Prescription Drugs: Policy Options for States
Iowa Prescription Drug Interim Committee
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1. PRICING PROVISIONS

There are several basic approaches to directly addressing drug prices. Iowa already has a comprehensive Preferred Drug List (PDL) combined with rebate negotiation, and participates in the multi-state non-profit Sovereign States Purchasing Consortium, which increases purchasing clout by combining the purchases of several states. Nonetheless there may be additional savings to be had through increasing rebates in the following ways:

- **Negotiation of generic supplemental rebates.** If Iowa does not already do so, it should seek rebates from generic as well as brand name drugmakers. For example, the prices paid by the state of Maine for prescription drugs in its Medicaid program average around 50% of the "Average Wholesale Price" (AWP) as a result of both the federal Medicaid rebate, rebates through the state's supplemental rebate program, and a tiered Preferred Drug List (PDL). Link to presentation on Maine's purchasing savings: http://www.reducedrugprices.org/october2007portlandmeeting.asp

- **Converting the Recommended Drug List to a PDL.** Other states have made the choice to include mental health and other specialty drugs that Iowa list on its RDL on a PDL, achieving greater savings. Streamlined Prior Authorization (PA) and appeal procedures need to accompany such a change to insure patients who need non-preferred drugs receive them.

- **RFPs for specialty drugs.** It is likely that the rebates for specialty drugs are minimal, if the experience in Iowa is similar to the experience in other states. These drugs are the fastest growing, most expensive component of Medicaid and Corrections pharmacy spend. One option may be to issue an RFP for specialty drug purchases to increase rebates and better manage these drugs. Maine opted for this approach after also investigating 340B options which may also be effective for certain specialty drugs administered at FQHC's (HIV, hemophilia). See also 340B discussion below.

In addition to the rebate approach to negotiating prices, some states are more directly addressing drug pricing through anti-price gouging provisions, reference pricing and laws giving authority to the state or to consumers to go to court to reduce drug prices under certain circumstances. There are some state examples on the books; these laws probably could be improved upon to address practical and legal issues:

- ***Co-pay provision.*** **Maryland has** enacted HB 1033, Chapter 638, which prohibits insurers from imposing a copayment requirement for a covered drug or device that

exceeds the retail price of the drug or device.[1] **Maine** passed a similar law, LD 807, Public Law Chapter 431, which requires a pharmacy benefits manager or insurer to require a contracted pharmacy to charge to an enrollee or insured person the pharmacy's usual and customary price of filling the prescription or the contracted copayment, whichever is less.[2]

- ***Colorado Price gouging law:*** Says emergency drug shortage may be declared to prevent practice of unfair drug pricing, defined as charging 10% more than pre-shortage price (SB 05-22, signed in April 2005). This law is fairly typical of several such laws around the country. Has limited effect (emergencies).

- ***West Virginia Reference Pricing***: Includes both price-gouging language and provisions providing for reference pricing as the basis for negotiating prices. Defines as unlawful restraint of trade or unreasonable commerce actions to fix, control or maintain the market price, rate or fee of pharmaceuticals; to allocate or divide customers or markets; or to establish, maintain or use of a monopoly to exclude competition or control, fix or maintain pharmaceutical prices. Also gives state Pharmaceutical Costs Management Council authority to establish a "reference price" based on FSS and excluding advertising & marketing costs. West Virginia recently adopted rules for marketing cost disclosure as part of its plan to implement this provision.

- ***Maine Rx Pricing Provisions.*** Maine law contains provisions *(never implemented)* providing for the setting of maximum retail prices for prescription drugs sold in the state based on whether the cost of prescription drugs provided to qualified residents under the Maine Rx Plus Program is "reasonably comparable" to the lowest cost paid for the same drugs delivered or dispensed retail. The Maine Rx price is generally the Medicaid price. This provision was enjoined by the District Court on Commerce Clause grounds and the state did not appeal. As the state interprets the court decision, it may only enforce this provision as top pharmacies, not manufacturers.

- ***Wisconsin Best Price Law:*** Wisconsin has a similar provision which has not been challenged, W.S.A. 100.31, "Unfair discrimination in drug pricing." The law requires "every seller" to "…offer drugs from the list of therapeutically equivalent drugs published by the federal food and drug administration to every purchaser in this state, with all rights and privileges offered or accorded by the seller to the most favored purchaser, including purchase prices for similar volume purchases, rebates, free merchandise, samples and similar trade concessions," which would appear to

[1] Law accessed at: http://mlis.state.md.us/2007rs/billfile/HB1033.htm.
[2] Law accessed at: http://janus.state.me.us/legis/LawMakerWeb/externalsiteframe.asp?ID=280023388&LD=807&Type=1&SessionID=7

include the excellent Medicaid or FSS price. The law provides for treble damages and injunctive relief.

- Link to Wisconsin pricing law: http://www.reducedrugprices.org/read.asp?news=335

2. PRICE DISCLOSURE

- ***Pharmacy prices.*** Quite a few states (including Michigan, New Jersey, New York) provide for the posting of drug pricing information on a website. This enables consumers to compare prices among pharmacies. There can be significant differences from pharmacy to pharmacy for particular drugs. This approach does not deal with excessive drug pricing set by manufacturers, and can lead to consumers shopping at multiple pharmacies. Some question whether this is a good idea since multiple pharmacists may not catch drug interactions; moving to electronic records that can be exchanged between pharmacies would address this concern.

- ***Retail price disclosure.*** Maine has a provision requiring the retail price to be printed on the receipt even when the purchaser pays only a copay.

- ***Generic pricing disclosure and pass-through provisions.*** West Virginia requires "(e]very pharmacy [to] post in a prominent place that is in clear and unobstructed public view, at or near the place where prescriptions are dispensed, a sign which shall read: West Virginia law requires pharmacists to substitute a less expensive generic-named therapeutically equivalent drug for a brand name drug, if available, unless you or your physician direct otherwise." The sign must be of a size and clarity as prescribed by the WV Board of Pharmacy, §30-5-12b(o). Pharmacies are required to maintain a record of any substitution of an equivalent generic name drug product for a prescribed brand name drug product.

