DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF DIRECTOR

ACTION REFERRAL

TO	DATE
Medical Services/ Giese	3-10-11

DIRECTOR'S USE ONLY	ACTION REQUESTED
1. LOG NUMBER 101404	[X] Prepare reply for the Director's signature DATE DUE 3-17-11
2. DATE SIGNED BY DIRECTOR cc: Mr. Keck, Deps, Cleared 4/14/11, letter attached.	[ ] Prepare reply for appropriate signature DATE DUE [ ] FOIA DATE DUE [ ] Necessary Action

APPROVALS (Only when prepared for director's signature)	APPROVE	* DISAPPROVE (Note reason for disapproval and return to preparer.)	COMMENT
1.			
2.			
3.			
4.			

a. It appears that 8.5 percent of the SC Medicaid drug spend is for anticonvulsants. Therefore, prior authorization for that level of expenditure is appropriate.
b. It appears that 4.7 percent of the SC Medicaid drug spend is for atypical antipsychotic medication. The proper management of this expenditure, including prior authorization, is appropriate.

3. The utilization of e-prescribing tools in the highest prescribing Medicaid physician group to mirror the Florida Gold Standard Project. You requested information on the status of e-prescribing in South Carolina. The latest figures we could find indicated that, for the 2009 Safe Rx Awards by Surescript, South Carolina ranked 39th. For reference: NC -5th, FL -10th, GA -26th and AL- 27th.
    a. Provide the top 1000 SC Medicaid prescribers with a free e-prescribing tool.
    b. The state of Florida showed savings of $700 per patient per month based on the prevention of poly-physician, poly-pharmacy and formulary management.
    c. We will seek out vendors to meet with the Department to achieve this goal

4. To work to develop adherence and medication therapy management programs that provide a favorable return on investment and can achieve the best care per expended state dollar.
    a. We ask the Department while working towards this savings goal to provide all the community pharmacy partners with some high cost patient groups and outcome goals so we may assist the state in their goal to provide the best health care possible to the citizens in SC Medicaid.

We have attached additional policy detail on each proposal. Additionally, we request that the agency provide a key contact with which we can establish a series of meetings. It may also be collaborative to establish a pharmacy or provider group that will allow the continued exchange of high quality cost saving approaches to the department and align the goals of all involved. We seek to be a partner with your agency and the companies represented by the SC Association of Chain Drug Stores have a proven track record across the country.

Thank you again for your time. Please let us know who on your staff we should work closely with as we seek to bring these proposals to fruition.

Sincerely,

James H. Quackenbush, Jr.
SC Association of Chain Drug Stores

In 2006, the Institute of Medicine (IOM) recommended that all prescriptions be written and received electronically by the year 2010. Both ARRA and the Medicare Improvements for Patients and Providers Act (P.L. No. 110-275) include incentives for providers to adopt e-prescribing under Medicare and/or Medicaid. When used in combination with other related technologies – such as on-line drug and patient information databases – e-prescribing can help providers to make cost-saving patient care decisions regarding necessary medication therapy management and other healthcare needs.

Proof of e-prescribing as an effective cost savings initiative can be seen with the Florida Agency for Health Care Administration's Medicaid pilot program. *(See Attachment A for more details on the Florida E-Prescribing program and similar programs in Mississippi and New Jersey).* In 2003 Florida Medicaid implemented a program using e-prescribing and related technologies – such as on-line drug and patient information databases that providers use to make cost-saving patient care decisions regarding necessary medication therapy management and disease management. In 2007, Florida Medicaid reported $1.8 to $2 million in monthly savings for calendar year 2006. An additional $4 million in quarterly cost avoidance savings is reported due to the reduction in severe drug interactions. Total savings for calendar year 2007 was approximately $33 million.

- **South Carolina has approximately 8,693 physicians providing services in the state. If South Carolina achieved results similar to Florida's with just 20 percent (1,739) of its providers, the state could save as much as $14.6 million annually by implementing e-technology.**

Generic Dispensing Rate

The South Carolina Code of Laws §40-43-86(H) states that a pharmacist may substitute a less expensive generically equivalent drug for any brand name drug unless the product selection is expressly prohibited by the prescriber. Brand name products may be prescribed and dispensed if the prescriber certifies in his own handwriting "dispense as written" on the prescription form to the dispensing pharmacist. South Carolina's 67.2 percent generic utilization rate in 2009 ranked 39th among state Medicaid generic utilization rates for that year. Numerous opportunities to increase South Carolina's generic utilization rate exist, and would yield significant Medicaid program savings.

In Calendar Year 2009, every one percent increase in the South Carolina Medicaid Program's generic utilization rate saved about $7 million. It remains crucial to the program's continuing cost-savings efforts that generics are preferred, not only in statute, but also in the minds of those who prescribe and dispense prescription drugs.

The average cost of a generic dispensed to South Carolina Medicaid enrollees in calendar year 2009 was about $25.42, which is just 7.8 percent of the $323.99 average cost for a single-source (patented) brand name medication, and an average difference of about $298.57 per prescription. Despite being dispensed 67.2 percent of the time, generics constituted only about 14.2 percent of program spending on prescriptions.

Enhanced Prior Authorization of Anticonvulsants and Antipsychotic Drugs

We commend South Carolina Medicaid for its program requiring prior authorization for non-preferred drugs. We encourage South Carolina to further strengthen its prior authorization program for antipsychotic drugs.

Anticonvulsants: South Carolina Medicaid's spending on anticonvulsants during 2009 was $17.9 million – 3.7 percent of the program's total expenditures on drugs. A study reported in the May 8, 2006 *Archives of Internal Medicine* found that 46 percent of anticonvulsants are prescribed for an off-label use, and that most off-label uses among 160 commonly prescribed drugs had little or no scientific support.[2] *(Attachment B)* While off-label use may be appropriate where there is strong peer-reviewed evidence supporting such use and all other avenues of treatment have been exhausted, the decision to use off-label treatments should be subject to prior review and authorization by the state.

- **The exact savings from the use of clinical prior authorization and step therapy to ensure that there is on-label use of other appropriate drugs before off-label use of anticonvulsants is authorized is unknown. However, with 8.5 percent of the state's Medicaid drug expenditures spent on anticonvulsants and peer-reviewed literature in the field suggesting there is a high percentage of off-label use of this drug class, there is clearly the potential for significant savings from the use of tighter prior authorization procedures and mandated step therapy.**

Atypical Anti-Psychotics:

South Carolina Medicaid's spending on the four most frequently prescribed atypical anti-psychotics constituted about 4.7 percent ($22.6 million) of South Carolina Medicaid drug spending during 2009. However a study reported in the December 2006 *American Journal of Psychiatry*[3] *(Attachment C)* found one of the first generation of anti-psychotics – specifically perphenazine – to be as clinically effective as atypical anti-psychotics and far more cost-effective. The study, conducted as one of the National Institute of Mental Health's (NIMH's) Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) investigations, found total medication costs for patients initially assigned to perphenazine were $200 to $300 per month (about 40 to 50 percent) lower than drug costs for the patients assigned to each of the four second-generation anti-psychotics (again, Zyprexa, Risperdal, Geodon, and Seroquel) tested. As the savings under the CATIE study prove, an enhanced clinical prior authorization and step therapy program requiring first use of the earlier generation of anti-psychotics could yield additional savings.

- **A clinical prior authorization step therapy approach that requires the use of perphenazine before movement of the patient to one of the atypical anti-psychotics could save the state as much as 40 to 50 percent of its expenditures on those drugs, or $9.0 million to $11.3 million per year. If just 10 percent of those**

[2] "Off-Label Prescribing Among Office-Based Physicians," by Radley, David C., Finkelstein, Stan N., Stafford, Randall S., *Archives of Internal Medicine,* Vol. 166, May 8, 2006, p. 1021.

[3] *Cost-Effectiveness of Second-Generation Anti-Psychotics and Perphenazine in a Randomized Trial of Treatment for Chronic Schizophrenia,* Robert A. Rosenheck *et al, Am J Psychiatry 2006;* 163:2080–2089.

participants and potential savings in South Carolina from this approach of $1.96 million.

Conclusion

NACDS believes that there are appropriate, effective, and long-term approaches to cutting Medicaid prescription drug costs. Each of the abovementioned initiatives is long-term cost-saving approaches that have been proven to be cost effective in other states. We strongly urge the South Carolina Medicaid program to consider these approaches that have proven so successful elsewhere before making changes to the Medicaid program that could negatively impact the quality of care beneficiaries receive.

informed decisions

The EMPOWERx Program for New Jersey Medicaid

Informed Decisions LLC, an Elsevier company, is a leading developer of drug information applications and clinical information solutions. Specializing in the development and implementation of patient-specific, point-of-care medical information applications, such as the proposed solution contained herein; and the provisioning of services to government agencies, payor/provider organizations, and healthcare consumers.

Extensive State Medicaid Experience

EMPOWERx, as the core system proposed for a medication history and e-Prescribing service for New Jersey, is currently available and utilized by several state Medicaid agencies. Informed Decisions considers e-Prescribing to be an important means to deliver our expert content to healthcare professionals, and has been providing this service to physicians via EMPOWERx since 2003.

The EMPOWERx solution allows New Jersey to:

- Focus on improving health outcomes with integrated clinical decision support
- Mitigate financial exposure with unlimited medication history transactions
- Add value today to the user community with unlimited e-Prescribing transactions
- Meet the need to transform healthcare with a proven track record of rapid Program deployment in 60-90 days

EMPOWERx integrates formulary information with the Clinical Pharmacology® ("CP" or "Clinical Pharmacology") drug information database. Providers thus have the capability to query the database by specific drug or indication to and can determine the most appropriate medication based upon the patient's medication history and the formulary.

Further, medication histories are automatically screened for possible adverse drug events, including:

- Duplications in therapy
- Relevant drug interactions,
- Allergies (where available) and cross-sensitivities
- Suggested clinically screened alternatives and alternative therapies on formulary

EMPOWERx's e-Prescribing features are fully compliant with all industry standards and are integrated with the provider's patient list in such a manner as to allow providers to auto-populate the prescription with patient name and date of birth, medication, dosage, and pharmacy information using standard protocols selected by the provider.

EMPOWERx is certified by Surescripts to ensure that medication history data is provided real-time through Surescripts electronic transaction gateways. Informed Decisions', EMPOWERx has:

1. Demonstrated track record of success both with implementation and financial savings (ROI for health plans) for Medicaid Programs and Medicaid HMOs
2. Demonstrated interoperability with other systems offering ease of expansion
3. Extensive Medicaid experience and presence within three other state Medicaid programs (Florida, Louisiana, Mississippi)
4. Ability to enable e-Prescribing immediately at deployment, or phased in based upon New Jersey's determined timeline
5. Integrated point-of-care decision support to avoid adverse outcomes
6. Six years experience in successful deployments of e-Prescribing technology to Medicaid providers.

Program upgrades are seamless to the customer. Program enhancements and updated data are pushed to the customer in real-time through the website application.

New Jersey Should Act to Implement Electronic Prescribing Initiatives

An electronic prescribing system in New Jersey would add new dimensions of safety and efficiency to the practices of medicine and pharmacy. Electronically created and transmitted prescriptions streamline the prescribing process and enhance communication among health care professionals while offering safe and high quality services. Electronically created and transmitted prescriptions can reduce or eliminate errors both at the physician's office, at the point of prescribing, and at the pharmacy when a written or oral prescription is entered into a pharmacy's computer system.

Besides enhanced efficiency and safety, other benefits to electronic prescriptions include:

- Improved patient compliance: Physicians will know to which pharmacy a prescription has been sent and whether the patient has picked it up. This will offer opportunities for physicians and pharmacists to better track and communicate about patient compliance.
- Superior prescription documentation: Prescriptions will be completely legible, and physicians will have an electronic record of what has been prescribed. Pharmacy prescription records will be completely electronic and immediately retrievable.
- Secure authentication of prescribers: Electronic prescriptions will provide pharmacists with a higher level of confidence in the authenticity of prescriptions. Prescriptions will be received only through trusted partners or agents; and will be securely signed with electronic signatures.
- Enhanced health care quality and efficiency: Provision of clinical and formulary information at the point of care will improve quality and efficiency.

Informed Decisions' eMPOWERx Solution can provide a comprehensive electronic prescribing solution for New Jersey, its providers and most importantly their patients. State Medicaid Agencies can realize substantial savings, the following outlines States that have recognized savings.

eMPOWERx in Florida: In June 2003, the Florida Agency for Health Care Administration (AHCA) purchased wireless hand-held personal digital assistants (PDAs) for 1,000 Medicaid prescribers to reduce fraud and abuse in the healthcare community and improve the quality of care.

In 2004, AHCA announced it distributed an additional 2,000 PDAs to Medicaid physicians. This increased the number of physicians using the PDAs to cover the 20% of providers writing 80% of the prescriptions for Medicaid patients.

In 2006, the PEW Center on the States independently reported the Florida program saves $50 million over two years. http://www.pewcenteronthestates.org/report_A2.html

In 2007, AHCA reported $1.8 to $2 million in monthly savings for calendar year 2006. An additional $4 million in quarterly cost avoidance savings is reported due to the reduction in severe drug interactions.

eMPOWERx in Mississippi: The Mississippi Division of Medicaid implemented its electronic patient care program in 2006, distributing PDA devices to 225 physicians in the state. One year later, the state had realized savings on average of $1.2 million per month or $14.4 million in 2006, as a result of physicians prescribing fewer and less costly prescriptions per patient. In 2006, the program's drug interaction alert system also generated an additional cost avoidance savings of $922,000 in hospital costs.

eMPOWERx in Louisiana: The Department of Health and Hospitals (DHH) launched its new electronic system for the prescribing of medications in April 2008. DHH will spend approximately $1.2 million on devices which will be placed in approximately 500 Medicaid provider offices. Anticipated savings from this program is estimated at $4.8 million annually. Savings will be generated from the reduced number of prescriptions per patient, reduced cost per prescription by using the most cost effective medication and physicians' ability to readily access the Preferred Drug List using PDA devices.

ORIGINAL INVESTIGATION

Off-label Prescribing Among Office-Based Physicians

David C. Radley, MPH; Stan N. Finkelstein, MD; Randall S. Stafford, MD, PhD

Background: Unlike medicines prescribed for Food and Drug Administration–approved indications, off-label uses may lack rigorous scientific scrutiny. Despite concerns about patient safety and costs to the health care system, little is known about the frequency of off-label drug use or the degree of scientific evidence supporting this practice.

Methods: We used nationally representative data from the 2001 IMS Health National Disease and Therapeutic Index (NDTI) to define prescribing patterns by diagnosis for 160 commonly prescribed drugs. Each reported drug-diagnosis combination was identified as Food and Drug Administration–approved, off-label with strong scientific support, or off-label with limited or no scientific support. Outcome measures included (1) the proportion of uses that were off-label and (2) the proportion of off-label uses supported by strong scientific evidence. Multivariate analyses were used to identify drug-specific characteristics predictive of increased off-label use.

Results: In 2001, there were an estimated 150 million (95% confidence interval, 127-173 million) off-label mentions (21% of overall use) among the sampled medications. Off-label use was most common among cardiac medications (46%, excluding antihyperlipidemic and antihypertensive agents) and anticonvulsants (46%), whereas gabapentin (83%) and amitriptyline hydrochloride (81%) had the greatest proportion of off-label use among specific medications. Most off-label drug mentions (73%; 95% confidence interval, 61%-84%) had little or no scientific support. Although several functional classes were associated with increased off-label use ($P<.05$), few other drug characteristics predicted off-label prescription.

Conclusions: Off-label medication use is common in outpatient care, and most occurs without scientific support. Efforts should be made to scrutinize underevaluated off-label prescribing that compromises patient safety or represents wasteful medication use.

Arch Intern Med. 2006;166:1021-1026

THE FOOD AND DRUG ADMINISTRATION (FDA) focuses on market entry for prescription drugs rather than regulating physicians' prescribing practices, allowing off-label use of medications for indications beyond those formally evaluated by the manufacturer. Off-label prescribing of medications is legal,[1] often thought to be supported by scientific evidence,[2] and common in certain clinical settings.[3,4] Although this practice provides a pathway to innovation in clinical practice, it raises key concerns about risks to patients and costs to the health care system.[5-7]

Despite sufficient evidence justifying some off-label practices, lack of FDA approval means that off-label uses are not given the same degree of scientific scrutiny as labeled indications. Scientific evidence documenting the efficacy of off-label uses in routine practice settings commonly falls short of what the drug's manufacturer would be required to provide the FDA to receive approval for that indication. Although regulation in this area is evolving, FDA policy prohibits direct-to-consumer promotion of drugs for unapproved uses and restricts such promotion to physicians.

