO findings were not valid for several reasons including the GAO study did not account for changes published in the July 2007 final regulations.

Dispensing Fee Increase Because of FUL Change

Pharmacy associations have asked states to increase dispensing fees to offset perceived losses resulting from DRA and CMS regulations.

- 12 of 50 states indicated they were very likely or likely to increase their dispensing fee.
- 15 states said no change was likely.

AMPs and Brand Name Drug Reimbursement

Revised AMPs calculated under DRA provisions should be available to states in December 2007. There has been some expectation that states may use the AMPs for brand name drugs. (Figure 3)

When asked whether their program was considering basing its pharmacy reimbursement on AMP:

- Nine of 50 states indicated consideration of AMP-based reimbursement was likely or very likely.
- 15 states indicated use of AMP-based reimbursement is not very likely or not likely.
- The remaining states did not report consideration of AMP-based reimbursement.

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FIGURE 3  States Considering AMP Reimbursement for Brand Name Drugs

LEGEND:
- Yes
- No
- Unknown or Preferred Not to Answer

Source: NASMD 2007 Rx Survey
Impact of DRA Medicaid Rx Reforms

Pharmaceutical Coverage under the Medical Benefit

Deficit Reduction Act of 2005 Mandates Rebate Collection on Physician-Administered Drugs

The DRA mandates that Medicaid programs collect manufacturer rebates for certain physician-administered drugs billed on the professional and institutional medical claim formats. Requirements include that states must bill rebates for sole-source drugs beginning January 2006 and for the top 20 multiple-source drugs by January 2008. States not complying by January 1, 2008, will risk loss of federal matching funds.8 The Healthcare Common Procedure Coding System (HCPCS) codes for physician-administered drugs (frequently called J-Codes, as most begin with “J”) do not capture necessary detail to bill manufacturer rebates. Prior to DRA mandates, some states created bridges that linked J-Codes with National Drug Codes (NDCs). This strategy was successful for J-Codes that represented only one drug entity (a sole-source drug), but not for others that represent multiple-source drugs or different forms of a sole-source drug.

To comply with the DRA mandates, states are requiring that healthcare providers billing for physician-administered drugs with J-Codes also must supply National Drug Codes. The electronic 837 professional and institutional claim formats and the paper Health Insurance Claim Form (CMS 1500) include fields for National Drug Code entries. The paper Uniform Billing (UB-04) institution claim, however, does not.

Collection Manufacturer Rebates on Physician-Administered Drugs

- 28 of 50 states reported collecting rebates on some, but not all physician-administered drugs.
- 11 of 50 states reported collecting rebates on all physician-administered drugs.
- 26 of 50 states claims processing systems now collect National Drug Codes for physician-administered drugs. (Figure 4)
- 19 of 50 states reported working on system upgrades to allow National Drug Code for J-Codes.

Reimbursement on Physician-Administered Drugs

- When asked about the likelihood that the medical benefit’s drug reimbursement or physician fees for drugs would change from July 2007 to July 2008:
  - 50 percent said no change likely or very likely.
  - Two reported a likely increase.
  - One reported a likely decrease.
  - 14 were unsure whether changes would occur.

Others described:

- Rates adjusted annually or based on Medicare’s Average Sales Prices (ASP).
- Plans to change to a National Drug Code-based reimbursement scheme.
- Physician-administered drugs paid under the pharmacy benefit, but the drug administration fee is under the medical benefit.
- A physician administration fee decrease is likely.

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8 CMS identified the list of top 20 multiple-source physician-administered drugs. This list may be modified from year-to-year. Deficit Reduction Act of 2005, State Requirements Regarding Physician-Administered Drugs available at http://www.cms.hhs.gov/DeficitReductionAct/40_PhilicianAdministeredDrugs.asp
Policy for Physician-Administered Drugs

- When asked which area within Medicaid was responsible for management of physician-administered drugs:
  - 29 of 50 states responded the medical benefit.
  - 11 responded the pharmacy director.
  - Two indicated they were evaluating which area would manage these drug coverages.
- Several states commented that management was being transferred to pharmacy services or that a co-management approach was used.