  The law further requires pharmacists to substitute therapeutically-equivalent generic drugs for brand-name drugs unless the pharmacist or prescribing practitioner believes the brand-name drug is medically necessary for the patient, WV Code §30-5-12b(b), and mandates that pharmacists pass on to purchasers the cost-savings realized by the pharmacies' lower acquisition cost of generic drugs. Specifically, the statute requires that "[a]ll savings in the retail price of the [generic] prescription shall be passed on to the purchaser," and that "in no event shall such savings be less than the difference in acquisition cost of the brand name product prescribed and the acquisition cost of the substituted product." §30-5-12b(g). See articles on West Virginia lawsuit: http://www.wvrecord.com/news/221343-mcgraws-drug-pricing-suit-removed-to-federal

- ***Average Wholesale Price (AWP) disclosure.*** Maine and Vermont have laws requiring drug companies to provide data directly to state regulators concerning AWP and other pricing criteria, backed up by sworn statements that the data is

correct. This provision was sought by the AG in response to investigations and lawsuits against drug companies for Medicaid "best price" violations. A recent settlement in the First Databank price fixing lawsuit will "roll-back" the AWP of over 386 drugs, or 1442 NDCs, by four percent starting on September 29, 2009. This change poses the potential to reduce what health plans pay pharmacies for these 400 drugs, and could result in future savings of approximately $1 billion nationwide. Note that this cost savings is available to Medicaid but may not be passed through by PBMs; Iowa may want to pursue recouping these savings for any state health plan managed or administered by a PBM.

- For more on the recent AWP settlement: http://www.prescriptionaccess.org/lawsuitssettlements/settlements?id=0014
- Link to Maine AWP disclosure law, PL 603 (2005): http://www.reducedrugprices.org/read.asp?news=111

3. 340B INITIATIVES:

Another policy option for increasing savings and expanding access to prescription drugs is to maximize participation in 340B pricing under the federal Public Health Act. The 340B price is 19% below the average Medicaid "best price" net or rebates, 39% below the average insurance reimbursement, and 51% less than AWP.[3] States that aggressively pursue 340B opportunities can save significantly. 340B strategies are administratively complex and must be developed based on the characteristics of your state and in compliance with federal rules which require that patients be treated at federally Qualifies health Centers (FQHCs) and other 340B-approved facilities. Expanding the pharmacy programs at FQHC's is one strategy. Another is to focus on the largest individual cost drivers for a state Medicaid program, which tend to include such populations or disease states as mental health patients, transplant recipients, hemophiliacs, People Living With HIV/AIDS, or other categories of patients with expensive and chronic disease states. In addition, there are very significant non-Medicaid savings if 340B is extended to your corrections population.

Some facts about 340B opportunities, as presented by Bill von Oehsen, President of the Association of Safety Net Hospitals for Pharmaceutical Access:[4]

- 340B hospitals are saving state Medicaid programs an average of $300,000 per hospital per year; Boston Medical Center has saved over $1 million a year. Drugs are about 30-35% more costly when purchased through PBMs instead of through a 340B program
- 340B providers participating in managed care plans under Medicaid can develop disease management programs for enrollees with high drug costs
- 340B providers can use mail order or contracted retail pharmacies to increase access

[3] Lewis, "The Oregon Blueprint" at 18.
[4] Posted on our website: http://www.reducedrugprices.org/read.asp?news=650

  - Utah's Medicaid program has a sole source contract with the University of Utah to provide medication and case management to the hemophilia population statewide; Massachusetts, Arizona & North Carolina have also received 1915(b) waivers
  - States and counties may contract with 340B providers to provide health care and pharmacy services to correctional populations

- ***Using 340B for correctional populations:*** In 2001, the Texas Legislature passed Senate Bill 347 to implement a program to access 340B pricing for prisoner medications. In Texas, 340B has translated into significant savings. In April 2006, Allen Hightower, executive director of the state's Correctional Managed Health Care Committee, told a House legislative committee that the program is generating an estimated $10 million a year in savings. "Savings are 30 to 35 percent [over previous prices]," said Dick Cason, director of pharmacy for UTMB's Correctional Managed Care program. "It has done exactly what it was supposed to do, for patient care as well as the taxpayers of the state of Texas. It's an effective program--it's been nothing but positive."[5]

  In Texas, The University of Texas Medical Branch at Galveston (UTMB) provides medical services for about 80 percent of TDCJ's inmates, as well as juvenile offenders incarcerated by the Texas Youth Commission, and prisoners in several county jails and a federal prison facility--about 167,000 people in all. The remaining TDCJ inmates are served though a contract with Texas Tech University Health Sciences Center. According to UTMB, its Correctional Managed Care pharmacy fills about 300,000 medication orders for prisoners each month. UTMB also operates a network of hospitals and clinics, including a disproportionate share hospital, which opened the way for the Comptroller's proposal. Virginia has also used 340B to obtain medicine for correctional institutions, as have county jails, such as Dade County's in Florida and San Bernadino County's in California.

  While it may be administratively complicated to change over your current corrections health care system so that it complies with the 340B requirements and links care to a disproportionate-share hospital or other facility, it is well worth investigating how this would be done, as the savings are so significant. Moreover, there is significant assistance available, which would not cost you much to avail. Information about these resources, including the U.S. Pharmacy Affairs Office and the Association of Safety Net Hospitals for Pharmaceutical Access, is available on our website.