Previously published studies of off-label prescribing typically consider this practice in the context of narrowly defined clinical populations, including those with psychiatric disorders,[3,8] those with human immunodeficiency virus and AIDS,[9] children,[10,11] pregnant women,[12] and others commonly underserved by FDA-approved medicines.[4,13] None of these studies have systematically described the overall magnitude of off-label prescribing or the consequences of prescribing drugs for unevaluated or underevaluated indications. A study published in 1985 examined the 100 most common uses of marketed medicines and found that 31 were for indications not initially approved by the FDA, of which 18 were not subsequently scrutinized.[14]

Using a nationally representative sample documenting physician prescribing by diagnosis, we examined the overall frequency and clinical circumstances of off-label prescription among commonly prescribed medications as a function of the strength of scientific support for those practices.

Author Affiliations: Center for Evaluative Clinical Sciences, Dartmouth Medical School, Hanover, NH (Mr Radley); Program on the Pharmaceutical Industry, Sloan School of Management, Massachusetts Institute of Technology, Cambridge (Dr Finkelstein); and Program on Prevention Outcomes and Practices, Stanford Prevention Research Center, Stanford, Calif (Dr Stafford). Dr Finkelstein is now additionally with Harvard Medical School, Boston, Mass.

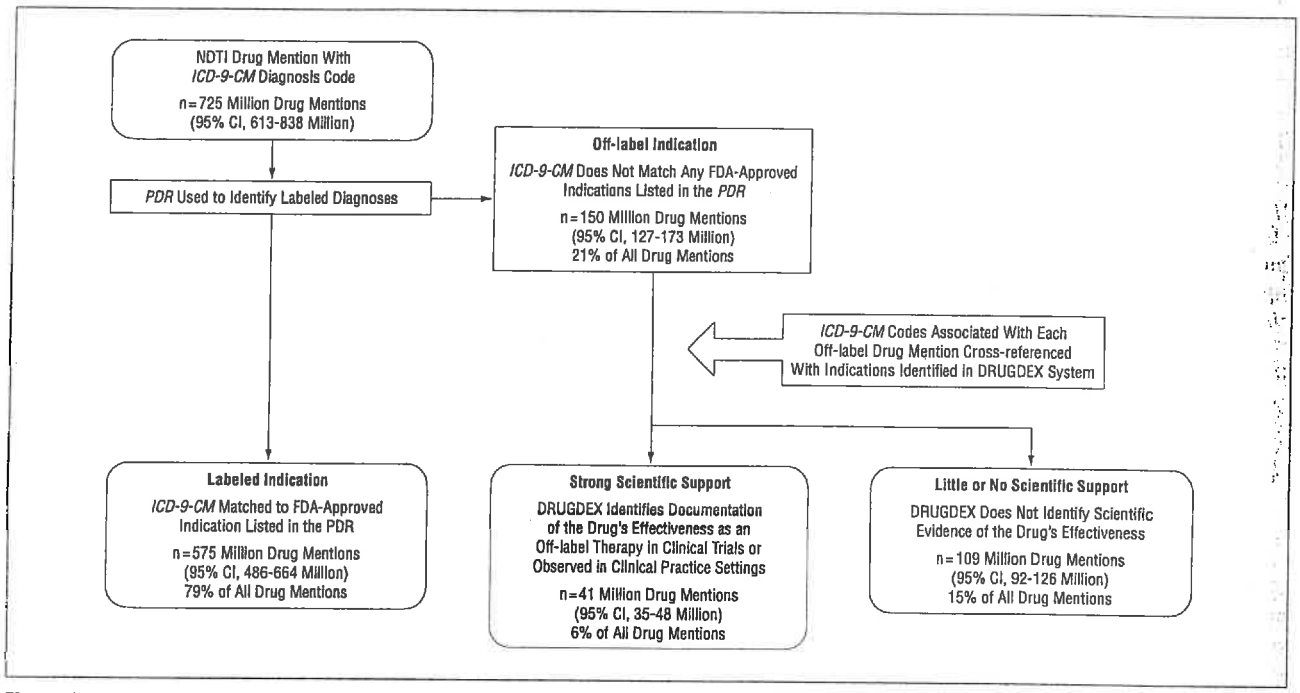

Figure. Assessment of scientific support for each drug-diagnosis combination. Drug mentions are weighted estimates of national prescription drug occurrences based on observed medication use. CI indicates confidence interval; FDA, Food and Drug Administration; *ICD-9-CM, International Classification of Diseases, Ninth Revision, Clinical Modification*[18]; NDTI, National Disease and Therapeutic Index; and *PDR, Physicians' Desk Reference*.[19]

STATISTICAL ANALYSIS

The unit of analysis was the drug mention; the principle outcome measures were proportion and frequency of off-label prescription among sampled medications. We used multivariate regression to evaluate the ability of specific drug characteristics to predict off-label prescription. This allowed us to test several hypotheses: for example, that increased off-label prescription is associated with particular functional classes, use as a long-term therapy, older drug age, generic availability, a high degree of direct-to-consumer promotion, or manufacturer. The dependent variable was the counted number of drug mentions for off-label uses, and was transformed using a natural logarithm to normalize the distribution. Drugs from the same chemical class share many physical and therapeutic characteristics and, therefore, are not independent with regard to likelihood of prescription. To account for this lack of independence, models were fit clustering on the chemical class with robust variance estimates for the standard error.[25,26] Reported risk ratios (RRs) represent the independent likelihood of that characteristic predicting increased off-label prescription. Data analysis was performed using STATA software, version 8 (StataCorp, College Station, Tex).

RESULTS

The NDTI reported an estimated 725 million total drug mentions among the sampled drugs for year 2001. Although most (575 million [79%]) were for FDA-approved indications, many drug mentions (150 million [21%]) lacked FDA approval for the condition they were used to treat. Therapeutic activity among these medicines was largely supported by scientific evidence, with 85% of all drug mentions (616 million) being FDA-approved or evidence-based off-label uses; 15% of the drug mentions reported herein lacked scientific evidence for the indication they were used to treat. Among off-label mentions, most (73%) lacked evidence of clinical efficacy, and less than one third (27%) were supported by strong scientific evidence (Figure).

Substantial variation in off-label use was observed across functional classes. Considering medication uses with strong and limited or no scientific support together, off-label prescription was rare among medications for glycemic control in diabetes mellitus (<1%) and infrequent among analgesics (6%) and medications to lower lipid levels (7%). Off-label prescription was most common among cardiac medications (antianginals, antiarrhythmics, and anticoagulants) (46%; 95% confidence interval [CI], 39%-53%), anticonvulsants (46%; 95% CI, 39%-53%), and antiasthmatics (42%; 95% CI, 35%-48%) (**Table 1**). Off-label prescription with limited or no scientific support was more common than supported off-label use in all therapeutic classes except diabetes therapies. The greatest disparity between supported and unsupported off-label prescription occurred among psychiatric (4% strong support vs 96% limited or no support) and allergy therapies (11% strong support vs 89% limited or no support).

High volumes of off-label prescription were correlated with high number of total drug mentions for specific drugs ($P<.001$). This is evident in **Table 2**, which shows the top 5 medications by volume of off-label mentions, 3 of which (albuterol sulfate, amoxicillin, and azithromycin) were among the top 5 medications by overall use. Gabapentin had the highest proportion of off-label prescription (83%), followed by amitriptyline hydrochloride (81%) and dexamethasone (79%). Among medications with the highest proportions of off-label use, most lacked evidence of clinical efficacy. This is especially true for gabapentin, where only 20% of its off-label use had strong support compared with 80% with

limited or no support. Conversely, off-label use for several medications was supported by a high degree of scientific evidence. Among the 24 medications for which most (>50%) of the off-label uses were scientifically supported, hypertension therapies were most common (7/21), followed by antimicrobials (4/21) and medications to lower lipid levels (3/21). It is not surprising, then, that 3 hypertension therapies (losartan potassium, atenolol, and a combination of hydrochlorothiazide and metoprolol tartrate) were among those medications with the highest degree of scientifically supported off-label use.

Few drug-specific characteristics were associated with off-label prescription (**Table 3**). Relative to analgesics, diabetes medications (RR, 0.04) were associated with less likelihood of off-label prescription, whereas anticonvulsants (RR, 5.7), psychiatric agents (RR, 4.1), allergy therapies (RR, 4.8), antiasthmatics (RR, 3.4), medications for peptic ulcer and dyspepsia (RR, 4.6), and cardiac medications (RR, 6.8) were associated with increased likelihood of off-label prescription. Other drug characteristics, including age, long-term use, combination therapies, formulation, dosing frequency, direct-to-consumer promotion, and manufacturer, showed few meaningful associations with off-label prescription.

Table 3. Drug-Specific Characteristics Associated With Off-label Prescription

Characteristic	RR (95% CI)	
	Unadjusted	Adjusted*
Analgesics	1.00	1.00
Allergy therapies	4.64 (2.80-7.69)	4.83 (2.19-10.62)
Antiasthmatics	3.33 (1.89-5.88)	3.44 (1.60-7.46)
Anticonvulsants	3.54 (1.98-6.31)	5.67 (2.49-12.91)
Antimicrobials	1.94 (1.02-3.72)	1.96 (1.09-3.54)
Cardiac therapies	6.80 (3.29-14.05)	6.75 (2.66-17.11)
Diabetes therapies	0.02 (0.00-0.11)	0.04 (0.01-0.16)
Peptic ulcer and dyspepsia therapies	3.04 (2.14-4.33)	4.58 (2.17-9.76)
Psychiatric therapies	3.18 (2.04-4.96)	4.08 (1.99-8.36)
Tablet	1.00	1.00
Capsule	1.09 (0.61-1.94)	0.61 (0.41-0.93)
Other medication forms†	0.10 (0.01-0.82)	0.33 (0.14-0.78)
No. of approved indications identified in *PDR*	1.05 (1.02-1.07)	1.03 (1.01-1.05)

Abbreviations: CI, confidence interval; *PDR, Physicians' Desk Reference*; RR, relative risk.

*Only drug-specific characteristics with a statistically significant association with off-label prescription are presented here. Adjustments were made for manufacturer, functional class, drug age, degree of direct-to-consumer promotion, use as a long-term therapy, medication form, frequency of use, and generic availability.

†Includes solution/suspension and injectable medication.

COMMENT

Using data from a nationally representative survey of office-based physicians, we found that about 21% of all estimated uses for commonly prescribed medications were off-label, and that 15% of all estimated uses lacked scientific evidence of therapeutic efficacy. We believe that ours is the first study to systematically characterize the extent of off-label prescribing in general outpatient care. The magnitude of off-label use varied widely among specific medications and drug classes, exceeding 50% for some anticonvulsants, psychiatric medications, and antiasthmatics. No more than 30% of the off-label practices we observed were supported by strong scientific evidence.

Many of the observed off-label drug mentions, particularly among medications frequently used off-label, represent a logical extension of the FDA-approved indication. For example, certain unapproved uses of antibiotics could be justified by laboratory studies demonstrating that the disease-causing organism responds to drug therapy. Albuterol, which is approved to treat asthma, is a clinically accepted off-label therapy for physiologically similar chronic obstructive pulmonary disease. Other medications are seen to exhibit a "class effect," such as the use of a particular angiotensin-converting enzyme that lacks approval for congestive heart failure.

In contrast, some of the observed off-label uses were as therapy for indications distinctly different from those for which the drug was approved. Examples include the use of metformin hydrochloride, approved for glycemic control in type 2 diabetes, as a therapy for relatively few patients with polycystic ovary syndrome and gabapentin, labeled for use as an anticonvulsant, as a widely used therapy for chronic nonspecific pain. Substantial heterogeneity remains in the degree to which many off-label practices, even those that seem to represent logical extensions of the labeled indication, are supported by scientific evidence.

Our findings echo those of an earlier study conducted 2 decades ago that considered the degree of evidence supporting a drug's efficacy for a limited number of specific drug-indication pairs.[14] Both studies indicate a need for more extensive postmarketing surveillance to identify non–evidence-based prescribing practices that lacked FDA approval. We suggest that policy makers confront these issues by asking the following questions: (1) What kinds of data could inform our understanding of the clinical and economic implications of off-label and non–evidence-based prescribing? (2) How can such data be collected or accessed once a drug has entered the market? and (3) Should decisions to "sanction" additional therapeutic uses without regulatory scrutiny consider the evidence or be left to market forces?

Differentiating off-label situations that are clinically reasonable from those that may be of concern is an essential first step. Such issues are at the forefront of prescription drug policy in Europe, where various systems have been established to monitor medication use after initial approval by regulatory authorities.[27] Regulators in Britain may label new drugs with a black triangle, signaling physicians to exercise caution when prescribing them; they can also monitor outcomes through a voluntary database of physicians' prescribing experiences. In France, pharmacovigilance centers track postapproval prescribing of drugs, whereas the European Medicines Agency can require drug manufacturers to collect and analyze postapproval surveillance data and mandate license renewal at shorter time intervals. These examples are designed primarily to protect patient safety, although simi-

Article

Cost-Effectiveness of Second-Generation Antipsychotics and Perphenazine in a Randomized Trial of Treatment for Chronic Schizophrenia

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Jeffrey Lieberman, M.D. for the CATIE Study Investigators

Background: Second-generation antipsychotics have largely replaced first-generation antipsychotics for the treatment of schizophrenia, but a large-scale cost/effectiveness analysis has not been attempted.

Method: Patients with schizophrenia (N=1,493) were assigned to treatment with a first-generation antipsychotic (perphenazine) or one of four second-generation drugs (olanzapine, quetiapine, risperidone, or ziprasidone) and followed for up to 18 months. Patients with tardive dyskinesia were prohibited from assignment to perphenazine. Patients could be reassigned at any time to another second-generation drug, including clozapine, but not to perphenazine. The cost analysis included medications plus health services use. Quality-adjusted life year (QALY) ratings were assessed on the basis of Positive and Negative Syndrome Scale (PANSS) subscale scores and side effects. An intention-to-treat analysis included all available observations, classified by initial drug assignment, and costs of reassignment of most patients to another second-generation drug. The analysis was repeated considering only treatment on initially assigned medications.

Results: Although QALY ratings, PANSS scores, and other quality of life measures indicated modest improvement over 18 months, there were no significant differences between perphenazine and any second-generation medication. Average total monthly health care costs were $300–$600 (20%–30%) lower for perphenazine than for second-generation antipsychotics because of lower drug cost. Differences in costs remained when maximally discounted drug prices were used for all patients and when only observations during treatment with the first medication were included.

Conclusions: Treatment with perphenazine was less costly than treatment with second-generation antipsychotics with no significant differences in measures of effectiveness. However, the trial was limited by a high dropout rate, and longer-term neurological and metabolic side effects require further study.