Physician-Administered Drugs under Rx Benefit

- While not asked directly, three states (Hawaii, Missouri, and Pennsylvania) noted their policies mandate that most physician-administered drugs be billed under the pharmacy benefit, not the medical benefit.
- Respondents were asked to comment on “brown-bagging” policies that permit pharmacies to dispense (and be paid for) drugs which beneficiaries bring to a physician office for administration.
  - 31 of 50 states reported allowing brown bag policies; 13 states reporting not allowing this.
  - 14 states reported policies that explicitly discourage “brown-bagging”.

Prior Authorization (PA) on J-Codes

- 28 of 48 states reported using PA on J-Codes and another nine states reported using PA only sometimes.
Medicaid Managed Care and Pharmacy

Snapshot of Medicaid Managed Care
In 2004, 48 states plus the District of Columbia reported offering some form of managed care delivery arrangement as part of the Medicaid program. Models of managed care vary from state-organized and administered models (Oklahoma and Vermont) to Primary Care Case Management models to full risk contracts with licensed Managed Care Organizations (MCOs).

Enrollment of Medicaid beneficiaries in managed care arrangements continues to grow across the states, with 61 percent of beneficiaries enrolled in some form of managed care by 2004.9

Parents and children have traditionally been the most likely population groups enrolled in managed care, but states are increasingly including individuals with disabilities, especially those who are not dually eligible for Medicare. Some states also encourage Medicaid managed care for dual eligibles.

The increase in managed care enrollment often results in a reduction in the size of the fee-for-service pharmacy program managed directly by the state.

Manufacturer Rebates and Capitated Plans
Section 1927 of the Social Security Act precludes states from billing manufacturer rebates on prescriptions paid under capitation arrangements. Some states have opted to “carve-out” some or all prescription drugs from the capitation rates paid to managed care organization in order to qualify for manufacturer rebate revenue.

- 32 of 50 states reported offering MCOs.
- 15 of 30 states (up from 12 in 2006) reported that MCOs have a great or extreme amount of flexibility to establish a formulary; eight states report allowing a moderate amount of flexibility.
- 11 of 32 states with full-risk managed care arrangements carve-out all drugs from the MCO capitation rates, while nine states carve-out selected drug classes. Seven additional states reported considering carving all drugs out of the capitation rate in the past year. (Figure 5 and Appendix C, Table 3)
- 13 of 25 states (60 percent) with PCCM arrangements carved out all or selected classes of drugs from the PCCM payments.
- 16 of 47 states reported allowing Medicaid managed care plans to provide drug coverage to aged, blind or disabled populations (unchanged from 2006). None of these states reported requiring any special pharmacy provisions for Aged, Blind, and Disabled (ABD) enrollees (e.g., special restrictions on prior authorization, quantity limits, generic substitutions, etc.).
- 11 of 46 states report using the actual rebate experience of managed care plans in setting capitation rates, while eight states used the state’s federal rebate levels.

9 “Medicaid Managed Care and Traditional Enrollment, 1990-2004” Exhibit 2.16, Trends and Indicators in the Changing Health Care Marketplace, Kaiser Family Foundation, 200X.
FIGURE 5

Rx Carve-Outs From Managed Care Capitation Rates

LEGEND:
- No Carve-Out
- Full Carve-Out
- Partial Carve-Out
- Not Applicable
- Data Unavailable

Source: NASMD 2007 Rx Survey
Multi-State Prescription Drug Purchasing Pools

State Supplemental Rebates
In 2004, CMS approved states’ ability to form multi-state prescription drug purchasing pools. A number of states have formed purchasing coalitions to negotiate additional manufacturer rebate contracts on prescription drugs purchased for Medicaid. Participating states often report that these partnerships have helped to reduce Medicaid fee-for-service spending on prescription drugs.