- ***Expanding 340B pricing within Medicaid.*** One example of a program to utilize 340B pricing for high-cost Medicaid populations is an Oregon pilot project in which a State AIDS Drug Assistance Program creates an unfunded eligibility category for HIV positive Medicaid beneficiaries. Doing so will allow the Medicaid programs to, in effect, gain access to 340B pricing for those patients. This will result in an approximate 10% savings, yet the actual dollars saved will be greater due to the high morbidity and high costs of the patient population. In addition, the State will realize greater indirect savings due to an

[5] Information from Texas Comptroller's website Fiscal Notes, "Comptroller proposal for inmate health care yields millions annually," http://www.window.state.tx.us/comptrol/fnotes/fn0609/340.html

increase in prescription adherence and the resulting improvement in outcomes. This same model can be used for HIV positive prisoners to create savings for the State Corrections Department.[6]

- ***Savings for specialty drugs under 340B:*** A recent study which was developed for the University of Michigan Benefits Office by the Center for Medication Use Policy and Economics at the University of Michigan College of Pharmacy found $250,000 in savings achieved in 2006 through 340B for specialty drugs, including medications for Rheumatoid Arthritis, Multiple Sclerosis, Cancer, Antivirals, Infertility, Anticoagulants, and Hematopoetics.[7]

- ***Vermont Community Health Centers:*** A 2005 report mandated by the Vermont legislature concluded the best vehicle to expand 340B in that state was to expand FQHCs. The legislature provided $400,000 to develop new health centers and to study options for 340B development in VT. Act 71 of 2005, Section 277(f): "Funds appropriated … shall be expended for the purpose of providing to federally qualified health center (FQHC) look-alikes funds for initial capitalization and to establish an income sensitized sliding scale fee schedule for patients of these organizations… The goal shall be to ensure there are FQHCs in each county in Vermont." Vermont's health centers increased from two Section 330 grantees with seven sites in 2002 to seven FQHCs (six grantees and 1 Look-Alike) with 28 sites in 2008. Two additional FQHCs are in active development, a third is in a feasibility study planning phase, and three of the existing health centers plan additional site expansions.

  VT worked with the Heinz Family Philanthropies to develop a model for greater 340B utilization; Heinz provided grant funding to help underwrite the costs of issuing an RFP and creating a governance structure. The Vermont Pharmacy Network, LLC (composed of 5 of Vermont's 7 FQHCs) is essentially a purchasing co-op designed with several advantageous features. It affords significant opportunity to leverage the buying power of multiple health centers, as well as the shared contracting power (i.e. for Medicare Part D plans). The LLC owns and operates a pharmacy operated under contract by Maxor National Pharmacy Services Corporation, but the LLC member health centers bear ultimate control and responsibility for how their 340B programs are implemented. The FQHC provider prescribes the medication, asking the patient if they would like it filled by the health center's pharmacy. If so, the Rx is transmitted to the Central Fill pharmacy. The prescription claim is adjudicated under the supervision of a pharmacist at the Central Fill and then dispensed, via electronic instructions and bar-code authentication, on-site at the FQHC for acute meds or mailed for next day delivery. Link to presentation on Vermont 340B model: http://www.reducedrugprices.org/documents/blair.pdf

[6] See reports posted on our website: http://www.reducedrugprices.org/read.asp?news=217 . See also study of Rhode Island 340B options by the Heinz Foundation posted here: http://www.reducedrugprices.org/read.asp?news=221

[7] Appendix D, "Specialty Drug Whitepaper," Ruth Ann C. Opdycke, Pharm.D., M.S., Jeffrey J. Ellis, Pharm.D., MS Duane M. Kirking, Pharm.D., Ph.D., August 24, 2007, accessed at: http://www.umich.edu/~benefits/forms/SpecialtyDrugReport.pdf

4. PROMOTING GENERICS

States have a variety of policies to promote generic use, including requiring the generic to be dispensed when available unless the treating medical provider overrides; generics are also promoted through preferred drug lists, lower co-pays, and counter detailing.[8] Vermont's omnibus 2007 prescription drug legislation S.115 established a generic drug sample voucher program as a way to encourage generic drug prescribing.[9] Even though many states already have policies to promote generics, significantly more could be saved in the next several years because the patents of many top-selling brand name drugs are expiring – in fact more than $38 billion in drug sales are expected to lose patents over the next 4 years.[10]

States are also recognizing the need to address patent policies. In 2007, 11 state governors asked the FDA to issue guidelines allowing insulin to be produced in generic form. People with diabetes in this country, as well as government and private insurers, spend a combined $3.3 billion a year on insulin, including $500 million spent by state Medicaid programs in 2005. Insulin prices could drop by 25% if generic versions become available.[11]

Cost savings: On average, a generic drug costs about $45 less than a brand name drug and it is estimated that for each 1% increase in generic fill rate, pharmacy spend decreases by 1%.[12] According to the generic drug industry, Massachusetts saved more than $150 million by changing a policy related to the way doctors can prescribe brand drugs when a generic is available, and Texas saved more than $223 million simply by changing its prescription pads, making it easier for doctors to prescribe generics. Florida saved roughly $30 million by eliminating special brand name "carve outs" in its Medicaid program.[13] The Georgia prior authorization program for anti-ulcer medications increased the use of generics from 31% to 79% for net savings of $20.6 million the first year.[14]

Even though many states already have policies to promote generics, significantly more could be saved in the next several years because some of the most expensive and most frequently prescribed drugs have recently gone off patent, or will do so in the next several years. As a result these drugs will be available in generic versions which cost substantially less than brand name drugs (30-80% less than AWP). Although the

[8] Crowley & Ashner, "State Medicaid Outpatient Prescription Drug Policies: Findings of a National Survey, 2005 Update," (October 2005).
[9] Crowley & Ashner, "State Medicaid Outpatient Prescription Drug Policies: Findings of a National Survey, 2005 Update," (October 2005).
[10] Express Scripts Report, 2005.
[11] "States, Bridling At Insulin's Cost, Push for Generics," By STEPHANIE SAUL, New York Times, January 11, 2007
[12] Ibid.
[13] Source: Generic Drug Association, accessed at: http://www.gphaonline.org/AM/Template.cfm?Section=State_Affairs&TEMPLATE=/CM/HTMLDisplay.cfm&CONTENTID=1967
[14] Medical News Today reporting on January 2005 study in the American Journal of Managed Care, see: http://www.medicalnewstoday.com/medicalnews.php?newsid=18888

savings will vary by program depending on the size of the rebates currently being negotiated, these savings could be realized across state government including corrections, state employee benefits, Medicaid, and programs for seniors and others.