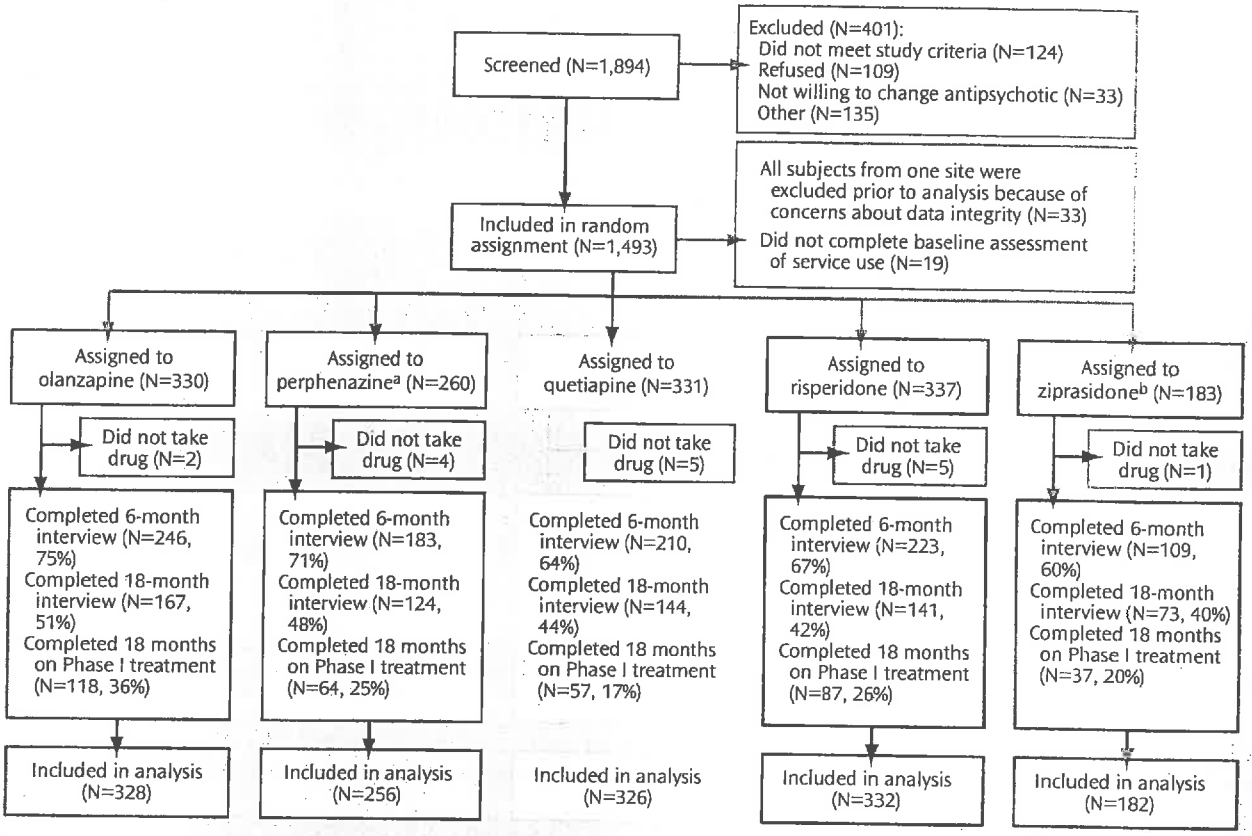
(Am J Psychiatry 2006; 163:2080–2089)

Since their introduction in the 1990s, second-generation antipsychotics have become the drugs of choice in the treatment of schizophrenia at a cost of over $10 billion annually in the United States, 75% of which is paid through Medicaid (1). Studies involving patients with chronic schizophrenia reported that these medications are more effective and have fewer side effects and a lower risk of hospitalization than older drugs, generating sufficient savings to offset greater drug costs (2–5). However, many of these studies were based on nonexperimental designs, and a small number of randomized trials have shown either smaller net savings (6, 7) or increased total costs (8). Two recent 12-month trials failed to find advantages for the newer drugs in either clinical effectiveness, reduced parkinsonian side effects, or cost (8, 9), and an economic analysis showed increased costs to the California Medicaid program in association with the introduction of these medications (1).

To further evaluate these agents from a public health perspective, the National Institute of Mental Health (NIMH) initiated the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) investigation. The CATIE study used an experimental study design to compare the effectiveness of one first-generation antipsychotic (perphenazine) and all four second-generation antipsychotics (olanzapine, risperidone, quetiapine, and ziprasidone), other than clozapine, that were available in the United States in January 2002. A report on the primary clinical outcomes from the CATIE study, considering only treatment with the initial randomly assigned drug (phase 1), found that patients receiving olanzapine 1) stayed on their medicine longer than others, 2) were less likely to switch

This article is featured in this month's AJP Audio and is discussed in an editorial by Dr. Freedman and colleagues on p. 2029.

FIGURE 1. CATIE Participant Progression



[a] Patients with tardive dyskinesia were prohibited from assignment to this medication.
[b] Added to the study after 40% of the subjects had been enrolled.

TABLE 1. Initial Treatment Assignments and Subsequent Treatment During the 18 Months

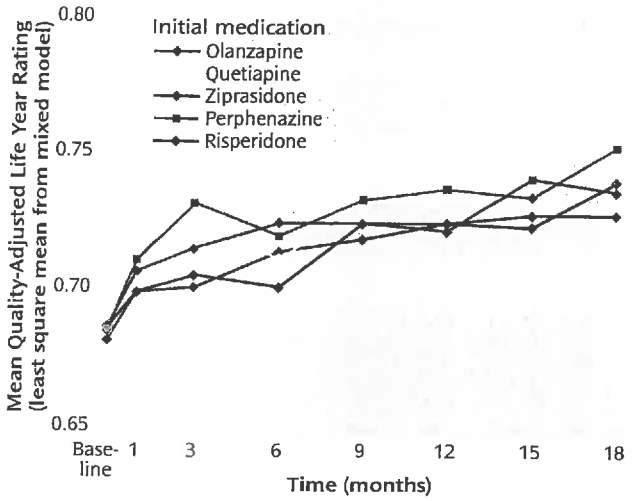
	Initial Assigned Medication											
	Olanzapine		Perphenazine		Quetiapine		Risperidone		Ziprasidone		Total	
Treatment Following Phase I	N	%	N	%	N	%	N	%	N	%	N	%
Olanzapine	—	—	366	32.0	414	30.4	420	35.4	232	32.8	1,432	26.2
Perphenazine	20	1.9	—	—	13	1.0	31	2.6	0	0.0	64	1.2
Quetiapine	292	27.4	362	31.6	—	—	238	20.1	139	19.6	1,031	18.9
Risperidone	353	33.2	251	21.9	346	25.4	—	—	191	27.0	1,141	20.9
Ziprasidone	175	16.4	76	6.6	289	21.2	245	20.6	—	—	785	14.4
Fluphenazine	22	2.1	14	1.2	39	2.9	17	1.4	3	0.4	95	1.7
Aripiprazole	47	4.4	5	0.4	65	4.8	58	4.9	89	12.6	264	4.8
Clozapine	155	14.6	70	6.1	195	14.3	178	15.0	54	7.6	652	11.9
Any atypical antipsychotic	1,022	96.1	1,130	98.8	1,309	96.2	1,139	96.0	705	99.6	5,305	97.1
Total	1,064	100.0	1,144	100.0	1,361	100.0	1,187	100.0	708	100.0	5,464	100.0

ratings for the eight schizophrenia health states ranged from 0.44 to 0.88, while side effect weights ranged from a low of 0.857 for tardive dyskinesia through 0.959 for weight gain and 1.0 when a side effect was not present. The final QALY rating estimate is the product of the QALY rating for the schizophrenia state and the QALY ratings for each side effect. Following the recommendations of the Public Health Task Force (13), this measure represents the health state of each subject on symptoms and side effects weighted for *societal* preferences (outcome measures based on *individual* preferences and their analysis are described in the supplement that accompanies the online version of this article). The Patient Perspective contains a clinical description of a typical patient in the study and describes the major features on which the QALY ratings are based.

Statistical Analysis

For consistency and comparability, the statistical methods used in the analysis of continuous measures in this study were the same as those used in the original publication from the CATIE investigation (10). Two hundred thirty-one patients with tardive dyskinesia were prohibited from assignment to perphenazine, and ziprasidone was added to the trial after 40% of the patients had been enrolled. Thus, randomization took place under four separate regimens: including and excluding patients with tardive

FIGURE 4. Average Monthly Quality-Adjusted Life Year (QALY) Rating by Initial Assigned Medication



ing a mixed model including terms representing treatment group, the baseline value of the dependent cost variable, time (treated as a classification variable for months 1–18), site, a history of recent clinical exacerbation, and baseline-by-time interactions. The baseline-by-time term adjusts for baseline differences in characteristics of patients who dropped out early and thus are less well represented at later time points. Group-by-time interactions, to evaluate differences in time trends between groups, were also tested. A random subject effect and a first-order autoregressive covariance structure were used to adjust standard errors for the correlation of observations from the same individual.

Use of any hospital days in each month was examined using a dichotomous measure (0=no, 1=yes) analyzed with generalized estimation equations using the GENMOD procedure of SAS (c).

Because of the skewed distribution of service use (i.e., nondrug) cost data, log-transformed data were used in the analysis of both 1) nondrug health service costs and 2) total costs, including medications, and both mean and median values are presented (23). Adjusted average log-transformed costs were then re-transformed into average costs using the "smearing estimation" method of Duan (24), after testing the data for heteroscedasticity (25). Untransformed monthly data were also averaged for each individual and compared using the Kruskal-Wallis nonparametric test.

The same mixed model analysis was used for effectiveness outcomes based on scores from months 1 and then quarterly from 3 through 18, again using a random subject effect and a first-order autoregressive covariance structure.

Results

Although 1,493 patients were enrolled in the study, all data from one site (33 patients) were excluded prior to analysis due to concerns about data integrity, and 19 never took their assigned study drug (Figure 1). Baseline utilization data were not available for an additional 19 patients, leaving 1,424 patients for analysis. Comparison of all patients on baseline assessments showed significant differences, as expected, on measures of tardive dyskinesia and akathisia, reflecting the exclusion of patients with tardive dyskinesia from randomization to perphenazine, as per the study design. There were no significant differences on these measures among patients who participated in the randomization that included perphenazine. Details of the baseline assessment data and comparisons of treatment groups both with and without perphenazine are presented in supplemental tables A and B that accompany the online version of this article.

In the intention-to-treat analysis using all available follow-up data, 68.2% of patients were still participating in follow-up interviews at 6 months, with significant differences in the proportion of participants across randomized treatments (χ^2=16.4, df=4, p=0.003). At 18 months, 45.7% were still participating, and differences in participation across these agents were no longer significant (χ^2=8.6, df=4, p=0.66).

In contrast to data on participation in follow-up interviews, data on treatment continuation show that only 25.9% of all patients completed 18 months with their original assigned treatment, with significant differences in the proportion of completers between groups (χ^2=31.5, df=4, p<0.0001).

Data on drug treatment following the first *change* in treatment after randomization show that virtually all treatments administered were second-generation drugs (range 96.0% to 99.6% across groups for all prescriptions following the first drug change) with a balanced distribution of agents across initial treatment groups (Table 1).

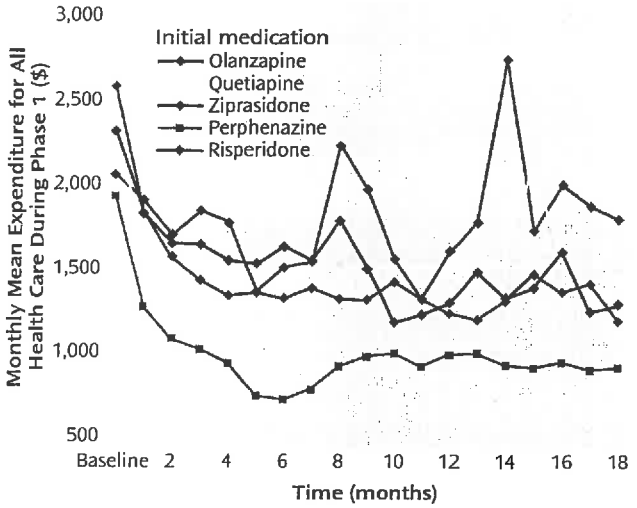
Service Use and Costs

Examination of all outcome data based on intention-to-treat analyses, which attributed all costs to the initially assigned drug, showed that total medication costs for patients initially assigned to perphenazine were $200–$300/month (about 40%–50%) lower than drug costs for patients assigned to each of the four second-generation antipsychotics (Table 2, Figure 2) (p<0.0001). Significant group-by-time statistical interactions (p<0.0001) reflect the narrowing of differences in drug costs during the first 8 months, after which perphenazine remained consistently less costly (p<0.0001 at each time point).

There were no significant differences in the proportion of patients who received inpatient care each month, the single greatest source of cost among people with schizophrenia (online supplemental figure A). The average total inpatient and residential treatment costs per month were also not significantly different between groups (Table 2, online supplemental figure B), nor were there any significant differences in the sum of inpatient, residential and outpatient health service costs (i.e., all nondrug costs) (Table 2, online supplemental figure C). Group-by-time interactions for these costs were not statistically significant, indicating continuous equivalence of these nondrug health services costs across groups over time.

When health service and drug costs were summed to generate total health costs (i.e., the primary cost outcome), average total monthly health care costs were $300–$600 (20%–30%) lower for perphenazine than for second-gener-

FIGURE 5. Total Average Monthly Health Costs During Phase 1[a] by Initial Assigned Medication



[a] Costs include inpatient, residential, and outpatient treatment and medication costs only for the period the patient was receiving the initial assigned medication.

perphenazine, was less costly and no less effective than assignment to each of four second-generation antipsychotics as measured by QALY ratings that combined measures of symptoms and side effects. Several different analytic strategies all yielded the same pattern of significant results, including: 1) analyses of all available outcome data, 2) analyses limited to the period of treatment with the initially assigned drug (phase 1), 3) comparison of both means and medians using parametric and nonparametric statistics, respectively, 4) examination of re-transformed log-cost data, and 5) sensitivity analyses in which less expensive Medicaid- and VA-discounted drug prices were applied to all patients. Since in this study perphenazine was consistently and significantly less costly and not less effective than the next most effective treatment, as measured by QALY ratings, calculation of the cost-effectiveness ratio was not performed (13).

These results extend the efficacy and safety outcomes analysis from the first report of the CATIE study, which used time to discontinuation of the initial treatment for any cause as the primary measure of effectiveness (10). The median time to discontinuation or completion of the trial in that study was 9.2 months for olanzapine compared with 5.6 months for perphenazine, a 64% increase for olanzapine in the length of time when both patient and doctor felt that no increase in benefit could be obtained by switching to another drug. The cost of treatment during these initial treatment periods, including the drugs, was $1,404 per month for olanzapine versus $960 per month for perphenazine, a 46% increase in cost per month for olanzapine. Among those who did not complete the study with their initial assigned medication and who were switched to other drugs, the difference in average monthly costs for the remainder of the 18-month study period, after the treatment period on their initially assigned drug, was only 3%.

Strengths of the study were its large sample size, long follow-up duration, and recruitment of patients from diverse representative sites with minimal exclusion criteria—all of which increase the generalizability of the results. The study was also enhanced by the use of a rigorously developed algorithm for evaluating health states specific to schizophrenia in terms of QALY ratings that take both symptoms of schizophrenia and side effects into account.

At the time the study was initiated, it was widely believed that perphenazine increased the risk of tardive dyskinesia, and differential randomization was used to minimize that risk. While a recent review suggested that second-generation antipsychotics are associated with less risk of tardive dyskinesia than first-generation antipsychotics (26), it noted that only three of 11 year-long studies were based on randomized trials and many others used relatively high doses of haloperidol for comparison. Results from the CATIE investigation (10) are consistent with the results of other recent studies (8, 9, 27–31) that have questioned the extent to which the risk of either tardive

Patient Perspective

"John" is a patient who typifies health state 5, which the community panel in the 2004 study of Lenert et al (18) gave a QALY rating of 0.65. John has moderately severe positive symptoms, including a wide range of poorly formed delusions that influence his behaviors. He smells bad smells and hears voices telling him he must clean up his mess or he will be punished. He thinks the smells are caused by leaks between the sewer and the tap water. As a result, he never drinks tap water and only washes his hands with towelettes. He talks repeatedly about the risk of catching hepatitis from tap water.

He does not have serious negative symptoms but has significant cognitive problems, with poor understanding of most analogies and difficulty placing items in categories. He is easily distracted and has difficulty concentrating on any one topic in conversation. He looks nervous, sometimes getting a little restless and agitated when you talk to him.

He has palpable emotional distress, saying he feels very nervous and complains of trembling hands and excessive perspiration. One can see John is anxious and that he has delusions, he mistrusts tap water, and washes his hands frequently with baby wipes. He spent part of last year living on the streets and in public shelters, but now he lives in a subsidized home. He goes out for walks, he shops, and sometimes he'll even go to a restaurant. But he hasn't developed meaningful relationships with other people because he is too anxious, he can't concentrate, and his delusions get in the way.