The three multi-state purchasing pools at present are:

- The First Health Multi-State Pooling Agreement (called the National Medicaid Pooling Initiative), which received CMS approval in April 2004.
- The TOPS Pool run by Provider Synergies, which received CMS approval in May 2005.
- The Sovereign States Drug Consortium, administered by MedMetrics Health Partners, a nonprofit Pharmacy Benefit Manager, which became operational in 2005

Intra-State Prescription Drug Pools
In addition to multi-state pools that allow state Medicaid programs to join with other state Medicaid programs to negotiate rebates on prescription drugs, some states have experimented with intra-state pools, where the state Medicaid program partners with other public sector health care purchasers or providers within the state to negotiate prices or rebates for prescription drugs.

Multi-State Purchasing Pools
- 24 of 50 states participate in multi-state purchasing pools, up from 17 states in 2006. (Figure 6; see Appendix C, Table 4 for details)
- Several states reported increased savings as a result of joining a multi-state purchasing pool, ranging from increased savings of two point five to three percent of total drug costs for some states to an increase of ten percent over state specific rebate arrangements for others.
- Six of 24 states reported that their entry into a multi-state purchasing pool was triggered in whole or in part as a result of dual eligibles moving to Part D for drug coverage; one state noted that the increased enrollment in managed care arrangements within the state’s program had also reduced direct pharmacy purchasing and therefore contributed to the state’s interest in a multi-state pool.
- States that have not joined a multi-state pool most often reported that they believed their state-specific rebate arrangements to be more or similarly advantageous to a multi-state arrangement (eight of 38 states). Five states indicated that the state is presently either evaluating whether to participate in a multi-state pool or in the process of joining a pool. One state noted that it finds a strong emphasis on use of generics more financially advantageous than a supplemental rebate/Preferred Drug List (PDL) approach for trade drugs; another state noted that almost all prescription drugs are purchased through managed care arrangements, negating the need for a state-level PDL/supplemental rebate program.
- All states participating in multi-state pools reported that the state retains flexibility in creating preferred drug lists.
- 16 of 24 states reported operational savings (excluding rebates) from participating in a multi-state pool. Savings ranges from under one million dollars (four states) from one to six million dollars (two states) to more than six million dollars (six states).
Intra-State Purchasing Pools

- No state reported participation in an intra-state purchasing pool at the time of the 2007 survey. This compares with three states which reported such participation in 2006 (New York, Louisiana and Washington).

- Three of 24 states reported considering participation in an intrastate purchasing pool. Two states noted that their states’ intrastate pools only accommodated state operated facilities or other programs that actually dispense drugs. One state noted that a Medicaid state plan amendment regarding participation had been denied.
Pharmacy Management Strategies and Policy Directions

Medication Therapy Management Programs
Many Medicaid programs have developed medication therapy management initiatives. Such programs focus on polypharmacy with its unwanted duplication of drugs and risks of drug contraindications and drug-drug interactions. Patients targeted for medication therapy management programs include those with complex medication regimens. Operationally, medication management programs manage medications in the context of comprehensive medical and multiple provider histories and conduct regular drug utilization reviews.

Evidence-Based Medicine
Medicaid programs are using evidence-based review to formulate their pharmacy policies. Clinical evidence review and advice from medical experts help develop pharmacy utilization management tools that assure cost effectiveness and higher quality of care. One example is the Drug Effectiveness Review Project coordinated by the Oregon Health and Science University’s Center for Evidence-Based Policy. 14 states participate in this project.

Pharmacy Management Strategies

Generic Dispensing Requirements
- 29 of 48 states reported mandatory generic substitution policies. Seven indicated none.
- 12 states listed details on their generic policies (e.g., brand coverage is allowed with prior authorization; generic requirements are limited to select multiple-source drugs with federal or state imposed pricing ceilings). Two states commented that generic dispensing requirements could be bypassed with a Dispense As Written notation on the prescription.

*ePrescribing (eRx)*
- Six of 48 states are implementing a Medicaid eRx program; 25 states noted eRx was being developed; and one state is involved in an all payer eRx collaborative.