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5. MEDICARE PART D

- ***Wraparound coverage and funding appeals of denials.*** The biggest issue for states is insuring a safety net for dual eligibles and other low-income consumers. Pennsylvania, Vermont and Wisconsin are some of the leaders in providing wraparound coverage. Maine funds a supervising attorney and 3 paralegals at Legal Services for the Elderly who automatically appeal any denial of a drug by a Part D plan, where that drug has been covered instead by the 100% state-funded wraparound program. The denials are generally for the most expensive drugs – costing $100 to more than $1,000 per prescription – and the modest investment of $300,000 in this strategy has saved many times this figure. A fiscal note for a similar proposal in New York estimated that an investment of $1 million funding such appeals could bring a return of $7-8 million in savings due to shifting coverage to Part D from state SPAPs. If Iowa does not have a wraparound program, the appeal funding would not save money for the state, although it would expand access to medicines.

- ***Consumer protections:*** A 2007 Maine law [PL 2007, chapter 52], prohibits insurance marketing tactics and solicitations that use Part D solicitations as a means to market other insurance policies such as life insurance, including door to door solicitations and cold calls. Vermont passed similar legislation as part of Act 80 in 2007.

6. AVOIDING MIDDLEMEN; INSURING TRANSPARENCY & ACCOUNTABILITY

States negotiating rebates, whether through inter- or intra-state purchasing pools, can insure that they achieve the greatest savings by directly negotiating rather than going through a middleman vendor such as a pharmacy benefit manager (PBM). At a minimum, states should require transparency, a fiduciary relationship, and annual audits

[15] "States, Bridling At Insulin's Cost, Push for Generics," By STEPHANIE SAUL, New York Times, January 11, 2007

with any PBM they contract with to insure that they receive the full value of any negotiated discounts, rebates or other financial consideration.

Iowa already has a law relating to PBMs, but it is a relatively weak law. Beefing up Iowa's law could be an effective way not only to realize savings for state pharmacy programs and the health care system as a whole, but also to protect consumers from certain PBM practices that can compromise patient privacy and medical care. Iowa's PBM law [Title XIII, Subtitle 1, Chapter 510B.1 – 510B.9] requires that PBMs obtain a certificate as a third party administrator and exercise "good faith and fair dealing" and notify the covered entity of any conflicts. It also provides for record-keeping and payment standards in their dealings with pharmacies.

In 2003 I sponsored and saw enacted into law the first comprehensive state legislation to regulate PBMs. Maine's PBM law requires full transparency of PBM practices and is intended to give PBM clients the tools to monitor self-interested PBM practices or to confidently choose a competing PBM that offers better terms. The law imposes a fiduciary duty onto PBMs, requiring them to act in the best interest of clients for the purpose of defraying costs for covered individuals, and requires PBMs to disclose possible conflicts of interest. Of great importance, our law requires PBMs to pass through to their clients (including the State) the full monetary value of the rebates they negotiate. This law was challenged in the courts but ultimately upheld in November 2005 in a sweeping decision issued by the First Circuit Court of Appeals. The U.S. Supreme Court declined to review the decision, so after several years in limbo, the law finally went into effect in 2006.

Maine's law, which is much more comprehensive than Iowa's, has nevertheless failed to fulfill its intent, as it lacks key oversight and audit provisions that are necessary to insure that it is complied with, and also doesn't fully address patient privacy concerns that have come to light since its passage. Therefore, I have pending legislation, LD 1339, to improve it and also to insure that the state's own pharmacy programs are benefitting fully from the rebate pass-through provisions.

Some background on PBMs - In the past 20 years, PBMs have become a prominent part of the American health care system, managing pharmacy benefits for nearly 95% of all Americans with medical coverage. PBMs are active in all aspects of prescription drug coverage, including:

- processing claims to pharmacies
- drug utilization review (DUR)
- developing and managing formularies
- negotiating with prescription drug manufacturers for rebates
- operating mail-order pharmacies to fill prescriptions directly
- therapeutic interchange, and
- reimbursement of providers and patients.

In their performance of these administrative duties, PBMs independently negotiate with three separate entities: pharmaceutical manufacturers, pharmacies, and health

coverage providers. Consequently, the terms of all of the contracts PBMs negotiate are known only by the PBMs, resulting in incomplete information for state government and other employers and health care providers. The result has been a sorry history of gaming transactions to the advantage of the PBM, with those who contract with the PBM in the dark about what is really going on. Examples of this gaming, which are well documented in various legal consent decrees, including consent agreements with the state attorneys general include:

- Accepting rebates from manufacturers in return for placing higher priced medications on the formulary. By not disclosing these rebates to the clients, PBM can retain some or all of the rebates while charging clients higher prices.

- "Playing the spread" between the prices paid by clients and the price paid at the pharmacy. Since PBMs negotiate contracts with employers and pharmacies separately, asymmetric information permits them to charge their employers more than the PBM actually pays to the pharmacy. For example, one investigation found that a PBM charged an employer $215 for a generic prescription but paid the pharmacy only $15. The PBM pocketed the $200 spread at the expense of the employer.

- Favoring higher priced drugs that provide PBMs with greater incentives and switching customers from low-cost to the higher-cost medication. PBMs may ask a health professional to permit them to switch medications, knowing that the switch serves the sole purpose of earning a higher rebate for the PBM. Drug-switching became the cause of action in the 20-state lawsuit (to which Maine was a party) against Medco when the PBM persuaded more than 71,000 doctors to switch patients from lower priced Lipitor, made by Pfizer, to more expensive Zocor, made by Merck. Similar allegations of drug-switching were made against Advance PCS, for encouraging doctors to switch patients from a generic ulcer drugs to Celebrex, which cost over ten times more. A drug-switching lawsuit also commenced against Express Scripts for accepting $500,000 from AstraZeneca to call 22,000 doctors to switch patients from Prilosec to Nexium. These lawsuits illustrate the prevalence of drug-switching when PBMs are left unmonitored.