Inc.; consulting or advisory board fees from Pfizer Inc. and Bristol-Myers Squibb; and lecture fees from Bristol-Myers Squibb Janssen and Pharmaceutica. Dr. Davis reports serving on an advisory board for Eli Lilly and Company and Pfizer, Inc., and is an employee of Quintiles, Inc. Dr. Keefe reports having received research funding from AstraZeneca, Eli Lilly and Company, and Janssen Pharmaceutica; consulting fees or advisory board payments from Bristol-Myers Squibb, Eli Lilly and Company, Forest Labs, Janssen Pharmaceutica, and Pfizer Inc.; and lecture fees from Eli Lilly and Company and Janssen Pharmaceutica. Dr. Swartz reports having received research funding from Eli Lilly and Company and consulting and educational fees from AstraZeneca Pharmaceuticals LP, Bristol-Myers Squibb, Eli Lilly and Company, and Pfizer Inc. Dr. Perkins reports having received research funding from AstraZeneca Pharmaceuticals LP, Bristol-Myers Squibb, Eli Lilly and Company, Janssen Pharmaceutica Products, Otsuka Pharmaceutical Co., Ltd, and Pfizer Inc.; and consulting and educational fees from AstraZeneca Pharmaceuticals LP, Bristol-Myers Squibb, Eli Lilly and Company, Forest Labs, GlaxoSmithKline, Janssen Pharmaceuticals, Pfizer Inc., and Shire. Dr. Lieberman reports having received research funding from AstraZeneca Pharmaceuticals LP, Bristol-Myers Squibb, GlaxoSmithKline, Janssen Pharmaceutica Products, and Pfizer Inc.; and consulting and educational fees from AstraZeneca Pharmaceuticals LP, Bristol-Myers Squibb, Eli Lilly and Co., Forest Pharmaceutical Company, GlaxoSmithKline, Janssen Pharmaceutica Products, Novartis, Pfizer Inc., and Solvay. Drs. Leslie, Sindelar, Miller, Lin, and Hsiao report no competing interests.

The first author (R.R.) had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. This article was based on results from the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) project, supported by the National Institute of Mental Health (N01 MH90001). The aim of this project was to examine the comparative effectiveness of antipsychotic drugs in conditions for which their use is clinically indicated, including schizophrenia and Alzheimer's disease. Medication was provided by AstraZeneca Pharmaceuticals LP, Bristol-Myers Squibb Company, Eli Lilly and Company, Forest Pharmaceuticals, Inc., Janssen Pharmaceutica Products, L.P., Otsuka Pharmaceutical Co., Ltd., Pfizer Inc., and Zenith Goldline Pharmaceuticals, Inc. The Foundation of Hope of Raleigh, N.C. also supported this work.

The authors thank Ingrid Rojas-Eloi, B.S., Project Manager of CATIE, and Tiffany Harris, staff assistant, Department of Psychiatry, School of Medicine, University of North Carolina at Chapel Hill for their contributions. Les Lenert, M.D., provided consultation on utility assessment; and Jennifer Cahill of the VA Northeast Program Evaluation Center provided analytic support. The authors are also indebted to the 1,493 CATIE patient participants for their collaboration.

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FlexPen (using the medication possession ratio [MPR]), follow-up time-adjusted odds ratio (OR) of hypoglycemic events, association between adherence and hypoglycemic events in a Poisson multivariate context, and diabetes-attributable (DA), total management, and hypoglycemia-attributable (HA) costs.
RESULTS: Data from 1,156 type 2 patients newly converted to FlexPen were identified and analyzed (mean age 45.4 + 13.7 years; 51.5% previously on human insulin vials). Postconversion, MPR was significantly improved (69% vs. 62%; P <0.01), regardless of previous type of insulin vial use. A significant reduction in the likelihood of experiencing a hypoglycemic event was also observed (odds ratio [OR] = 0.50; confidence interval [CI], 0.37-0.68; P <0.05), and such events requiring either emergency department visits or physician visits decreased by 56% (OR = 0.44; CI, 0.21-0.92) and 61% (OR = 0.39; CI, 0.24-0.64), respectively (both P <0.05). The incidence of hypoglycemic events in subjects with MPR ≥80% dropped by nearly two thirds (OR = 0.35; CI, 0.11-0.81; P <0.05). The correlation between optimal MPR and reduced hypoglycemia was confirmed by a Poisson multivariate analysis. Total annual HA costs fell 56% ($1,415 vs. $627; P <0.01), and total DA costs fell 7% ($8,827 vs. $8,227; P <0.01).
CONCLUSIONS: Medication adherence to insulin therapy based on MPR was significantly improved following the initiation of an insulin analog pen device among type 2 diabetes patients. Further analyses on these patients should aim to evaluate the specific impact of variances in cost sharing or managed care benefit design plans.

METABOLIC MONITORING IN MEDICAID PATIENTS RECEIVING ATYPICAL ANTIPSYCHOTICS

Strouss LA, Schuster JM, Ciocco G. Community Care Behavioral Health Plan, 100 Chatham Center, Suite 734, Pittsburgh, PA 15219; stroussla@ccbh.com, (412) 402-8719*

INTRODUCTION: In February 2004, the American Diabetes Association and American Psychiatric Association (ADA/APA) Consensus Development Conference on Antipsychotic Drugs and Obesity and Diabetes recommended that patients receiving atypical antipsychotic receive routine lipid and glucose monitoring.
OBJECTIVE: To assess whether members taking these medications were tested for lipid and glucose levels during the prior 12 months.
METHODS: Lab claims were extracted from the behavioral health managed care organization (BH-MCO) for the participating counties with service dates between April 1, 2004, and June 30, 2005. Claims were sent to the appropriate physical health plan in accordance with HIPAA (Health Insurance Portability and Accountability Act) guidelines. The physical health plan extracted the same lab claims data during that quarter and merged it with the BH-MCO file for completeness. Medicaid pharmacy claims data were analyzed from April 1 through June 30, 2005, to identify patients receiving an atypical antipsychotic (including Symbyax). These members were merged with the lab claims to identify if metabolic testing was performed. The prescribing physicians of members who were identified as not having testing were notified via fax. A summary letter of the findings was sent to all network physicians.
RESULTS: 9,388 unique members were identified in Allegheny County as having a paid prescription for an atypical antipsychotic (including Symbyax) during the period April 1 through June 30, 2005. 14.43% (n = 1,355) of those members were identified as having glucose and/or a lipid lab test during the prior 12 months. In Berks, York, and Adams counties, of the 2,408 unique members who were identified as receiving an antipsychotic, 7.27% (n = 175) had received a lab test.
CONCLUSION: On the basis of ADA/APA guideline recommendations, patients undergoing atypical antipsychotic therapy did not receive adequate lipid and glucose monitoring. Effective efforts to promote awareness and adherence with monitoring recommendations are needed.

MISSOURI MEDICAID'S DISEASE MANAGEMENT PROGRAM: A COMPREHENSIVE CARE MANAGEMENT MODEL USING PHYSICIAN AND PHARMACIST CARE TEAMS

Cornelius JE, Smith JC, Berringer RA, Oestreich GL. ACS Heritage, Inc., 2810 North Parham Rd., Suite 210, Richmond, VA; robert.berringer@acs-inc.com, (804) 965-8119*

BACKGROUND: Missouri Medicaid implemented a disease management (DM) program during the first quarter of 2003, covering its fee-for-service population.
OBJECTIVE: To determine how a DM model that included physician-pharmacist care teams would affect pharmacy and medical costs.
METHODS: In the first quarter of 2003, fee-for-service Medicaid patients who had a history of targeted diseases (e.g., asthma, depression, diabetes, and heart failure) were eligible and were invited to participate in the program via mail and select a physician and pharmacist DM care team. Providers were required to be registered as DM providers by Medicaid. Pharmacists were also required to complete an ACPE (Accreditation Council for Pharmacy Education)-accredited continuing education course. Providers received an automated severity and risk assessment, patient profiles with identified drug therapy problems, care plans, patient educational brochures, and listing of patients assigned to them, within 30 days of patient enrollment and every quarter thereafter. Both physicians and pharmacists were reimbursed for providing DM services.
RESULTS: Of the approximately 40,000 Medicaid fee-for-service patients eligible for the program, 1,604 were enrolled as of June 2005. Of those, 98 patients were enrolled for at least 1 year. For those 98 patients, the total amount paid per targeted member

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Continued from page 488

"The goals just keep getting stricter and stricter," she said, adding that health care providers who care for patients with diabetes want their patients to meet treatment goals when possible.

"But in the last couple of years, [I] have recognized how much more important it is to individualize therapy for patients," Rodis said. "You do want to try to achieve as strict a goal as you can, because the lower the blood sugar, to a certain extent, the better you can prevent complications."

"You reduce the risk as much as possible, but you have to balance how each individual patient is feeling," Rodis said.

Beyond HbA_{1c}. ADA's guidelines also provide updated diabetes management goals in hospitals.

Hospitalized patients with diabetes who are critically ill should be treated with i.v. insulin with the goal of keeping their blood glucose level as close to 110 mg/dL as possible, and less than 140 mg/dL in general, according to the guidelines.

Inpatients who are not critically ill should be treated preferentially with insulin to maintain fasting blood glucose levels of <126 mg/dL and random glucose values of <180–200 mg/dL, if these targets can be safely met, the guidelines state.

The guidelines also state that angiotensin-converting-enzyme inhibitors or angiotensin-receptor blockers are the preferred agents to control blood pressure in most patients with diabetes.

ADA also continues to emphasize the need to recognize prediabetes. The guidelines recommend that metformin treatment be considered to prevent or delay the onset of type 2 diabetes in overweight and obese people who have additional risk factors for diabetes, such as impaired fasting glucose or impaired glucose tolerance.

Rodis said her clinic does not focus on prediabetes, because her patients have already been diagnosed with full-blown diabetes. But she said prediabetes is addressed in periodic wellness programs offered by the clinic.

Rodis said she knows of "a handful" of patients with prediabetes who are taking metformin, but she said the pharmacologic treatment of prediabetes does not seem to be a big focus yet for most local health care providers. In most cases, she said, health care providers are emphasizing diet and exercise for patients with prediabetes.

—Kate Traynor

DOI 10.2146/news080021

State-paid medication therapy management services succeed

With health-system pharmacists in the lead, Minnesota has "effectively implemented" medication therapy management (MTM) services for low-income patients with complex medical and drug-related needs, according to a report on the program's first year.

The 10 "most productive" pharmacists, the report states, were part of an integrated health care delivery system and in "established collaborative practice relationships" with physicians and other primary care providers.

In all, 34 pharmacists billed the state for providing MTM services to 259 patients from April 1, 2006, to March 31, 2007.

The pharmacists received an average of $92.50 per patient visit, with the payment based on the complexity of care for the given patient.

They resolved an average of 3.1 drug therapy problems per patient, usually issues of inadequate therapy. The patients, ranging in age from 12 to 91 years, averaged six medical indications and 14 drugs each.

Through a variety of analyses, the research team, led by University of Minnesota Associate Professor Brian J. Isetts, concluded that pharmacist-provided MTM services improved patients' clinical outcomes and offered the state the potential to save on health care expenditures in the future.

For example, by checking patients' medical records, the research team found that 36% of the patients with diabetes mellitus met all five of the state's standards for diabetes care after starting to receive MTM services. Statewide in 2004, an estimated 6% of patients with

North Carolina funds service for seniors

Launched in late 2007, CheckMeds NC pays community pharmacists to help Medicare Part D enrollees residing in North Carolina avoid drug interactions and maximize their federal prescription drug benefit.

The North Carolina Health and Wellness Trust Fund selected pharmacist-operated Outcomes Pharmaceutical Health Care in Des Moines, Iowa, to run the new medication therapy management program.

According to the trust fund's most recent annual report, $2 million will be spent over three years to have local community pharmacists, under contract with Outcomes, counsel Part D enrollees on the most appropriate and cost-effective use of their federal drug benefit.

The trust fund claimed that North Carolina is the first state in the nation to use medication therapy management to help seniors maximize their Medicare drug benefit.

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state's willingness to help when problems arose.

"I needed a little help with some of the billing . . . so I called the help desk, and guess what happened? The help desk was helpful."

Isetts said the state's side of the program did not start rolling smoothly until mid-May 2006.

The state spent the first few weeks of April 2006 processing pharmacists' applications to enroll as providers in Minnesota Health Care Programs, he said. MTM services claim number 1 was transmitted around April 25.

"For the first two weeks [afterward] we had to work out some of the billing glitches that the state had," Isetts said.

The next challenge, he said, came January 1, 2007, when the state stopped paying directly for MTM services delivered to patients in prepaid medical assistance plans. Pharmacists had to submit their claims to the insurance companies running the plans.

"They weren't ready for it," Isetts said of the insurance companies. Some did a better job than others of credentialing pharmacists and setting up the process for claims submission and payment. Laggards took as long as six months.

"The good news is that they figured it out," he said.

But, as Isetts quickly added, the insurance companies had no choice but to figure it out.

The law authorizing the program put an end to what he described as the local health insurance industry finding excuses not to pay. "Now, the whole health insurance industry is up to speed in Minnesota with paying pharmacists for MTMS, and it's at the rate that the state has set."

Interviewed on February 11, Isetts said personnel from Abt Associates Inc., under contract with the federal Centers for Medicare and Medicaid Services, were expected that week to study the state's MTM services program.

—Cheryl A. Thompson

DOI 10.2146/news080022

EPA inspections of drug disposal practices can be a learning moment

Fred Massoomi was not quite sure what to make of his requested presence at a meeting between hospital representatives and U.S. Environmental Protection Agency (EPA) officials in September 2004.

The pharmacy operations coordinator for Nebraska Methodist Hospital, in Omaha, thought he might have to answer a few questions, but he soon found himself in the hot seat.

An EPA inspector began talking about a law Massoomi had not heard of—the Resource Conservation and Recovery Act (RCRA).

Passed in 1976, the law dictates how certain hazardous wastes must be handled. RCRA in recent years has become a familiar term around hospital pharmacies.

There were no reported violations for Nebraska Methodist Hospital to prompt the 2004 visit. Instead, EPA inspectors had come to the area based on violations at a nearby U.S. Department of Veterans Affairs medical facility. Massoomi's hospital was one of two local medical centers randomly selected for inspection while the EPA team was in town.

Since Nebraska Methodist Hospital has a cancer center, the inspector began asking for manifests and disposal records for the cytotoxic drug cyclophosphamide. The purchasing records were not a problem, but there was no documentation for disposal of the drug, he said.

Massoomi soon learned that this drug was identified as U058 on RCRA's U list of hazardous substances. Along with the P list, pharmaceutical substances on the U list are discarded commercial chemical products considered to be ignitable, corrosive, reactive, or toxic.

Pharmacies that work with any P- or U-listed substances must have a separate waste stream for disposing of those materials. The drugs should not be mixed with needles or other typical medical waste heading for disposal.

Nebraska Methodist Hospital was careful to put cyclophosphamide in yellow "sharps" containers, but this action was in violation of RCRA.

Hospital officials learned they had 90 days to come into RCRA compliance or face daily fines of up to $32,500. Additionally, Massoomi and the hospital's chief executive officer could be held personally liable for RCRA violations.

Despite the high stakes, Massoomi tried not to look at the inspection process as a crisis. Instead, he tried to make the best of the situation.

"We used her as a resource," Massoomi said of the inspector, taking the opportunity to ask for recommendations on waste management in the pharmacy. The hospital was not fined for any violations.

"We're responsible for these drugs from cradle to grave," he said.

Putting plans in place to manage RCRA substances was only part of the challenge facing the Nebraska hospital. Internal compliance was a significant hurdle, as busy nurses frequently tossed RCRA pharmaceuticals into the wrong disposal bins.

Massoomi said the hospital tried education programs with limited success. The pharmacy even began placing RCRA drugs into black plastic bags that were specifically labeled for disposal in corresponding black bins, but results did not improve much.

"I can only get the nurses to do what they can do," he said of disposing the RCRA drugs in separate containers.

He realized that nurses felt burdened with enough regulations already as they doled out up to 300 medication doses a day, and this was one more drain on their time. Massoomi is hopeful that technology can help solve the nursing compliance issues.

"We're trying to take the . . . thinking out of the process," he said of the decision-making process for disposing of excess or unneeded portions of RCRA drugs.