Mental Health Drugs
- 29 of 47 states reported their programs had implemented (or plan to) steps to contain costs for mental health drugs. Ten states indicated no such plans.
  - Some states have included atypical antipsychotics, antidepressants, and attention deficit hyperactivity disorder drugs in their Preferred Drug Lists.
  - Other states had implemented medication management programs that provide prescribers best prescribing practices for specific behavioral health clients; implemented quantity limits on atypical antipsychotics; or begun to work with stakeholder groups to implement “limited steps” based on an evidence-based review process.
- One state reported cost efficiencies of $72 Per-member Per-month on implementing duplicate therapy edits for atypical antipsychotics.
- Several noted that legislation in their state restricts cost containment actions on mental health drugs.

Medication Management Programs
- 22 of 49 states reported that their state runs medication management or poly-pharmacy programs; six indicated such programs were under development. States described medication management initiatives including lock-in, prospective/retrospective Drug Utilization Review, and pharmacy case management programs.

Pay-For-Performance (P4P)
- One state reported a P4P initiative initiative for pharmacy services; nine states are considering P4P.
Pharmacy Payment Cycles, 2007

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<th>Timeframe</th>
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<td>8 to 14 days</td>
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<td>60 days (average)</td>
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Source: NASMD 2007 Rx Survey

Cost-Sharing

- Three of 43 states reported that they were implementing new or increased cost-sharing on brand name drugs in 2007.
- 36 of 50 states (82 percent) reported that cost sharing for physician administered drugs was not implemented or being considered, and five states reported such a change as unlikely, but not yet determined; one state reported copayments on physician-administered drugs under the medical benefit.
- Nine of 50 states reported enforceable cost-sharing for pharmacy, while 21 of 48 states pharmacists have the discretion to waive cost-sharing.

Decision-Making for Rx Coverages

- 96 percent of states reported no difference in their state pharmacy policies for the aged, blind, and disabled populations.
- States were asked to rate whether selected resources were useful in developing Medicaid pharmacy policies. Findings showed that decisions are based primarily on sound clinical, evidence-based research.

![Figure 7: Percentage of Resources Used for Rx Coverage Decisions, 2007](chart.png)
May 25, 2007 Mandate for Tamper-Resistant Pads

Signed on May 25, 2007, the U.S. Troop Readiness, Veterans’ Health Care, Katrina Recovery and Iraq Accountability Appropriation Act of 2007 required the use of tamper-resistant pads for all non-electronic prescriptions written for Medicaid beneficiaries. The mandate was to begin October 1, 2007.

August 2007 CMS Guidance\(^\text{10}\)

CMS clarified the mandate did not apply when a Medicaid managed care plan pays for a prescription or for electronic, fax, or telephone ordered prescriptions. CMS also listed the elements that define a tamper-resistant pad. For the initial roll-out, a prescription pad must contain *industry-recognized features* designed to do at least one of the following:

1. Prevent unauthorized copying of a completed or blank prescription form
2. Prevent the erasure or modification of information written on the prescription by the prescriber
3. Prevent the use of counterfeit prescription forms

No later than October 1, 2008, a prescription pad must contain all three of the foregoing characteristics. Failure of a state to enforce the use of a tamper-resistant pad may result in the loss of federal financial participation.

Mandate Delayed from October 2007 to April 2008

Both Medicaid officials and healthcare providers raised concerns regarding the short implementation timeframe for Medicaid tamper-resistant prescription pads. On September 29, 2007, President George W. Bush signed the “Extenders Law,” which delayed implementation from October 1, 2007 until April 1, 2008 (H.R. 3668).\(^\text{11}\)

Actions to Comply with the Federal Mandate for Medicaid Tamper-Resistant Rx Pads

Medicaid officials reported activities to comply with the new tamper-resistant prescription requirement, including (1) educational outreach to pharmacies, prescribers, managed care organizations, and advocates and (2) drafting needed statutes, rules, regulations, and policy changes.