Cost savings: Several recent reports have pointed to the value of transparency requirements in achieving savings for state government. A plan prepared for the Governor of Oregon by the Heinz Family Philanthropies recommended Oregon "require the greatest level of transparency possible" with PBMs as well as annual audits of the PBMs and insurance companies the state contracts with to insure that rebates are passed through.[16] A report to the Illinois Commission on Government Forecasting and Accountability recommended the state stop using PBMs entirely, or at least require a fiduciary relationship. By directly negotiating pharmacy benefits in its state employee

[16] Lewis, "The Oregon Blueprint," at 11-12.

health plan instead of paying a PBM $2.81 per enrollee per month to negotiate on its behalf, the report estimated savings of $1.35 per claim or about $10 million per year.[17]

The University of Michigan dropped the five benefit managers it had been working with, hired a single new manager that has less control over how the drug plan is administered, and imposed strict new transparency rules, enabling UM to hold its drug spending to $43 million in 2003, or $8.6 million less than it would have paid under the previous plans.[18]

In August 2008, the Texas State Auditor's Department issued a report, "An Audit report on Pharmacy Benefit Manager Contracts at Selected State Agencies and Higher Education Institutions." I highly recommend that this committee review this useful and thorough 68-page report, which provides a template for state policy and reveals the extent of potential savings to the state through better purchasing procedures and regulating PBM practices. The report can be accessed online here: http://www.sao.state.tx.us/reports/main/08-042.pdf .

The Texas report found that various state agencies and the university system lacked expertise to negotiate cost-effective contracts and had failed to exercise appropriate audit rights, adequately protect the personal data of plan members in accordance with federal and state laws, prevent drug-switching and other activities, and procure the best prices available. The report made a series of recommendations to address this situation, including that state agency pharmaceutical contracts be amended to include many of the transparency and audit provisions already enumerated in Maine's PBM law, and that pharmaceutical procurement assistance and expertise be provided to these agencies to insure that future contracts were properly drafted.

This report prompted me to request Maine's State Auditor to conduct a review of our own state agencies' compliance or lack thereof with Maine's PBM transparency law, which was designed to address many of the issues raised in the Texas report. The Maine Auditor's report concluded:

- Most of the agencies covered by our PBM law did not even know about it.
- The State employees' contract with Anthem and its PBM Wellpoint NextRx was not complying with the PBM law because Anthem claims the law does not apply to it (not the position of the state).
- The county jails contracts that are not part of the Corrections contract do not comply.
- Dirigo Choice does not comply.
- State agencies lack expertise needed to negotiate the best contracts and to comply with the law

[17] "Potential for Savings on Pharmacy Benefit Management Costs," Illinois Commission on Government Forecasting and Accountability, prepared by Winkelman Management Consulting (April 2006) at 11-16.
[18] Katz, David. "Drug Discount Peddlers" CFO.com 10/28/05 http://www.cfo.com/printable/article.cfm/5079733?f=options and Saxl, Michael. "Making PBMs Work for North Dakota" http://www.legis.nd.gov/assembly/59-2005/docs/saxlpresentation.ppt

The Auditor stated: "State agency personnel are not pharmacy or prescription drug specialists and do not have the understanding necessary to be able to secure the best prices. State agency requirements do not facilitate a one-size-fits all contract. We recommend that the State employ a specialist to negotiate agreements to acquire prescription drugs. We recommend revision of the statute to accommodate Medicaid and group purchasing organizations. We recommend that there be improved communication of legislative actions to enable compliance. We also recommend that agency personnel ensure consistency of accounting coding and compliance with purchasing regulations."

About the time I received a draft of the State Auditor's report to review, an alarming investigative report on the activities of CVS Caremark, one of the three large PBMs that control most of the PBM business in the country, was issued by Change to Win. This report raised many concerns about CVS Caremark's practices, including repeated accusations of drug switching, selling patient data or improperly handling patient medical and other private information, and fraud including improperly selling returned drugs.

- The report is summarized and linked here: http://www.reducedrugprices.org/read.asp?news=2879

Like Maine's law, Iowa's PBM rules do not address all of the issues raised in the Texas and CVS reports. The Legislature may want to review your law and revise it to insure greater accountability and oversight of PBMs, and to provide more hands-on assistance to state agencies to insure they have sufficient expertise to draft contracts that comply with the terms of the PBM law and help insure that the best rebates and discounts are achieved. Potentially millions of dollars in state savings are achievable through better contracting in compliance with existing state law. You may also wish to close a gap in your PBM law which does not adequately address the need to protect patient medical and other personal data from sale for marketing purposes or from improper disclosure. CVS Caremark is not the only company that has been accused of improperly handling patient data, and it is routine to sell or trade such data for use by other in marketing pharmaceuticals.

- PBM model bill (needs additional audit and enforcement provisions): http://www.policychoices.org/projects/PDF/ModelPolicy_PBMs.pdf
- Link to Maine LD 1339 (pending): http://www.mainelegislature.org/LawMakerWeb/summary.asp?ID=280032429
- Link to NCSL presentations on PBMs: http://www.reducedrugprices.org/read.asp?news=422

7. COMMUNICATING EFFECTIVENESS AND SAFETY EVIDENCE

There are a number of reforms that provide better information to health providers and also address cost control through improved practices.

- ***Academic detailing and other prescriber education programs*** aim to provide better information to medical providers and consumers about which drugs are the most effective and have the least adverse effects, and the costs of these drugs. Pennsylvania has operated an academic detailing program since October 2005. ***The Pennsylvania Independent Drug Information Service*** (www.rxfacts.org) is the most comprehensive of the state programs. The program makes use of sophisticated "marketing" materials ("unadvertisements"), clinical information, drug information consultants, and patient education materials to help facilitate prescribing change. The academic detailers have clinical background (nursing, pharmacy). *Cost savings:* Although it is early in the implementation of Pennsylvania's program to be able to calculate savings, a formal benefit-cost analysis of a 4-state Medicaid study involving 435 doctors showed savings of $2 for every $1 the program cost, based on just Medicaid paid claims data.[19]

  A number of states have established programs following the Pennsylvania model. Vermont's program is run by the University of Vermont Medical School; a new Maine program is being run under the auspice of the Maine Medical Association, governed by an advisory board. Both of these programs were established in statute and receive state funding. Massachusetts and New York created academic detailing programs by statute in 2008, so these programs have yet to be fully realized.