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Evaluating Effectiveness of the Minnesota Medication Therapy Management Care Program

FINAL REPORT

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EXECUTIVE SUMMARY

Genesis of the Minnesota Medication Therapy Management Care Law can be traced to legislator visits in 1993 to pharmacies implementing new practices in the Minnesota Pharmaceutical Care Demonstration Project. Bills introduced in five legislative sessions over 12 years culminated in the enactment of Minnesota Statute §256B.0625, subd. 13h., 2005. Data pertaining to favorable clinical, economic and humanistic outcomes, as well as experiences of other Medicaid programs in states such as Missouri, North Carolina, Ohio, Florida and Iowa were used to support this legislative initiative. Hallmarks of the Minnesota Law include defining the medication therapy management component of pharmaceutical care services, recognition of qualified pharmacists as providers, authorization for program evaluation, and initial stewardship of program implementation entrusted to collegial relationships among the Department of Human Services (DHS), pharmacist providers, professional associations, and academia (through the DHS Medication Therapy Management Advisory Committee).

The primary goal of this analysis was the development of measurement parameters to be utilized in evaluating program improvements and enhancements, and to support the program's continued application. The analytical study period for this evaluation was April 1, 2006 to March 31, 2007 (the first year of the program). During the first year of the MTM Care Program 34 pharmacists provided medication therapy management services (MTMS) to 259 recipients. The 259 recipients had a total of 431 MTMS encounters and pharmacists were paid $39,866 for the delivery of these services. The age range of recipients receiving MTMS was 12 to 91 years (median age 52) with 97% (250/259) of recipients under the age of 65.

The four attributes of outcomes data included in this analysis were: clinical, economic, program implementation, and program improvement. Clinical outcomes analysis included evaluating drug therapy problems identified and resolved, goals of therapy achieved, and performance-based benchmark standards achieved for recipients with diabetes and coronary heart disease. Economic outcomes analysis included comparing total health care expenditures for recipients before and after receiving MTMS, and measuring the value-based purchasing impact of recipients meeting performance-based benchmark standards. Program implementation and program improvement were evaluated using medical records chart abstraction review, self-assessment surveys, and focus group interviews and meetings.

Pharmacists in this one-year evaluation identified and resolved 789 drug therapy problems in 259 recipients (3.1 drug therapy problems per recipient). Inadequate therapy (e.g. dose too low for effectiveness, needs additional preventive therapy, and noncompliance) represented 73% of resolved drug therapy problems. Based on the number of drug therapy problems resolved, the number of drugs (14 drugs/recipient), and the number of medical indications (6 indications/recipient) demonstrates that State of Minnesota medical assistance and general assistance medical care recipients with complex medical and drug-related needs were served in the first year of the program.

Continuous quality improvement analysis indicates that the State of Minnesota effectively implemented the MTM Care Program by developing tools, procedures and communications processes that were not previously available in other State Medicaid programs. Work of the DHS MTMS Advisory Committee prior to program implementation was very important to successful implementation. Pharmacists participating in the program effectively screened recipients to comply with statutory recipient enrollment qualifications. Processes of care used by pharmacists indicate that recipients' received comprehensive assessments of their drug-related needs and extensive attempts were devoted to conducting follow-up evaluations.

The ten most productive pharmacists in the first year of the MTMS program were those with established collaborative practice relationships with physicians and other primary care providers and were also part of an integrated health delivery system. This finding is consistent with health care delivery improvements advanced in the chronic care model and the medical home model concepts. Pharmacists appropriately identified recipients qualifying for MTMS coverage, although there was a high rate of appointment non-adherence and difficulty maintaining follow-up contact with recipients. Increasing physician awareness of the availability of MTMS may be important for encouraging recipient utilization of the MTMS benefit. It was also suggested that recipients' physicians, case managers and social workers be contacted to assist in coordinating care and resolving recipient transportation problems.

The program implementation and program improvement analyses were conducted by using a continuous quality improvement framework. A number of tools and procedures were used to implement the program including provider enrollment, on-line billing, and provider communications. Cooperation in program implementation among the state professional association, academia, private industry and the State of Minnesota were essential to successful program implementation.

Analysis of pharmacists' documentation in comparison to statutory and regulatory requirements indicated that there was greater than 90% compliance with 11 of 14 essential documentation elements. Medical records chart review of 48% (126 of 259) of recipient records demonstrated that MTMS providers adhered to the resource-based relative value scale (RBRVS) billing criteria with approximately one-third of claims being conservatively billed or potentially under-billed.

The provision of MTMS improves patient care and positively affects quality of care. Although the time frame for economic analysis was limited, the potential impact of MTMS on health expenditures due to improvements in QCare quality standards is noteworthy. The results of this analysis indicated that the State of Minnesota MTM Care Program was effectively implemented and that providers cared for recipients with complex medical and drug-related needs.

number of drug therapy problems. On April 1, 2006 the Minnesota Medicaid MTMS program began enrolling pharmacist MTMS providers who would then identify eligible recipients, deliver and document MTMS, and bill the State for the appropriate level of services delivered.

The MTMS legislation also directed the commissioner to evaluate the effect of medication therapy management on quality of care, patient outcomes, and program costs, and to include a description of any savings generated in the medical assistance and general assistance medical care programs that can be attributable to this coverage. The law enabled the commissioner to contract with a vendor, or an academic institution that has expertise in evaluating health care outcomes, to complete the evaluation. Pursuant to a Request for Proposal issued by the Minnesota Department of Human Services, the University of Minnesota received notification of intent to enter into negotiations and the program evaluation contract was signed on May 10, 2007.

Project Personnel, Disclosure and IRB Oversight

Personnel leading this evaluation project were Brian J. Isetts, B.S., Ph.D., BCPS, FAPhA (Principal Investigator) and Stephen W. Schondelmeyer, Pharm.D., M.A.Pub.Adm., Ph.D., FAPhA (Co-Investigator). Dr. Brian Isetts directed the overall project and the day-to-day research and evaluation activities. Dr. Schondelmeyer provided oversight of the design and implementation of the economic analysis. Two Graduate Research Assistants (Tabitha Leighton and Shriram Parashuram) worked on the data management and the economic analysis. An advanced-standing Pharmacy Doctorate student (Jenifer Morgan) assisted in conducting chart abstractions, organizing focus group meetings and completing other project tasks. There are no financial interests to disclose among any personnel working on this contract in relationship to any of the products, services or business entities evaluated in this analysis. This project was approved by the University of Minnesota's Research Subjects' Protection Program Office at the University of Minnesota (IRB Study Number 0706E10744).

Definition of Acronyms in this Report

AMA - American Medical Association
CHD - Coronary Heart Disease
CPT - Current Procedural Terminology
CQI - Continuous Quality Improvement
DHS – Minnesota Department of Human Services
FFS - Fee for Service
HEDIS - Healthcare Effectiveness Data and Information Set
ICSI - Institute for Clinical Systems Improvement
LDL – Low-density Lipoprotein Cholesterol
MDH – Minnesota Department of Health
MTMS - Medication Therapy Management Services
PPHP - Pre-Paid Health Plan
QCare - Quality Care and Rewarding Excellence
RBRVS - Resource-based Relative Value Scale

Drug therapy problem analysis

Drug therapy problems are undesirable events experienced by the patient involving drug therapy that impedes progress toward achieving desired goals of therapy.[27] The result of a pharmacotherapy assessment provided during an MTMS encounter is to identify, describe and prioritize drug therapy problems to be resolved through specific interventions within a patient-specific care plan. The number and nature of drug therapy problems identified and resolved by delivery of MTMS to program recipients during the first year of the program were analyzed. Drug therapy problems identified during MTMS were classified using the following drug therapy problem taxonomy (Cipolle, et. al., McGraw-Hill, 2004):[27]

Drug Therapy Problem Taxonomy

Drug-related needs	Categories of drug therapy problems
Indication	1. Unnecessary drug therapy 2. Needs additional drug therapy
Effectiveness	3. Ineffective drug 4. Dosage too low
Safety	5. Adverse drug reaction 6. Dosage too high
Compliance	7. Noncompliance

In this project, drug therapy problems were studied by compiling the total number of drug therapy problems identified and resolved among all MTMS recipients during the first year of the program, analyzing pharmacists' documentation summary records for those providers utilizing pharmaceutical care documentation software, and conducting chart abstraction of a sample of pharmacists' MTMS records.

The total number of drug therapy problems (for n=259 recipients) equals the number of drug therapy problems verified by chart abstraction (n=126 recipients) added to the number of drug therapy problems represented within the RBRVS classification system for the remaining (n=133 recipients) MTMS claims not reviewed by chart abstraction. The RBRVS compensation system with definitions is presented in Table 1, as well as inserted on the next page for quick reference. The RBRVS compensation system was developed between 1985 and 1992 by the American Medical Association, Harvard School of Public Health and the Health Care Financing Administration in response to Congressional demands for a physician reimbursement system founded on resource costs rather than usual and customary billing.[28,29] This initiative resulted in the current allocation of resource input costs in the *CPT Manual* for physician work including pre-, intra-, and post-service work, practice expenses, and professional liability insurance.[30] It is noted that in the case of services delivered by physicians, physician assistants, nurse

Goals of Therapy Analysis

Goals of therapy are desired endpoints for pharmacotherapy expressed in terms of parameters (signs and symptoms) and laboratory values which are observable, measurable and realistic. The pharmaceutical care process used to provide MTMS includes assessment, care planning, and follow-up evaluation to determine actual outcomes of pharmacotherapy. Therefore, the achievement of goals of therapy can be tracked over time as a result of MTMS. Documentation in the electronic pharmaceutical care record system used by the majority of MTMS providers in the program permits analysis of goals of therapy achieved over the course of recipients' MTMS encounters. In the summary report of 167 recipients' MTMS records (described in the drug therapy problem analysis previously), the achievement of recipients' goals of therapy were analyzed.

Performance-Based Standards of Care

Measuring performance on important dimensions of care and service has been an intense focus of interest in the U.S. healthcare system over the last 15 to 20 years. The National Committee for Quality Assurance (NCQA) was formed in 1990 to build consensus around important health care quality issues by working with large employers, policymakers, doctors, patients and health plans to decide what's important, how to measure it, and how to promote improvement. The Healthcare Effectiveness Data and Information Set, or HEDIS (formerly the Health Plan Employer Data and Information Set) is a tool used by more than 90 percent of America's health plans to measure performance on important dimensions of care and service.

Obtaining value for health spending is important to employers who seek ways to reward providers who achieve quality care benchmark standards. In 2003 the Governor of Minnesota announced the formation of a panel of 18 respected citizen leaders to engage the public in a dialogue about health care costs and to develop recommendations for cost control strategies. Panelists of the Minnesota Citizens Forum on Health Care Costs traveled throughout the State listening to Minnesotans at town hall meetings and informal fireside discussions. The final report reflected a deep-seated desire of many Minnesotans to work together to create a better system of health care.[32]

One of seven key recommendations contained in the Minnesota Citizens Forum Report called for reducing costs through better quality by coordinating existing state quality improvement efforts and rewarding better quality and effectiveness. The appeal to employers and payers of competing on results, known as "value-based purchasing," relates to improving quality in healthcare by achieving evidence-based goals of therapy.[33,34] By achieving desired goals of therapy while decreasing drug-related morbidity and mortality, the provision of MTMS has value-based purchasing implications. The integration of MTMS into healthcare delivery has been cited by the National Business Coalition on Health as a viable means for helping patients achieve their health goals.[35]

Diabetes Benchmark Parameters

Optimal care for patients with diabetes for 2006 according to the Minnesota QCare Project required meeting all five of the following diabetes benchmark standards:

(1) Hemoglobin A_1C measurement below 8%,
(2) LDL-cholesterol measurement below 130 mg/dL,
(3) Blood pressure measurement below 130/85 mm Hg,
(4) Daily aspirin use if over 41, and
(5) No tobacco use.

In 2004, 6% of Minnesotans who were diagnosed with diabetes were estimated to have received optimal care for their diabetes based on these QCare benchmarks. The identification of patients with diabetes for QCare chart audits was based on ICD-9-CM Codes for diabetes,[1a] reported in or obtained from medical and hospital claims data supplied by the State of Minnesota. IRB and other research committee approvals were obtained to conduct chart abstracts in the Fairview and Health Partners health systems. Rather than selecting a sample group, the records of *all* MTMS recipients with diabetes in the Fairview and Health Partners systems as identified by claims data were reviewed in this analysis.

Coronary Heart Disease Benchmark Parameters

Optimal care for patients with coronary heart disease for 2006 according to the Minnesota QCare Project required meeting all five of the following benchmark standards:

(1) LDL-cholesterol measurement below 100 mg/dL,
(2) Blood pressure measurement below 140/90 mm Hg for all ages,
(3) Blood pressure measurement below 130/80 mm Hg for patients with co-morbidity of diabetes,
(4) One aspirin per day, and
(5) No tobacco use.

The identification of patients with coronary heart disease for QCare chart audits was based on ICD-9-CM Codes for coronary heart disease,[2a] reported in or obtained from medical and hospital claims data supplied by the State of Minnesota. IRB and other research committee approvals were obtained to conduct chart abstracts in the Fairview and Health Partners health systems. The records of all MTMS recipients with coronary

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[1a] The ICD-9-CM Codes for Diabetes Mellitus begin with code 250 and exclude: gestational diabetes (648.8), hyperglycemia – not otherwise specified (790.6), neonatal diabetes mellitus (775.1), non-clinical diabetes (790.2), and diabetes complicating pregnancy, childbirth, or the puerperium (648.0).

[2a] The ICD-9-CM Codes for Coronary Heart Disease include the following: acute myocardial infarction (410), percutaneous transluminal angioplasty (PTCA), and coronary artery bypass graft (CABG) (36), coronary atherosclerosis (414), stable coronary angina (413.9), unstable coronary angina (411.11), and chest pain (non-anginal) (786.5).

patient optimal care annual cost savings amount ($403.30) times the number of MTMS recipients achieving optimal care above the state average. Results are reported as a potential cost-saving amount per MTMS recipient for improvements in performance-based benchmark criteria above the statewide average.

Program Implementation Analysis

Documentation analysis

Comparisons of practitioners' MTMS documentation to statutory and regulatory documentation requirements was accomplished by two methods: 1) Practitioner self-assessment and, 2) Desk review records chart abstraction of the 126 recipient records used in the QCare performance benchmark evaluation. Pharmacist self-assessment of regulatory requirements has been used successfully by the Wisconsin Pharmacy Examining Board in lieu of Board Inspector verification of compliance.[39] Results from this analysis are reported as a percentage compliance rate with documentation elements contained in the DHS Program Guide. The service definition and documentation specifications used in this analysis have been drawn from the DHS Program Guide, MHCP Provider Update PRX-06-02R (available at: http://www.dhs.state.mn.us/main/idcplg?IdcService=GET_DYNAMIC_CONVERSION&RevisionSelectionMethod=LatestReleased&dDocName=dhs16_136889#P146_6142). The pharmacist documentation self-assessment instrument and the documentation chart abstraction instrument used in this analysis are presented in Appendices D and E. This information was then presented and discussed at MTMS Provider CQI Focus Group meetings held on 9/26/07 and 10/2/07 so that providers could review, clarify, rate and enhance documentation.

Documentation analysis also included an accounting of drug therapy problems identified and resolved, goals of therapy achieved in recipients receiving MTMS, and comparison of MTMS claims to resource-based relative value scale documentation elements (e.g. number of medical indications, number of active medications, and number of drug therapy problems resolved). Desk review chart abstraction of pharmacists' MTMS was performed for the 126 recipient records analyzed in the QCare quality of care performance benchmark evaluation.

Relationship of MTMS Documentation to the RBRVS Reimbursement Grid

Chart abstraction of the 126 recipient records used in the quality of care performance benchmark analysis was also used to analyze the consistency of billing in relationship to the RBRVS billing schematic. The five-level RBRVS reimbursement grid is presented in Table 1.

In the reimbursement grid presented in Table 1 it is important to note that the American Medical Association's CPT Panel recently migrated pharmacists' MTMS CPT codes from Category III status (0115T, 0116T, 0117T) to Category I status (99605,

both sites received a report of Medicaid recipients who were receiving prescriptions at each of their respective sites, including prescription claims and diagnosis codes from ambulatory clinic visits. Suggestions from the case managers combined with utilization review by the State resulted in a list of diseases to be included in the algorithm that would capture chronic diseases characteristic of FFS recipients in need of MTMS.