One respondent asked whether CMS would consider the method described a healthcare provider as meeting “industry recognized features” as tamper-resistant. *A dentist generates his own prescriptions from the computer. They [the prescription blanks] have a four color prescription print that cannot be duplicated.*

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\(^{10}\) Dear State Medicaid Director Letter, SMDL #07-012, August 17, 2007, available at www.hhs.cms.gov

\(^{11}\) Medicaid Tamper-Resistant Prescription Delay, CMS Physician List Serve (CMS PHYSICIANODEL-L), October 1, 2007
Technical Assistance Desired By States

- Best practices from states which have implemented tamper-resistant pads, including procedures for secured mailing of pads.
- A list of companies providing compliant pads.
- A field on the National Council for Prescription Drug Programs claim format that identifies the media used to order a prescription.
- Additional CMS guidance on:
  - Enforcement and audit procedures.
  - Prescriptions written when Medicaid is a secondary payer.
  - Retroactive eligibility—prescriptions written on non-compliant pads prior to Medicaid eligibility.
  - Prescription orders from nursing homes and other long-term care facilities.
  - Definition of “industry-recognized features” for tamper resistant pads.

Implementation Challenges and Issues

- Provider resistance due to the cost of the prescription pads—especially if a provider serves a small Medicaid population.
- Hospitals will need to develop new forms for discharge instructions and prescriptions.
- The tamper-resistant pad mandate may conflict with state statutes “to decrease the burden on providers and to improve client access”.
- Providers serving patients from two or more states may face different policies.
- Medicaid beneficiaries may face restricted access to emergency prescriptions and reduced access to physician services (especially if requirements apply only to Medicaid).
- States lack resources to cover the costs to states and providers of implementing this mandate, including any required compliance audits.

June 2007 Tamper-Resistant Pad Requirements

- 43 states had no existing policy for tamper-resistant prescription pads on June 1, 2007.
- Six states had tamper-resistant pad requirements: New Jersey and New York for all payers, Florida and Mississippi for Medicaid only (Others did not provide details).
- California, Idaho, Indiana, Kentucky and Texas explained that tamper-resistant prescription pads are required for Schedule II prescriptions, regardless of payer (Others did not provide details).

To comply with the federal requirements for tamper-resistant prescription pads:

- 14 states reported that actions will depend on additional CMS guidance.
- Two states reported that new state legislation was needed.
- 13 states reported that state regulations or administrative code had to be approved or amended.

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12 Thirty-seven Medicaid officials replied to the survey before the tamper-resistant pad mandate was delayed from October 1, 2007 to April 1, 2008. Accordingly, comments related to tight implementation timeframes were not listed in this report.
The National Association of State Medicaid Directors (NASMD) 2007 Medicaid Pharmacy Survey was a web-based survey sent to Medicaid officials in the states, the District of Columbia, and the United States territories. Specific lines of inquiry included: (a) Medicaid pharmacy provisions of the Deficit Reduction Act of 2005; (b) drug reimbursement methodology; (c) Medicaid managed care formulary development; (d) supplemental manufacturer rebates and drug purchasing pools; (e) coordination with Medicare Part D; (f) the use of medication management programs; (g) tamper-resistant prescription pads; and (h) the use of evidence-based medicine when developing Medicaid pharmacy policy. Prior to the survey’s launch, survey questions were reviewed by the NASMD and Centers for Medicare and Medicaid Services Pharmacy Technical Advisory Group (TAG).

NASMD distributed the survey to Medicaid directors on August 6, 2007 including a text copy of the survey and a link to the web-based version. The survey instrument consisted of open-ended and multiple choice questions. In October 2007 Health Management Associates was commissioned to follow up with states not replying; to analyze response data; and draft a report to be presented at the fall NASMD meeting with state Medicaid directors.