  - For a good model that both promotes better medical care and cost effectiveness, see the report issued by Prescription Policy Choices, "A Template for Establishing and Administering Prescriber Support and Education Programs" and a toolkit of policy options and resources, which includes funding ideas and specifics on potential savings: http://www.policychoices.org/AcademicDetailingToolkit_000.shtml

  - See also fact sheet produced by Community Catalyst: "Cost-Effectiveness of Prescriber Education ("Academic Detailing") Programs": http://www.prescriptionproject.org/tools/fact_sheets/files/0007.pdf

  - Link to report on the cost-effectiveness of prescriber education programs: http://www.reducedrugprices.org/read.asp?news=1209

  - Link to report on Northern New England Academic Detailing Summit: http://www.reducedrugprices.org/read.asp?news=1100

  Funding options. The challenge in implementing these programs is the need to invest money in order to save money, and figuring out how to come up with the initial financing. One option is to use funds collected in settlements in Medicaid fraud

[19] Email from Dr. Jerry Avorn, March 22, 2006; see "Economic and Policy Analysis of University-Based Drug 'Detailing," by Stephen B. Soumerai and Dr. Jerry Avorn, Medical Care, Vol. 24, No.4, April 1986. Dr. Avorn noted in my conversation with him that The Cochrane Group also did a formal evaluation of academic detailing studies and judged the intervention effective in improving prescribing.

cases. Just last month the U.S. Department of Justice announced the largest drug marketing fraud settlement in history, requiring Pfizer to pay $2.3 billion for marketing the drug Bextra for unapproved uses. The settlement has a consumer component; state might apply to their AGs for funding for a variety of projects that address improper marketing, prescriber education included. See, DOJ release: http://www.hhs.gov/news/press/2009pres/09/20090902a.html

The federal ARRA stimulus funding includes a comparative effectiveness component that may be used for academic detailing; Secretary of HHS has $400m in stimulus funds for comparative effectiveness research, some of which may be allocated for academic detailing initiatives. AHRQ is implementing a comparative effectiveness program that also appears to be consistent with state academic detailing programs. In addition, pending federal legislation would create a grant program that could be used for this purpose (the IDEA act). Vermont and Maine have programs funded in part by fees on pharmaceutical manufacturers participating in the states' Medicaid programs.

- ***Participation in evidence-based information project:*** More than a dozen states involved in the Oregon Drug Effectiveness Review Project, and New York based its PDL on the information from this project. We have drafted a model bill linking state purchasing pool and PDL provisions with evidence-based decisionmaking.

- ***Posting clinical trials results***: Maine law requires internet posting of all clinical trials results, including adverse results, and has linked its information to the federal website clinicaltrials.gov. The law went into effect 10/15/05. A 2007 federal law requiring clinical trials results posting will preempt such state laws once the federal law goes into effect.

8. ADVERTISING & MARKETING

Since at least 1993, when Minnesota passed the first state law banning certain gifts and requiring disclosure of drug industry marketing activities and payments targeted to doctors and other health practitioners, states have been at the forefront of efforts to insure that the pharmaceutical industry does not unduly influence the practice of medicine and adversely affect patient health and safety. At least 30 states have enacted laws, or had legislation pending, on one or more of the following topics:

- Disclosing marketing spending and practices, including gifts and payments to doctors; banning gifts to health practitioners
- Beefing up state authority to enforce misleading advertising and marketing rules
- Protecting patient and doctor privacy by restricting the commercial use of prescriber-identifiable prescription data
- Restricting advertising in electronic prescribing software
- Regulating drug industry sale representatives or detailers

- Establishing independent evidence-based academic or counter detailing programs and requiring disclosure and posting of clinical trials information

Although the federal government has a major role regulating drug safety, advertising and marketing, the states have exercised their traditional authority to protect public health and safety and stepped in to fill the gaps where the federal government has failed to regulate or vigorously enforce its laws. These state laws and enforcement actions have put a spotlight on standard drug industry and medical practices, revealing conflicts of interest, questionable clinical decisions, and marketing tactics that raise serious concerns both for the medical profession and for policymakers at the state and federal level.

- ***Banning gifts and disclosing payments to providers.*** A **Minnesota** law enacted in 1993 bans "gifts of value" to health care practitioners from drug manufacturers and wholesalers, excluding drug samples, items of less than $50 in a calendar year, payments to the sponsor of a bona fide educational purposes, honoraria for a practitioner who serves on the faculty at a professional or educational conference or meeting; compensation for consulting services of a practitioner in connection with a genuine research project; publications and educational materials; or salaries or other benefits paid to employees. More recently, **Massachusetts** and **Vermont** have enacted sweeping gift ban and payment disclosure statutes that have few exceptions.
    - The 2009 Vermont law is discussed in this presentation: http://www.reducedrugprices.org/documents/shumlin.pdf
    - Link to Minnesota Gift ban and Disclosure law: http://www.reducedrugprices.org/read.asp?news=334

The **District of Columbia** has a modified gift ban, limiting gifts to medication advisory committee members. The D.C. SafeRx Act also addresses conflicts of interest by prohibiting pharmaceutical companies from offering a gift or remuneration of any kind to a member of a medication advisory committee, which is defined as "any committee or panel that is responsible for making recommendations or decisions regarding a formulary to be used by a health program administered by the government of the District of Columbia." A member of a medication advisory committee likewise may not accept a gift or remuneration of any kind from a pharmaceutical company.

In addition to **Minnesota, Massachusetts** and **Vermont, West Virginia,** the **District of Columbia, Maine** and **California** have enacted laws requiring disclosure of marketing and/or advertising spending. None of these laws is perfect; several have sweeping trade secret loopholes and rely on aggregate reporting. The most effective are the Massachusetts and Vermont laws, which apply to pharmaceuticals and medical devices, require reporting of specific payment amounts to providers by name, and have few exemptions. Vermont has extensive reports on data collected on the Attorney General's website from an earlier version of its disclosure law. Although the data are incomplete and reported only in aggregate form, the conclusions are eye-opening.