The State then worked with the contractor ACS-Heritage to devise the final algorithm to be used for prospectively identifying priority MTMS recipients. The final list of ten chronic disease conditions (fourteen diseases) included: chronic heart failure, migraine headaches, hypertension, hyperlipidemia, asthma, osteoporosis, osteoarthritis, chronic obstructive pulmonary disease, diabetes, and mental health (depression, schizophrenia, post-traumatic stress disorder, bipolar disorder, and attention deficit hyperactive disorder). The algorithm was based on the presence of two or more occurrences of the ICD-9-CM codes for the 14 diseases within the previous two years and two or more prescriptions corresponding to the 14 diseases within the previous 135 days. In June 2007 the final algorithm was applied to all Minnesota Medicaid recipients to determine the number of individuals who would be identified using this tool.

In addition, the predictive value of the algorithm was examined in MTMS recipients who had previously received MTMS during the first year of the program. The subgroup of 77 MTMS fee-for-service (FFS) recipients utilized for the economic analysis was employed to determine the percentage of these recipients who would have been identified by the algorithm.

Program Improvement Analysis

The MTMS provider focus group process described above served as the basis for developing the program improvement recommendations and suggestions provided in this analysis. An experienced program facilitator (Ms. Marsha K. Millonig, MBA, RPh, President, Catalyst Enterprises LLC of Eagan) assisted in coordinating discussions among MTMS providers at the 9/26/07 and 10/2/07 focus group meetings. Results of the pre-meeting surveys plus three program case studies were shared with providers to stimulate discussions pertaining to program implementation.

RESULTS

The primary goal of this analysis has been the development of measurement parameters to be utilized in evaluating program improvements and enhancements, and to support the program's continued application. The analytical study period for this evaluation is 4/1/06 to 3/31/07 (first year of the program).

Therefore, a total of 789 drug therapy problems were identified and resolved among the 259 MTMS recipients (3.1 drug therapy problems per recipient). In a national sample of over 2,985 patients who received pharmaceutical care services between the years 2000 and 2003, pharmacists found and resolved 9,845 drug therapy problems (or 3.3 drug therapy problems per patient over the four-year period).[42]

The top 20 ICD-9-CM condition codes listed on the 259 recipients' initial MTMS encounter claims are presented in Table 2. It is noted that diabetes represented the most frequently listed condition code on MTMS claims.

There were a total of 34 pharmacists who provided care to recipients during the first year of the program. Table 3 displays the profile of care delivered by each of the 34 pharmacists during the study period. The ten most active MTMS pharmacists, in terms of recipient encounters and drug therapy problems resolved, were collaborating with physicians and other primary care providers within an established integrated health delivery system (the Fairview and Health Partners systems). This finding is consistent with health care delivery improvements advocated in the chronic care model[43] (which identifies interrelationships among essential health system elements necessary for productive interactions between proactive practice teams and activated patients), and the medical home model[44] (in which linking patients to a patient-centered medical home helps eliminate barriers and improve access) concepts.

Table 4 summarizes the categories of drug therapy problems for 126 recipient records reviewed by chart abstraction. Dosage too low, noncompliance, and need for additional drug therapy represented 73% of drug therapy problems resolved by MTMS pharmacists. A subset analysis of medications and conditions associated with the 21 "unnecessary drug" category of drug therapy problems is presented in Table 5 to illustrate the medications and corresponding indications found in the desk review analysis for this category of drug therapy problems.

Desk review chart abstraction was also used to record the indications associated with drug therapy problems. A summary report of drug therapy problems with corresponding medical indications is presented in Table 6. It is noted that diabetes represents the predominant condition in this review. This result would be expected as diabetes was the most frequently listed condition code on MTMS claims (*See* Table 2), as well as one of the medical claims review criteria employed for the quality of care performance-based benchmark analysis.

For MTMS providers who use pharmaceutical care documentation software (e.g. the Assurance™ system) in their practices, an analysis of 167 recipients' pharmaceutical care documentation summary reports indicates that MTMS recipients had an average of 6.3 indications per patient (range = 2 – 12) and were taking 14.1 drugs (prescription plus non-prescription drugs) per patient (range = 4 – 25). The 14.1 drugs per recipient included 10.5 prescription and 3.6 non-prescription medications per recipient.

Association, it is noted that the prevalence of CHD increases to 10% in men after the age of 60 and in women after the age of 65.[45] Therefore, the small number of recipients with CHD alone limits analysis of results from this subgroup of recipients.

Improvements in QCare standards exemplify the contribution of pharmacists' MTMS to quality of care and health care effectiveness. When drug therapy problems are resolved patients achieve desired goals of therapy. Noteworthy in this analysis is that 77% (88/114) of recipients with diabetes achieved the QCare 2006 hemoglobin A_1C benchmark goal. For more than 25 years the hemoglobin A_1C test has been the most widely accepted outcome measure for evaluating glycemic control in individuals with diabetes[46], and is considered to be the most objective and reliable measure of long-term metabolic control.[47,48]

Economic Outcomes Evaluation

Claims analysis evaluation

Among the 431 MTMS claims submitted in Year One, 408 MTMS claims were submitted to the State of Minnesota and 23 were submitted to the pre-paid health plans (PPHP) Medica and U Care. MTMS and other health care claims for Health Partners and BlueCross and BlueShield of Minnesota recipients were requested, but could not be supplied, for this analysis. It is noted that the State of Minnesota was responsible for the payment of MTMS claims in 2006 regardless of a recipient's enrollment in a FFS or PPHP program, while starting in 2007 PPHP's were required to be responsible for MTMS claims for PPHP recipients. The initiation of PPHP responsibility for MTMS claims in 2007 increased administrative complexities of the program and led to a number of administrative challenges for MTMS providers.

There were 77 FFS recipients with continuous enrollment for a minimum of 6 months pre-MTMS intervention and 6 months post-MTMS intervention. These 77 of 259 MTMS recipients qualified for the economic analysis based on continuous enrollment over the minimum 6-month pre,- and 6-month post-intervention period. Total health care claims (including payments for MTMS) were $3,027 per person per month in the pre-intervention period compared to $3,271 per person per month in the post-intervention period for an 8.0% difference in expenditures. (*See* Table 8).

Total health care services were broken down into ten specific categories including MTMS and prescriptions and the expenditures before and after MTMS. (*See* Table 8). Prescription drugs were the single largest expense for Medicaid recipients receiving MTMS and accounted for nearly one-third (32.7%) of the total health expenditures. Inpatient care followed by home and community based services were the next largest expenditure categories with each accounting for nearly one-fourth of the total expenditures for the Medicaid MTMS recipients.

Division of Health Policy, Health Economics Program has established estimated statewide annual savings from QCare standards for diabetes care (*see* Appendix H).

Among the 114 MTMS recipients with diabetes, 36% (41/114) of these recipients achieved all performance benchmark standards. It is noted that the statewide average for achieving all diabetes performance benchmarks is 6% although comparisons between medical assistance MTMS recipients with diabetes and diabetes patients statewide are difficult to make based upon results of this analysis. The MDH estimates include an annual cost savings amount of $403.30 per patient for individuals in Minnesota over the age of 18 achieving the "optimal care" benchmark for diabetes. There were 41 individuals in this study who achieved optimal care, and if it could be assumed that 6% of these recipients were achieving optimal care previously, then 38 additional MTMS recipients achieved optimal care. The annual cost savings estimate in this analysis could then be calculated by multiplying the MDH per patient cost savings amount times 38 MTMS recipients resulting in a potential annual cost savings of $15,325 (*see* Appendix J).

The limitations of this analysis are that the number of MTMS recipients with diabetes achieving all QCare benchmarks in the pre-intervention period was unknown, and that this cost savings estimate may not be directly attributable to the care provided by an individual MTMS provider. When MTMS is delivered there is collaboration among all health providers to achieve patients' goals of therapy, and therefore this cost savings benefit may be due as much to improved systems of care as it is to the effect of an individual MTMS provider. Nevertheless, this potential cost savings estimate provides additional support for the impact of MTMS on improving quality and effectiveness of health care delivery.

Program Implementation Analysis

The program implementation and program improvement analyses were conducted by using a continuous quality improvement framework. A number of tools and procedures were used to implement the program including provider enrollment, on-line billing, and provider communications. MTMS providers found that program implementation was facilitated by use of a DHS Help Desk Phone Line, recipient eligibility verification through the MN-ITS system, and communication of MTMS program requirements on the DHS MHCP Web site.

Documentation analysis

Analysis of documentation elements in comparison to statutory and regulatory requirements indicates that there was greater than 90% compliance with 11 of 14 essential documentation elements. The documentation requirement of linking recipients' medical conditions to the drugs and dosages being used to treat each condition (60% compliance) represents an area in which pharmacists in this analysis could improve documentation. Results of the MTMS provider documentation self-assessment surveys

In addition, the 77 recipients in the 6-month pre-, and 6-month post-intervention economic analysis were reviewed to determine the predictive value of the algorithm among current MTMS recipients. All 77 recipients had continuous fee-for-service medical assistance coverage and had at least one year of medical claims data. In this analysis, 49% (38 of 77) of these MTMS recipients were identified by the algorithm.

Program Improvement Analysis

This section is divided into areas in which the Minnesota Medicaid MTM Care Program is working well (program effectiveness) and areas in which the program can be improved. The results presented below were gathered from 26 MTMS providers who attended either the 9/26/07 or 10/2/07 focus group sessions conducted by interactive television (ITV) throughout the State of Minnesota. ITV bridging was provided by the State of Minnesota Office of Enterprise Technology (OET), Videoconference Reservation Center (VRC), (video.services@state.mn.us, www.oet.state.mn.us).

Program Effectiveness Analysis

Participants generally agreed that recipient identification was not a significant barrier. Three unique ideas for recipient identification were generated during discussions. In one system, pharmacists working in the dispensing area of the community pharmacy are able to refer patients with an online referral form to the pharmacist MTMS providers who follow-up and make patient appointments. The referring pharmacist then receives credit for identifying and referring eligible patients for MTMS. In an integrated clinic, a colored dot system is used on the recipient's health record to notify physicians, nurses and other providers that the recipient is eligible for MTMS. In two other sites, local community pharmacies are collaborating with physician offices to interact periodically with clinic personnel and to access electronic medical records for patients, easing their ability to obtain laboratory results as well as to identify eligible recipients.

Pharmacists participating in the program effectively screened recipients to comply with statutory recipient enrollment qualifications. Processes of care used by pharmacists indicate that recipients received comprehensive assessments of their drug-related needs and extensive attempts were devoted to conducting follow-up assessments. An analysis of MTMS pharmacists' workflow procedures and patient care processes, as reported by self-assessment, indicates that providers were in substantial compliance with statutory and regulatory requirements for recipient identification, documentation of care, and delivery of complete and comprehensive services.

Another area in which it was reported that the program is working well is physician communication. Physician communication is occurring in various ways among different practice sites. Those with integrated electronic medical records document MTMS in the patient chart attaching a summary note to the physician. In other sites, pharmacists see patients with physicians and their recommendations are acted upon at the point of care. In others, documentation is provided by phone and fax. Establishing a

RECOMMENDATIONS

The following recommendations for program improvement were developed through discussions and interviews with pharmacists (n=26) providing MTMS during the first year of the program using focus group surveys and meetings. The specific recommendations presented below represent recurring themes cited by a majority of focus group participants.

Recommendations for program improvement include:

General:

- Increasing physician awareness of the MTMS health benefit.
- Coordinating benefits of recipients to foster collaboration between recipients' case workers, social workers and MTMS providers.
- Integrating electronic medical records with pharmaceutical care documentation systems to reduce data entry.

Identifying potential eligible recipients:

- Matching eligible recipients to MTMS providers by geographic location.
- Using the DHS MTMS algorithm to identify eligible recipients in geographic areas that do not currently have an enrolled MTMS provider.
- Sending lists of eligible recipients to MTMS providers so that providers may contact eligible recipients.
- Communicating with eligible recipients, if possible, to explain MTMS and providing them with a list of enrolled MTMS providers.

Removing potential barriers to recipients:

- Incorporating tools available through the Minnesota Literacy Council and the Minnesota Department of Children Families and Learning to deliver MTMS more effectively to recipients who speak languages other than English (LaRue Medical Literacy Exercises available at: http://www.mcedservices.com/medex/medex.htm).
- Providing transportation for recipients' MTMS appointments.
- Providing coverage for MTMS delivered in recipients' homes.
- Providing a prescription co-payment incentive to recipients for continued use of the MTMS benefit.

Improving billing procedures:

- Continuing to clarify procedures for obtaining MTMS prior authorization for recipients requiring more than eight visits per year, as well as for a recipient with a drug therapy problem that has resulted or is likely to result in significant non-drug program costs.
- Improving the PPHP recipient identification, verification, and billing processes. It was suggested that recipient PPHP Identification Numbers be added to the DHS MN-ITS Web site.

Professional development:

- Encouraging MTMS providers to mentor other pharmacists to accelerate program expansion and recipient access to MTMS.

The four components of outcomes data included in this analysis are: clinical, economic, program implementation, and program improvement. Clinical outcomes analysis included evaluating drug therapy problems identified and resolved, goals of therapy achieved, and performance-based benchmark standards achieved for recipients with diabetes and coronary heart disease. Economic outcomes analysis included comparing total health care expenditures for recipients before and after receiving MTMS, and measuring the value-based purchasing impact of recipients meeting performance-based benchmark standards. Program implementation and program improvement were evaluated using medical records chart abstraction review, self-assessment surveys, and focus group interviews and meetings.

Pharmacists in this one year analysis identified and resolved 789 drug therapy problems (3.1 drug therapy problems per patient), which can be compared to the 3.3 drug therapy problems resolved in a national sample of nearly 3000 patients over a four year period (2000 – 2003). Combining the high number of drug therapy problems resolved with the number of drugs (14/recipient) and medical indications (6/recipient) demonstrates that recipients with complex medical and drug-related needs were served in the first year of the program.

Clinical outcomes achieved in this analysis were very good as demonstrated by improvements in goals of therapy achieved as well as drug therapy problems resolved. In addition, quality of care performance benchmarks (QCare standards) achieved in recipients with diabetes was higher than the State average.

An analysis of a sample of 167 recipients' pharmaceutical care documentation summary reports indicated that MTMS recipients had an average of 6.3 medical indications per patient (range = 1 – 20, std. dev. = 4.8) and were taking 14.1 drugs (10.5 prescription plus 3.6 non-prescription drugs) per patient (range = 1 – 35, std. dev. = 6.5). In the analysis of these same 167 recipients' records, goals of therapy achieved improved from 76% to 87% after recipients' MTMS encounters during Year One.

Medical records chart abstraction used to evaluate the achievement of performance-based benchmark standards indicates that 36% (41/114) of recipients with diabetes achieved all performance benchmark criteria using State of Minnesota QCare (Quality Care and Rewarding Excellence) standards. Achievement of QCare standards demonstrates an important contribution of pharmacists' MTMS to quality of care and health care effectiveness. When drug therapy problems are resolved patients achieve desired goals of therapy. Noteworthy in this analysis is that 77% (88/114) of recipients with diabetes achieved the QCare 2006 hemoglobin A_1C benchmark goal.

Economic evaluation of recipient claims before and after MTMS was restricted due to the fact that only 77 recipients had at least 6-months pre-, and 6-months post-intervention health care claims at the time of this analysis, and because 35% of health claims for recipients with pre-paid health plan (PPHP) coverage could not be supplied by PPHP's for use in this analysis. Although total health expenditures were higher in the post-intervention period, 24% of this difference was accounted for by increases in

Although pharmacists were able to identify recipients qualifying for MTMS coverage, there was a high rate of appointment non-adherence among recipients, and there was difficulty maintaining follow-up contact with recipients. The State of Minnesota tested a claims-based algorithm for identifying recipients eligible for MTMS with a limited number of MTMS pharmacists. During focus group interviews, pharmacists noted that the MTMS algorithm could be useful in helping to identify eligible recipients who may visit other clinics or pharmacies that do not offer MTMS.