Fifty-one responses to the survey were logged into the web application from August through mid-October. Most responses were received from Medicaid pharmacy directors (28); pharmacy consultants (five); or other pharmacy policy or operational staff (16). Responders also included two Medicaid directors. Included were 49 states, the District of Columbia, and Puerto Rico. South Dakota, the one state not responding, experienced key staffing changes during the survey period and subsequently was unable to complete the survey questions timely. The data and findings contained throughout this report are based solely on NASMD and Health Management Associates interpretations of the responses of Medicaid officials.

The following caveats should be noted when reviewing the report findings.

- Although 51 Medicaid officials participated in the survey, the number responding to an issue varied from question-to-question.
- Puerto Rico’s responses related only to issues on tamper-resistant prescription pads.
- Eight states provided hard copy or faxed responses that were entered into the web-based application by Health Management Associates staff.
- Given the dynamic nature of Medicaid policy, answers provided by respondents are subject to change and are descriptive of the Medicaid pharmacy policy environment as it existed when the responses were provided.
- 37 Medicaid officials replied to the survey before the tamper-resistant pad mandate was delayed from October 1, 2007, to April 1, 2008. Accordingly, respondent issues with tight time-frames are not included in this report.

APPENDIX A:
Survey Design and Methodology
APPENDIX B: Glossary

**AMP (Average Manufacturer Price)** means the price paid to manufacturers by wholesalers (and pharmacies purchasing directly from manufacturers) for drugs distributed to the retail pharmacy class of trade. Congress created AMP in 1990 as one of the benchmarks used to calculate federal manufacturer rebates. AMP is calculated as a manufacturer’s net sales divided by the number of units sold (e.g. tablets, capsules, milliliters, etc.). DRA changed AMP by defining which sales are included, e.g. nursing home pharmacy sales are not included, but mail-order pharmacy sales are included. DRA also stipulated that CMS make the previously confidential AMPs publicly available.

Federal law at Sec 1927 of the Social Security Act and regulations at 42 CFR 447.5204 define AMP as "The average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade. AMP shall be determined without regard to customary prompt pay discounts extended to wholesalers. AMP shall be calculated to include all sales and associated discounts and other price concessions provided by the manufacturer for drugs distributed to the retail pharmacy class of trade unless the sale, discount, or other price concession is [1] specifically excluded by statute or regulation or is [2] provided to an entity specifically excluded by statute or regulation."

**ASP (Average Sales Price)** means the weighted average of all non-federal sales to wholesalers and is net of chargebacks, discounts, rebates, and other benefits tied to the purchase of the drug product, whether it is paid to the wholesaler or the retailer. Medicare uses ASP-based payments for physician-administered drugs reimbursed under Part B.

**AWP (Average Wholesale Price)** means the list price from a wholesaler to a pharmacy. AWP is typically not the price paid as pharmacies negotiate discounts. AWP is not defined in federal Medicaid law or regulation.

**FUL (Federal Upper Limit)** The regulations at 42 CFR 447.514 explain "CMS sets federal upper limits (FULs) for multiple source drugs when two or more drug products are therapeutically and pharmaceutically equivalent in the most current edition of ‘Approved Drug Products with Therapeutic Equivalence’…"

DRA changed the FUL calculation from 150 percent of AWP to 250 percent of the AMP for the least costly therapeutic equivalent that is widely available (i.e., without regard to terminated products and outlier prices.)

A state may implement its own Maximum Allowable Cost (MAC) rates on multiple-source drugs—as long as its payments do not exceed FULs, in aggregate.

**MAC (Maximum Allowable Cost)** means payment ceilings on multiple-source drugs. State MACs must not exceed FULs, in aggregate, as required by 42 CFR 447.514 (b).

**WAC (Wholesale Acquisition Cost)** means the manufacturer’s list price to wholesalers or direct purchasers. WAC is not defined in federal Medicaid law or regulation.