  - State laws are reviewed for effectiveness here (note Vermont's law has since been substantially revised to address deficiencies): http://www.reducedrugprices.org/documents/lurie01252008.pdf .
  - A model bill is posted here: http://www.reducedrugprices.org/read.asp?news=823 .
  - Link to disclosure fact sheet: http://www.prescriptionproject.org/tools/solutions_factsheets/files/0006.pdf

- ***Drug detailer registration and regulation:*** The **District of Columbia** in 2008 enacted the first law in the nation requiring licensing of pharmaceutical drug reps ("detailers") and regulating their activities. The District of Columbia's SafeRx Act authorizes the Board of Pharmacy to establish a code of ethics for the practice of pharmaceutical detailing; collects information from licensed pharmaceutical detailers relating to their communication with licensed health professionals or with employees or representative of a licensed health professionals located in the District; establishes a licensing process and enforcement provisions; and establishes licensing standards including minimum qualifications and continuing education requirements.

  Vermont and **Nevada** enacted legislation in 2007 to govern the behavior of drug industry sales representatives. Vermont's legislation also addressed misleading marketing to health care practitioners and direct to consumer advertising and established a state cause of action to enforce these standards. In Nevada, AB 128 as amended and signed into law (Chapter 409) requires marketers of drugs, medicines and devices to adopt and comply with a code of conduct, although it allows the code to be an industry-developed code. Nonetheless, the state has authority to audit compliance and publicize violations.
  - Final Nevada legislation: http://www.leg.state.nv.us/74th/Bills/AB/AB128_EN.pdf
  - D.C.'s SafeRx: http://www.reducedrugprices.org/read.asp?news=753

- ***Prescription data confidentiality:*** A first-in-Nation New Hampshire law prohibiting the use of doctors' prescription information for commercial purposes was enacted in 2006. The law prohibits the use of patient or prescriber-identified data for marketing purposes, with exceptions for aggregated data and uses defined as non-commercial such as tracking patient safety. Maine and Vermont passed similar, but less comprehensive laws in 2007. All three laws have been challenged in court on first amendment and commerce clause grounds. The New Hampshire law was upheld by the 1st Circuit Court of Appeals and the US Supreme Court declined to review that decision. The Vermont law was upheld by the Vermont Federal District Court, and that decision is on appeal to the 2d Circuit; oral argument was just last week. Maine's law was overturned in the federal District Court in Maine, but that decision is being appealed to the 1st Circuit.

  This legislation is aimed at reducing unnecessary prescription drug costs; safeguarding public health; protecting patient confidentiality; and protecting the

integrity of the medical profession and the doctor-patient relationship, including the confidentiality of decisions made by both doctor and patient. On the cost end, the use of this information for marketing purposes is a key factor in the skyrocketing costs of prescription drugs and the increased usage of expensive brand-name medicines. From a public health perspective, use of prescriber data for marketing facilitates the provision of biased and inaccurate information about health risks, and encourages prescribing new products that might be riskier to patients than known agents on the market. On the confidentiality front, currently patient data is inadequately protected and prescriber data isn't protected at all, and intrusive marketing techniques enabled by sophisticated data mining reach into the doctor-patient relationship.

Use of prescriber information for marketing increases costs. Drug manufacturers and their salespersons or "detailers" use sophisticated techniques including data mining to target their marketing efforts to specific subsets of doctors who are most likely to be receptive to their sales pitches. These practices do increase costs, for they are extremely effective at increasing sales of the most expensive drugs. According to the data mining industry itself, "Research has shown that winning just one more prescription per week from each prescriber yields an annual gain of $52 million in sales."[20] Medical experts who have studied drug marketing techniques agree. According to Dr. Jerry Avorn and Dr. Aaron Kesselheim of Brigham and Women's Hospital and Harvard Medical School and School of Public Health:

"Detailing is generally confined to high-margin, high-profit drugs, for which the manufacturer has a substantial incentive to increase sales. There is virtually no economic incentive for the manufacturers of generic drugs to send sales representatives to visit physicians about those products, even though there is clear evidence that these medications can provide therapeutically equivalent and much more affordable and cost-effective treatment in a wide variety of conditions. Thus, the work of pharmaceutical sales representatives drives drug use toward the most expensive products (as it is designed to do), and contributes to the strain on health care budgets for individuals as well as health care programs, especially Medicaid."[21]

These practices also have public health implications. One study of detailers' promotional brochures found that 15% of the pamphlets presented data that differed from the published studies on which they were based. In another study, 11% of the statements made by pharmaceutical representatives about drugs were scientifically inaccurate, and physicians generally failed to recognize the inaccurate statements.[22] Detailers are also key promoters of off-label use of drugs, a consistent finding of the Prescrire sales reps monitoring network in France. This Network was created in 1991 at the initiative of a group of subscribers. For 15 years, members of the

[20] "Datamining at IMS Health, How We Turned a Mountain of Data into a Few Information-Rich Molehills," by Paul Kallukaran & Jerry Kagan, IMS HEALTH Paper 127, Plymouth Meeting, PA
[21] Statement of Dr. Jerry Avorn and Dr. Aaron Kesselheim of Brigham and Women's Hospital and Harvard Medical School and School of Public Health submitted to the Maine Legislature in support of LD 4 and LD 828 (attached).
[22] See studies referenced in Avorn and Kesselheim statement referenced above.