The program implementation and program improvement analyses were conducted by using a continuous quality improvement (CQI) framework. The CQI framework is predicated on the concept that program participants have an inherent desire to increase quality and raise standards by continually solving problems and improving processes. A number of tools and procedures were used to implement the program including provider enrollment, on-line billing, and provider communications. Cooperation in program implementation among the state professional association, academia and the State of Minnesota were essential to successful program implementation.

Analysis of documentation elements in comparison to statutory and regulatory requirements indicates that there was greater than 90% compliance with 11 of 14 essential documentation elements. The documentation requirement of linking recipients' medical conditions to the drugs and dosages being used to treat each condition (60% compliance) represents an area in which pharmacists in this analysis could improve documentation.

Medical records chart review of 48% (126 of 259) of recipient records indicated that about 60% of MTMS claims were submitted at a resource-based relative value scale (RBRVS) level commensurate with evidence documented in recipients' records, 30% of recipients' records contained documentation that would have supported billing at an RBRVS level higher than that which was billed to the State, and 10% of MTMS claims were submitted at a level that was not fully supported by documentation contained in recipients' medical records. This finding indicates that MTMS providers adhered to the RBRVS billing criteria with one-third of claims conservatively submitted below permissible levels.

Based on results from the provider focus group interviews and meetings it is noted that providers were able to identify recipients who met the statutory qualifications for program participation. However, it was suggested that recipients from geographic areas without access to MTMS providers be referred to sites that are providing the MTMS service. In addition, it was demonstrated that program recipients had appointment scheduling non-adherence rates ("no-show rates") nearly twice the general population. Transportation difficulties were cited by MTMS providers as a primary reason for this no-show rate and it was suggested that recipients' case managers and social workers be contacted to assist in resolving transportation problems. There were also a number of implementation challenges that occurred with the transfer of MTMS payment responsibility to the pre-paid health plans in 2007.

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End of References Section.

(c) For purposes of reimbursement for medication therapy management services, the commissioner may enroll individual pharmacists as medical assistance & general assistance medical care providers. The commissioner may also establish contact requirements between the pharmacist and recipient, including limiting the number of reimbursable consultations per recipient

(d) The commissioner, after receiving recommendations from professional medical associations, professional pharmacy associations, and consumer groups, shall convene an 11-member Medication Therapy Management Advisory Committee to advise the commissioner on the implementation and administration of medication therapy management services. The committee shall be comprised of: two licensed physicians; two licensed pharmacists; two consumer representatives; two health plan company representatives; and three members with expertise in areas of medication therapy management, who may be licensed physicians or licensed pharmacists. The committee is governed by section 15.059, except that committee members do not receive compensation or reimbursement for expenses. The advisory committee expires on June 30, 2007.

(e) The commissioner shall evaluate the effect of medication therapy management on quality of care, patient outcomes, and program costs, and shall include a description of any savings generated in the medical assistance and general assistance medical care programs that can be attributable to this coverage. The evaluation shall be submitted to the legislature by December 15, 2007. The commissioner may contract with a vendor or an academic institution that has expertise in evaluating health care outcomes for the purpose of completing the evaluation.

[EFFECTIVE DATE.] This section is effective August 1, 2005.

Appendix C: QCare Coronary Heart Disease - MTMS Abstraction Instrument

CHD Chart Abstract

Name: _____
Recipient ID: _____
DOB: _____
Date of 1st MTMS encounter: _____

CHD OUTCOMES:	First Value [a]	Second Value [a]	Third Value [a]
☐ LDL <100mg/dl	Date: _____ Value: _____	Date: _____ Value: _____	Date: _____ Value: _____
☐ Diabetic			
☐ Blood pressure <140/90 (if diabetic, (must be <130/80)	Date: _____ Value: _____	Date: _____ Value: _____	Date: _____ Value: _____
☐ Daily aspirin use Contraindication to aspirin (y/n): ____			
☐ Tobacco Use History ☐ Current ☐Former ☐Never used			
☐ Meets all criteria			

a) Time period of measurements were up to one year after each recipients initial MTMS encounter.

Date of Review_____

Date of Audit: _____

Document Verification: _____ MTM Claim Audit: _____

Source of Record: _____

Appendix E: MTMS Documentation Chart Abstraction Instument

Name: _____

Recipient ID: _____

DOB: _____

Date of first MTM encounter: _____

Location of encounter: _____

Multiple encounters (y/n): _____

DOCUMENTATION:

- ☐ EMR
- ☐ Current & resolved medical conditions
- ☐ Allergies
- ☐ Physician contact info
- ☐ Time spent with patient
- ☐ List of all drugs and indications
- ☐ Drug doses, directions & use
- ☐ Relevant medical devices
- ☐ Alcohol/tobacco history
- ☐ Environmental factors
- ☐ Assessment of drug therapy problems
- ☐ Written care plan
- ☐ Info, instructions and resources delivered to patient

Visit Date: _____

# of medications: _____

# of drug therapy problems: _____

Indication

Unnecessary drug therapy _____

Needs additional drug therapy _____

Effectiveness

Ineffective drug _____

Dosage too low _____

Safety

Adverse drug reaction _____

Dosage too high _____

Compliance

Noncompliance _____

# of medical conditions: _____

Primary condition: _____

ICD9 Code: _____

Drug therapy problems:

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____

Conditions: _____

_____

_____

_____

_____

_____

Meds: _____

_____

_____

_____

_____

_____

Appendix G: MTMS Provider Pre-Focus Group Survey Instrument

Evaluating Effectiveness of the Minnesota Medication Therapy Management (MTM) Care Program—**Pre-Focus Group Questionnaire**
Please return by SEPTEMBER 17th via fax (612-625-9931) or e-mail to:

Brian J. Isetts
University of Minnesota College of Pharmacy
Weaver-Densford Hall, Room 7-175
308 Harvard Street, SE
Minneapolis, MN 55455
Phone: (612) 624-2140
Email: isett001@umn.edu

Your name: _____

Your primary practice site: _____

Date & Meeting Site You Will Attend _____

What educational programs did you complete to assist with your practice? _____

_____

What educational programs would help you in your practice in the future? _____

_____

How did you learn about the MN MTM Care Program? (Please describe): _____

Please indicate your level of agreement with the following statements pertaining to your MN MTM Program practice:

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
Being a MN MTM provider has been a positive experience.	1	2	3	4	5
I have been able to identify patients who need this service.	1	2	3	4	5
I have been able to recruit patients who need this service.	1	2	3	4	5
The care process I have established is working well.	1	2	3	4	5
I am satisfied with the documentation system I am using.	1	2	3	4	5
I am satisfied with the State of MN Help Desk.	1	2	3	4	5
The following have been barriers to providing care to patients in my practice:					
Finding time to provide the service	1	2	3	4	5
Level of payment for the service	1	2	3	4	5
Management support for my practice	1	2	3	4	5
Space and workflow for providing the service	1	2	3	4	5
Learning the patient care process	1	2	3	4	5
Learning my documentation system	1	2	3	4	5
Developing physician relationships	1	2	3	4	5
Communicating with physicians	1	2	3	4	5
Patient resistance to receiving the service	1	2	3	4	5
Identifying patients who need the service	1	2	3	4	5
Patient co-payments for prescription drugs	1	2	3	4	5
I would recommend that my colleagues become program providers	1	2	3	4	5

The greatest opportunity the MN MTM program offers is: _____

Appendix H: MDH QCare Cost Savings Estimates (Cardiac care and Diabetes care)

DIABETES CARE:	
National estimated savings from optimal care for 80% of patients with diabetes, over 30 years (5)	$150,000,000,000
Annual savings (assumes savings each year are the same) (6)	$5,000,000,000
Savings as % of annual US health care spending	0.29%
Adjustment to savings estimate to account for lower diabetes prevalence in MN:	
National estimated savings as % of total health care spending	0.29%
Ratio of diabetes prevalence in MN to national	0.79
Adjusted savings estimate, accounting for lower diabetes prevalence	0.23%
Adjustment to savings estimate to account for MN patients already receiving optimal care:	
Percent of MN patients receiving optimal care (8)	6%
QCare standard for % receiving optimal care	80%
Improvement needed (percentage points)	74%
Adjustment applied to savings estimate: Improvement as % of QCare standard	93%
Adjusted savings estimate (as % of total MN health care spending), accounting for patients already receiving optimal care (9)	0.22%
Total estimated cost saving	
Rough estimate of 2006 health care spending in Minnesota (10)	$30,536,900,000
Estimated % of MN health care spending saved	0.22%
Savings estimate from achieving QCare standard	**$66,007,441**

Annual savings	5,000,000,000
Annual US health care spending	1,700,000,000,000
Savings as % of US health care spending	0.29%

Diabetes prevalence, US (% of adults over age 18) (7)	7.3%
Diabetes prevalence, MN (% of adults over age 18) (7)	5.8%
Ratio of diabetes prevalence in MN to national	0.79

Notes and sources:

/1 Based on 2004 estimates from U.S. Bureau of the Census, and assuming growth of 0.7% per year in 2005 and 2006 (same as overall population growth from 2003 to 2004)

/2 Prevalence of coronary artery disease was estimated by adjusting the national prevalence rate from the National Health and Nutrition Examination Survey (NHANES) by the ratio of the percentage of adults in MN vs nationally who report ever having had a heart attack or angina in the Behavioral Risk Factor Surveillance System telephone survey. This adjustment was made because NHANES is considered a more reliable source than BRFSS, but no state specific estimates are available from NHANES.

/3 Estimate based on measure calculated by HealthPartners for its members with CAD. (No statewide measure for optimal care for CAD currently exists.)

/4 Estimates for number of cases saved per 1,000 patients, cost savings per event, and % of CAD patients with hypertension are from Towers Perrin, Cardiac Care Analysis Savings Estimates prepared for Bridges to Excellence, December 29, 2003. MDH used only the savings estimate associated with blood pressure control, which accounted for a majority of the savings estimated for optimal cardiac care. As a result, the MDH estimate is likely conservative because it does not include savings from achieving other aspects of optimal care. Towers Perrin estimated cost savings of $11,755 per event for 2004. MDH adjusted this figure to 2006 by applying projected national spending growth rates of 7.2% per year from CMS between 2004 and 2006.

/5 National estimate developed using Archimedes model, a complex mathematical model that evaluates effects of interventions on disease incidence and progression.

/6 Assuming the same savings each year likely overstates savings in early years and understates savings in later years.

/7 Diabetes prevalence rates for 2005 from Behavioral Risk Factor Surveillance System

/8 MN Community Measurement, 2005 Health Care Quality Report, revised measure for optimal diabetes care.

/9 The national baseline for % of patients currently receiving optimal care is unknown. This downward adjustment to the MN savings estimate likely understates the potential savings in MN (the adjustment assumes the national baseline is zero, while the true baseline is likely higher).

/10 Minnesota Department of Health, Health Economics Program. Most recent complete estimate is $24.8 billion in 2003. Growth from 2004 through 2006 estimated at 7.2% per year.

a) Estimated statewide annual savings from QCare standards for cardiac care and diabetes care were obtained from Ms. Julie Sonier, Director, Health Economics Program, Division of Health Policy, Minnesota Department of Health

Appendix I

Bill Description

This bill provides MA coverage for medication therapy management for a recipient taking four or more medications to treat or prevent two or more chronic medical conditions, or for a recipient with a drug therapy problem identified or prior authorized by the commissioner that has resulted in or is likely to result in significant nondrug program costs. It lists the criteria that pharmacists must meet in order to be eligible for reimbursement for medication therapy management.

The bill allows the commissioner to enroll individual pharmacists as MA providers, for purposes of reimbursement for medication therapy management services. Allows the commissioner to establish contact requirements between the pharmacist and recipient.

The bill requires the commissioner, after receiving recommendations from specified groups, to establish a nine-member Mediation Therapy Management Advisory Committee, to advise the commissioner on the implementation and administration of medication therapy management services. Specifies membership and governance of the committee.

The bill also requires the commissioner to evaluate the effect of medication therapy management on quality of care, patient outcomes, and program costs, and to include a description of MA savings. Requires the evaluation to be submitted to the legislature by December 15, 2007 and allows the commissioner to contract with a vendor or academic institution in order to complete the evaluation.

Assumptions

See attached worksheets.

Expenditure and/or Revenue Formula

Fiscal Analysis: SF 973 and HF 979
2005 Session

Projected MA enrollees not in managed care, excluding those with Medicare Rx coverage	130,000
Est. half meet inclusion criteria*	65,000
Est. 10% get PC services at full operation	6,500
Est. 2 encounters per recipient	13,000

Annual MA Program Costs

Reimbursement Level	Distribution of Encounters	Number of Encounters	Cost per Encounter	Service Payments
Level 1	20.00%	2,600	37.08	96,408
Level 2	30.00%	3,900	48.02	187,278
Level 3	30.00%	3,900	63.03	245,817
Level 4	15.00%	1,950	90.84	177,138
Level 5	5.00%	650	108.44	70,486
Total	100%	13,000	59.78	777,127

Annual MA Cost Avoidance**

Type Of Events Avoided	Minimum Events Avoided	Maximum Events Avoided	Mid-range Events Avoided	Cost per Event	Program Savings
Hospitalizations	40.0	60.0	50.0	14,000	700,000
Emergency room visits	165.0	210.0	187.5	455	85,313
Urgent care visits	120.0	150.0	135.0	135	18,225
Clinic office visits	4800.0	5400.0	5100.0	80	408,000

Estimated statewide annual savings from QCare standards for diabetes care

Prepared by Minnesota Department of Health, Health Economics Program
July 2006

DIABETES CARE:			
National estimated savings from optimal care for 80% of patients with diabetes, over 30 years (5)	$150,000,000,000		
Annual savings (assumes savings each year are the same) (6)	$5,000,000,000		
Savings as % of annual US health care spending	0.29%		
Adjustment to savings estimate to account for lower diabetes prevalence in MN:			
National estimated savings as % of total health care spending	0.29%		
Ratio of diabetes prevalence in MN to national	0.79		
Adjusted savings estimate, accounting for lower diabetes prevalence	0.23%		
Adjustment to savings estimate to account for MN patients already receiving optimal care:		# of Persons	
Percent of MN patients receiving optimal care (8)	6%	13,270	
QCare standard for % receiving optimal care	80%	176,938	
Improvement needed (percentage points)	74%	163,668	
Adjustment applied to savings estimate: Improvement as % of QCare standard	93%		
Adjusted savings estimate (as % of total MN health care spending), accounting for patients already receiving optimal care (9)	0.22%		
Number of people in MN (11)	5,167,101		
Number of people in MN (Over 18 years) (11)	3,813,321		
Number of people with diabetes in MN (Over 18 years)	221,173		
Total estimated cost saving			
Rough estimate of 2006 health care spending in Minnesota (10)	$30,536,900,000		
Estimated % of MN health care spending saved	0.22%		
Savings per year estimate from achieving QCare standard	**$66,007,441**		
Savings per year estimate for each person from achieving QCare standard	$403.30		
Number of Medicaid patients with diabetes achieving Q Care Standard	41		
% of Medicaid patients assumed to be at goal before MTM	6.0%		
Number of additional Medicaid patients with diabetes achieving Q Care Standard	38		
Savings per year estimate from achieving QCare standard	$ 15,325.46		
Savings over 30 year estimate from achieving QCare standard	$ 459,763.74		

Annual savings	5,000,000,000
Annual US health care spending	1,700,000,000,000
Savings as % of US health care spending	0.29%

Diabetes prevalence, US (% of adults over age 18) (7)	7.3%
Diabetes prevalence, MN (% of adults over age 18) (7)	5.8%
Ratio of diabetes prevalence in MN to national	0.79

Notes and sources:

/1 Based on 2004 estimates from U.S. Bureau of the Census, and assuming growth of 0.7% per year in 2005 and 2006 (same as overall population growth from 2003 to 2004)

/2 Prevalence of coronary artery disease was estimated by adjusting the national prevalence rate from the National Health and Nutrition Examination Survey (NHANES) by the ratio of the percentage of adults in MN vs nationally who report ever having had a h

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/5 National estimate developed using Archimedes model, a complex mathematical model that evaluates effects of interventions on disease incidence and progression.

/6 Assuming the same savings each year likely overstates savings in early years and understates savings in later years.