**Brand Name Drug** means a single-source or innovator multiple-source drug.

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13 Ibid.
**Benchmark Benefit Plan** Under the Deficit Reduction Act of 2005, states can create benchmark equivalent plans for certain Medicaid populations that provide alternative Medicaid coverage packages. Benchmark plans must have coverage equivalent to one of the following: Federal Employee Health Benefits Plan, the plan offered to state employees, the HMO plan with the largest commercial enrollment in the state, or a plan approved by the Secretary of the Department of Health and Human Services.

**Budget Neutrality** A federal requirement of Medicaid Section 1115 waivers that a change to the Medicaid program not allowable by statute must not increase federal Medicaid costs above projected spending levels.

**Comparative Effectiveness Review** A report that synthesizes clinical evidence on effectiveness and safety comparisons among drugs in the same class.

**Drug Effectiveness Review Project (DERP)** is a collaboration of organizations that have joined together to obtain the best available evidence on effectiveness and safety comparisons between drugs in the same class, and to apply the information to public policy and decision making in local settings. Current DERP participating organizations include Arkansas, Canadian Agency for Drugs and Technologies in Health, Idaho, Kansas, Michigan, Minnesota, Missouri, Montana, North Carolina, New York, Oregon, Washington, Wisconsin, and Wyoming.

**Drug Compendia** provide listings of medically accepted uses for over-the-counter and prescription drugs. Listings frequently include information such as FDA-approved dosing and drug indications, and may also include other indications generally accepted by the medical community.

**Federal Rebate** [See Rebates, Federal]

**Innovator Multiple-Source Drug** means a multiple-source drug that held the original patent and that was approved under an original new drug application by the Food and Drug Administration.

**J-Codes** [See Physician-Administered Drugs]

**Medication Therapy Management Programs (MTMPs)** are intended to reduce polypharmacy issues, such as drug contraindications and drug-drug interactions. Targeted Medicaid beneficiaries are typically persons with complex medication regimens—such as Long-Term Care (LTC) beneficiaries and persons with mental illness. Operationally, MTMPs manage medications in the context of a comprehensive medical and provider history, and conduct regular drug utilization and drug regimen reviews.\(^{14}\)

**Multiple-Source Drug** mean there are multiple manufacturers for a drug that are pharmaceutical equivalents having the same active ingredient(s), the same dosage form, route of administration, and identical strength or concentration.\(^{15}\) These drugs include non-innovator drugs (often called generics) and the innovator drug that originally held the patent. Multiple-source drugs, rated as therapeutic equivalents by the FDA, are included the Federal Upper Limit process.

**National Drug Code (NDC)** means the unique 11-digit numerical code maintained by the FDA that indicates the labeler, product, and package size.\(^{16}\) The first five digits identify a drug’s manufacturer. The next four digits represent the manufacturer’s product code. Last two digits are the manufacturer’s package size code.

\(^{14}\) Reester, Tumlinson, and Blum, Dual Eligible Home and Community Based Waiver Program Participants and the New Medicare Drug Benefit, October 2005, www.kff.org


\(^{16}\) 42 CFR 447.502 Definitions
Physician-Administered Drugs means drugs administered to a patient in a physician’s office or outpatient hospital setting. Physician-administered drugs are typically billed to payers using Healthcare Common Procedure Coding System (HCPCS) codes on a medical professional or institutional claim form (not on a pharmacy claim). Many physician-administered drugs are injectables that have HCPCS codes being with a “J”—so often these products are called J-Codes.

Preferred Drug List (PDL) identifies a program’s preferred drug coverage based on clinical and cost effectiveness. A drug not on a Medicaid preferred drug list typically may be obtained with prior authorization.

Prior Authorization is a policy that requires prescribers or pharmacies to obtain approval for reimbursement. Prior authorization may be set for clinical reasons to assure appropriate use or on based on a product’s “non-preferred” status on a preferred drug list. This process includes a prescriber or pharmacy providing an appropriate medical justification for the use of the non-preferred drug.

Poly-Pharmacy means the practice of prescribing many prescriptions simultaneously for a patient.