Network compared sales representatives' claims with the information contained in the summaries of product characteristics. Results were remarkably consistent over the years - sales reps highlight the efficacy of the drugs they present, often for unapproved as well as approved indications. In contrast, adverse effects are not mentioned in three-quarters of visits.[23]

- Links to fact sheets:
  http://www.prescriptionproject.org/tools/solutions_factsheets/files/0003.pdf
  http://www.prescriptionproject.org/tools/solutions_factsheets/files/0004.pdf
- Link to legal analysis: http://www.reducedrugprices.org/read.asp?news=518

- ***Restricting electronic marketing activities:*** In 2006 Florida enacted a law, Chapter 2006-271, restricting advertising as part of electronic prescribing software including "instant messaging, and pop-up ads, to influence or attempt to influence, through economic incentives or otherwise, the prescribing decision of a prescribing practitioner at the point of care." New Hampshire and Maine followed suit in 2007 [Maine law, PL362].[24] Maine's law prohibits the sale or use of prescribing software that seeks to direct health care providers, through advertising or messaging including pop-up ads, to prescribe a specific drug or use a specific pharmacy. It also regulated conflicts of interest in the distribution of this software.[25] New Hampshire's HB 134 is similar.[26]

- ***Misleading advertising:*** In 2005, Maine passed a law adopting federal misleading advertising standards and giving its Attorney General explicit authority to go after violators Maine is the only other state to have enacted standards for misleading advertising and providing for a state cause of action for violations [22 MRSA Section 2700-A]. The law also requires posting data on clinical trials and a consumer education initiative by the state, funded with a fee paid by manufacturers. Vermont enacted similar misleading advertising legislation in 2007, and extended its reach to pharmaceutical drug representatives and other marketing activities [S.115; see also discussion of D.C.'s SafeRx and Nevada law, above].

  Maine and **Vermont** have laws granting clear authority to their attorneys general to enforce misleading marketing standards in the courts. These states have acted in part in response to a significant reduction in the overall number of federal enforcement actions for misleading marketing, as well as FDA delay in acting to curb abuses.[27]

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[23] A review of the Network¹s findings "Don't expect sales representatives to help improve healthcare quality" can be found at: http://www.prescrire.org/aLaUne/dossierVMbilanEng.php

[24] See Florida Chapter 2006-271 enacted in 2006 restricting advertising as part of electronic prescribing software including "instant messaging, and pop-up ads, to influence or attempt to influence, through economic incentives or otherwise, the prescribing decision of a prescribing practitioner at the point of care."

[25] *Public Law Chapter 362, text:*
http://janus.state.me.us/legis/LawMakerWeb/externalsiteframe.asp?ID=280024211&LD=1440&Type=1&SessionID=7

[26] *Chapter 320 7/16/07, effective 9/17/07,* • Final bill text available here:
http://www.gencourt.state.nh.us/legislation/2007/HB0134.html

[27] Federal enforcement of marketing rules is lax. A 2005 report issued by Congressman Henry Waxman of the House Committee on Government Reform found that "there has been a marked decline in enforcement actions taken against drug manufacturers for illegally promoting their products" since December 2001. From 1999 to 2001, The FDA issued 250 "Notice of Violation" or "Warning" letters to drug companies, but from 2002 through 2004, the

Vermont's law not only regulates misleading advertising, but also marketing to health care practitioners, including at educational conferences, and requires pharmaceutical sales representatives to "disclose to the prescriber evidence-based information as provided for by rule describing the specific health benefits or risks of using other pharmaceutical drugs, including drugs available over the counter; which patients would gain from the health benefits or be susceptible to the risks described; the range of prescription drug treatment options; and the cost of the treatment options."[28]

9. FALSE CLAIMS ACTS

The Federal False Claims Act has been used in litigation against PBMs, chain drugstores and pharmaceutical manufacturers for fraudulent pricing and billing practices including drug switching, false reporting of Medicaid 'best price', short-filling prescriptions, failure to pay rebates, kickbacks and side deals. States involved in these federal cases, or bringing claims under similar state laws, have recovered millions of dollars.

Cost savings: One report concludes that every dollar invested by the government in investigation and prosecution of federal health care fraud returns $15 back to the American people.[29] States frequently share in these recoveries. For example, in August 2006 the drug manufacturer GlaxoSmithKline agreed to a $70 million settlement with Arizona, California, Connecticut, Montana, Nevada and New York over allegations that the company artificially inflated average wholesale prices of prescription drugs. Thirty-four other states and the District of Columbia also will be eligible to receive part of the settlement.[30] Recent changes in federal law create a financial incentive (an additional share of any recovery based on Medicaid funding formulas) for states to enact false claims laws that are as effective as the federal law. The additional recovery could be considerable. For example, in the recent Serono settlement, New York State recovered $80 million. If New York had a qualifying False Claims Act, however, it would have gotten $96 million -- an additional 20% over its initial recovery, or $16 million.[31]

- Model false claims act: http://www.reducedrugprices.org/read.asp?news=115

FDA sent only 70 letters. This is a reduction of more than two-thirds, despite a sharp increase in the number of drug ads and the money spent on them. The FDA does not have the resources to adequately police drug advertising. For example, in 2003, the FDA had only 18 staff assigned to review the roughly 37,000 ads and promotional pieces submitted by drug companies that year. See "*FDA Struggles to Police Print Ads for Prescription Drugs*," by Tony Pugh, January 29, 2004, Knight-Ridder.

[28] According to NCSL data, as of August 2007, nine states and District of Columbia (2003), California (2004, 2005, 2006), Florida (2006) Maine (2003, 2005), Nevada (2007), New Hampshire (2006), South Carolina (2006), Vermont (2002), West Virginia (2001) and Minnesota (1993) have laws or resolutions on the books affecting pharmaceutical marketing. Maine, Vermont and New Hampshire have since amended their laws to expand oversight of marketing activities. The NCSL report is here: http://www.ncsl.org/programs/health/rxads.htm.

[29] Taxpayers Against Fraud report accessed at: http://www.taf.org/FCA-2006report.pdf

[30] "*GlaxoSmithKline Settles Civil Suits for $70 Million,"* REUTERS NEWS SERVICE, August 11, 2006; Wall Street Journal; see this and other articles excerpted and posted at http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=39086

[31] See Taxpayers Against Fraud materials at http://www.taf.org/cashbackstatefca.htm

10. TRADE ISSUES

State legislators, through state trade policy commissions and the Legislative Working Group on Prescription Drugs and Trade (part of NLARx), are becoming increasingly active expressing views on trade agreements that have language that could be interpreted to limit state affordable prescription drug options. Look for states to pass resolutions objecting to trade agreements limiting imports and price regulation, and calling on Congress and the USTR to enact interpretive guidance to insure these agreements do not restrict state prescription drug programs and Medicaid.

- Link to policies and information on trade: http://www.reducedrugprices.org/trade.asp

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