Rebates, Federal Federal manufacturer drug rebates are mandated under Medicaid law at Section 1927 of the Social Security Act. The formula used to calculate federal rebates is complex. It uses Average Manufacturer Price and other pricing indices dependent on whether a drug is non-innovator (generic) or innovator (brand). The calculation is the same across all fee-for-service Medicaid programs. Federal rebate revenue is shared between the state and federal governments.

Rebates, State Supplemental Supplemental rebates vary from state-to-state—dependent on individual state negotiations with manufacturers. Manufacturers offer supplemental rebates in exchange for having their products receive preferred status on a state’s PDL. State rebate revenue is shared between the state and federal governments.

Sole-Source Drug means there is only one approved product available for that active ingredient, dosage form, route of administration, and strength.17

Wrap-Around Coverage refers to state payment for Part D patient cost sharing amounts or premium payments.

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### Table C1: Reported Medicaid Coverage of Part D Cost-Sharing for Individuals with Incomes Between 135-150 percent of the Federal Poverty Limit, 2007

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<th>Pay Part D Premiums for Individuals with Incomes Between 135 &amp; 150% FPL</th>
<th>Pay Part D Deductibles for Individuals with Incomes Between 135 &amp; 150% FPL</th>
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Appendix C: Table 1 continues on next page.
### TABLE 1  Continued

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### APPENDIX C: State-By-State Data Charts

**TABLE 2** Approval Process to Implement Selected Pharmacy Changes Mandated by the DRA, 2007

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<th>Approval Entity</th>
<th>Modify State Medicaid Payment Limits To Meet FUL Requirements on Generics</th>
<th>Switch from AWP to AMP Reimbursement For Brand Name Drugs</th>
<th>Change State Reimbursement Rates For Physician-Administered Drugs</th>
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18 Represents state process not CMS state plan approval.

*Appendix C: Table 2 continues on next page.*
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<th>Change State Reimbursement Rates For Physician-Administered Drugs</th>
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<td>Total (Y or N):</td>
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### APPENDIX C: State-By-State Data Charts

**TABLE 3**

Reported Medicaid Pharmacy “Carve-Outs” from Capitated Managed Care Rates

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<thead>
<tr>
<th></th>
<th>Not Applicable</th>
<th>No Rx Carve-Out</th>
<th>Full Rx Carve-Out</th>
<th>Partial Rx Carve-Out</th>
<th>Sample Drugs and Classes Included in Partial Rx Carve-Out</th>
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</tr>
<tr>
<td>California</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td>HIV/AIDS Drugs, Mental Health Drugs, Anti-Psychotics, Alcohol &amp; Drug Abuse Treatment</td>
</tr>
<tr>
<td>Colorado</td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
<td>HIV/AIDS Drugs, Mental Health Drugs, Anti-Psychotics, Alcohol &amp; Drug Abuse Treatment</td>
</tr>
<tr>
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<td></td>
<td></td>
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</tr>
<tr>
<td>Delaware</td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
<td>HIV/AIDS Drugs, Mental Health Drugs, Anti-Psychotics, Alcohol &amp; Drug Abuse Treatment</td>
</tr>
<tr>
<td>DC</td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
<td>HIV/AIDS Drugs, Mental Health Drugs, Anti-Psychotics, Alcohol &amp; Drug Abuse Treatment</td>
</tr>
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*Appendix C: Table 3 continues on next page.*
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<th>State</th>
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<th>Full Rx Carve-Out</th>
<th>Partial Rx Carve-Out</th>
<th>Sample Drugs and Classes Included in Partial Rx Carve-Out</th>
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## APPENDIX C: State-By-State Data Charts

### TABLE 4

**Reported Collection of State Supplemental Manufacturer Rebates and Participation in Multi-State Prescription Drug Purchasing Pools**

<table>
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<tr>
<th>Participates In Multi-State Drug Pool</th>
<th>Vendor for Multi-State Pool</th>
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\(^{19}\) National Medicaid Pooling Initiatives  
\(^{20}\) Sovereign States Drug Consortium

Appendix C: Table 4 continues on next page.
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