/7 Diabetes prevalence rates for 2005 from Behavioral Risk Factor Surveillance System

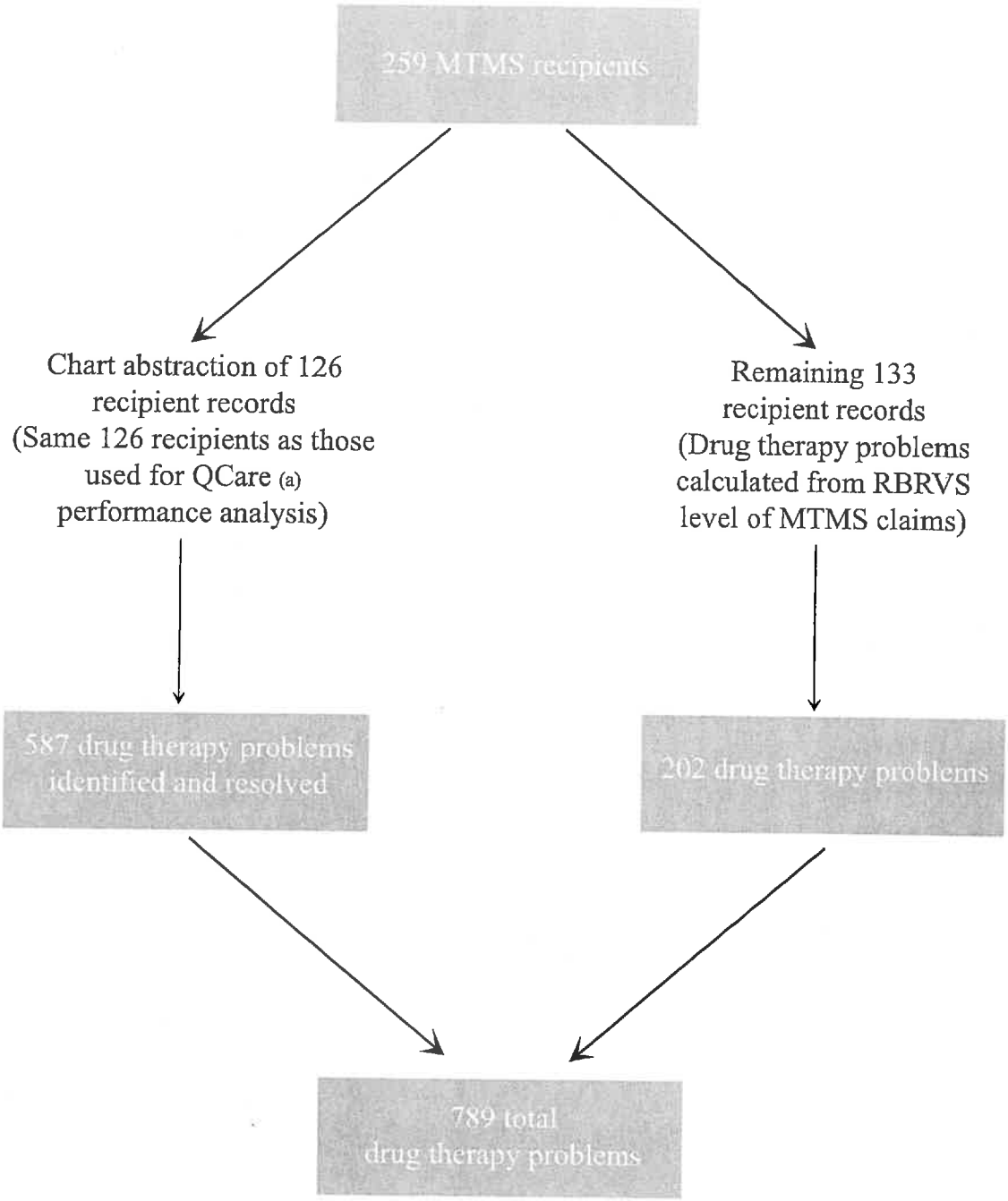
/8 MN Community Measurement, 2005 Health Care Quality Report, revised measure for optimal diabetes care.

/9 The national baseline for % of patients currently receiving optimal care is unknown. This downward adjustment to the MN savings estimate likely understates the potential savings in MN (the adjustment assumes the national baseline is zero, while the tr

/10 Minnesota Department of Health, Health Economics Program. Most recent complete estimate is $24.8 billion in 2003. Growth from 2004 through 2006 estimated at 7.2% per year.

/11 Minnesota population from 2006 U.S. Census Bureau of 5,167,101 less 26.2% persons age 18 and under.

Figure 2: Drug Therapy Problem Analysis Flow Diagram
Evaluation of the Minnesota MTM Care Program



(a) QCare = Quality Care and Rewarding Excellence

Figure 4. Change in Health Expenditures Before and After MTM Services

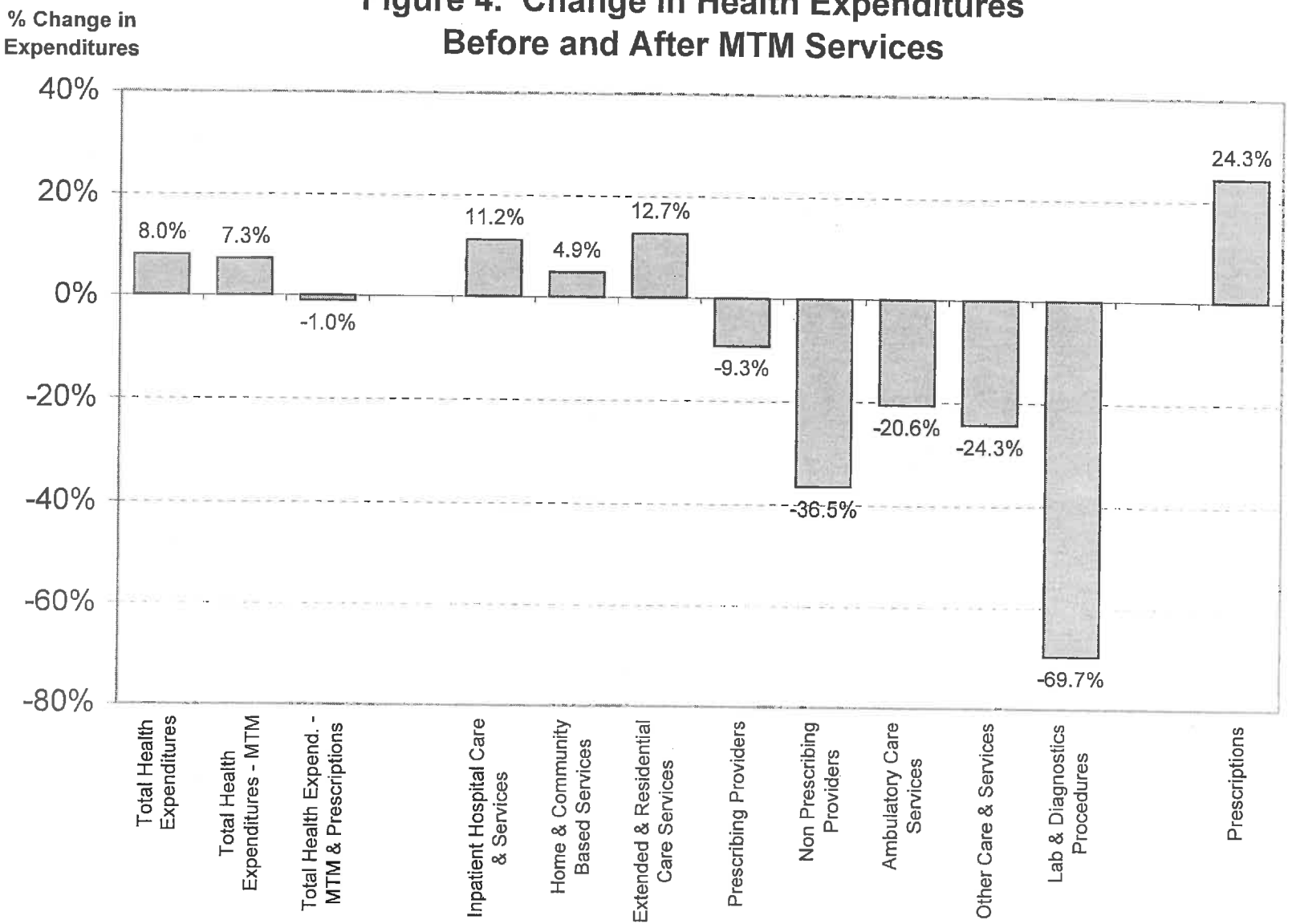
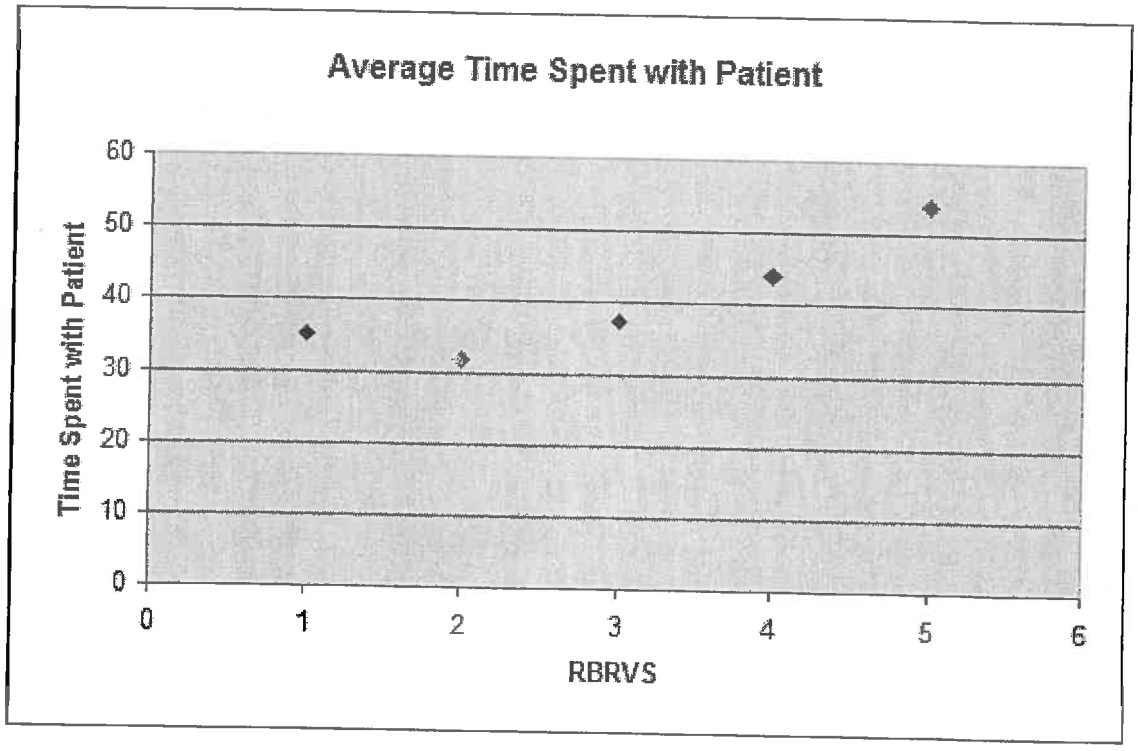


Figure 6.
Distribution of time spent with recipients as a function of the submitted RBRVS MTMS claim reviewed by chart abstraction

RBRVS	1	2	3	4	5
Time with Patient	35	31.67	37.2	44.1	54
(n = 224[a])	10	51	65	55	43



a (n = 224 instances in which the documentation element of, "time spent with patient," was recorded among the 236 MTMS recipient records reviewed by chart abstraction)

TABLE 2. ICD-9-CM CONDITION CODES LISTED ON RECIPIENTS' FIRST (INITIAL VISIT) MTMS CLAIMS [a]

Top 20 most frequently listed

ICD-9 Code	Number	
250	98	Diabetes
401	81	Hypertension
272	68	Hyperlipidemia
311	30	Depression
493	26	Asthma
477	25	Allergic rhinitis
530	23	Esophagitis
300	20	Anxiety
780	15	General symptoms/Alteration of consciousness
269	14	Nutritional deficiencies
244	12	Hypothyroidism
307	11	Special symptoms/Not specified elsewhere
724	11	Unspecified disorders of the back
733	11	Other disorders of bone and cartilage
719	10	Other joint disorders
496	8	Chronic airway obstruction
296	6	Affective psychoses
564	6	Functional digestive disorder
715	6	Osteoarthrosis
784	6	Symptoms involving head and neck

a) Up to four ICD-9 codes can be included in an MTMS claim.

Harris, Ila	Bethesda Clinic – St. Paul	4	5	7
Johnson, Michelle	Goodrich Pharmacy - Anoka, St. Francis	1	2	9
Eischens, Karla	Iverson Corner Drug - Bemidji	2	2	8
Zimmerman, Jodie	Fairview Ridges Medication Therapy Management - Burnsville	3	3	5
Mohr, Corinne	Mayo Clinic Pharmacy - Rochester	2	2	6
Kreiger, Carrie	Mayo Clinic Eisenberg Pharmacy - Rochester	2	3	6
Schlichte, Allison	Fairview Crosstown Medication Therapy Management - Edina	2	3	6
Reidt, Shannon	Bethesda Clinic - St. Paul	2	3	5
Okerlund, Ryan	Iverson Corner Drug - Bemidji	2	2	3
Isetts, Brian	Red Wing Corner Drug - Red Wing	1	2	3
Pederson, Jan	Hugo's Family Pharmacy - Thief River Falls	1	1	4
Boyko Frandson, Kara	Health Partners Como Clinic - St. Paul	1	1	3
Traynor, Andy	Fremont Clinic - Minneapolis	1	1	3
Weisenberg, Alan	Cash Wise Pharmacy - Hutchinson	1	1	2
Weckwerth, Kristin	Mayo Clinic Pharmacy - Rochester	1	1	2
Traynor, Laura	Gateway Clinic - Moose Lake	1	1	0
Wix, Kelly	Mayo Clinic Pharmacy - Rochester	1	1	0
TOTALS: 34 Pharmacists		**259**	**431**	**789**

TABLE 5:
Medications and Indications Associated with Unnecessary Drug Therapies (n = 21):

Diabetes (3)
Glipizide – 1, Glyburide – 1, Humalog – 1

Constipation (3)
Senna – 2, Docusate/Senna plus Equate – 1

Depression (2)
Celexa plus Cymbalta – 1, Wellbutrin – 1

Nutritional deficiencies (2)
Vitamin B, Zinc Picolin, Beta Carotene, Multivitamin, Pantothenic – 1
Vitamin C, Vitamin C with rose hips, Vitamin E – 1

Allergic rhinitis (2)
Advair – 1, Niaspan plus Grape seed – 1

Hypertension (1)
Lisinopril plus Prinizide – 1

Hyperlipidemia (1)
Fish oil – 1

Insomnia (1)
Temazepam plus Amitriptyline – 1

Prevent MI/Stroke (1)
Vitamin D – 1

COPD/Emphysema (1)
Advair – 1

Anemia (1)
Ferrous Gluconate - 1

Arthritis (1)
Devils claw plus Alfalfa – 1

Asthma (1)
Sprivia – 1

Pain (1)
Oxycodone plus Fentanyl – 1

Headache – 5
- Migraine – 3
- Headache prophylaxis - 2

Heart conditions – 5
- Coronary artery disease - 2
- Angina - 2
- Atrial fibrillation – 1

Infections – 5
- Infection management – 3
- Hepatitis C – 1
- Pneumonia – 1

Allergies – 5
- Allergic rhinitis – 3
- Allergies – 2

Anxiety – 4
Pneumovax – 4
Anemia – 3
Fibromyalgia – 3
Hypothyroidism - 3
Skin conditions – 3
- Contact dermatitis – 1
- Skin problem – 1
- Pruritus – 1

Schizoaffective disorder – 3
Edema – 2
Estrogen replacement – 2
COPD - 2
Microalbuminuria – 2
Other – 2
Renal/kidney management – 2
Crohn's disease – 1
Irritable bowel syndrome – 1
Diarrhea – 1
Gastritis – 1
Gout – 1
Hyperparathyroidism – 1
Muscle spasm – 1
Nausea/vomiting – 1
Post-traumatic stress disorder – 1
Hepatic encephalopathy – 1
Irritable bowel syndrome – 1
TMJ – 1

Table 8. Health Expenditures Before and After MTM Services

By Provider type	n =	Pre-Expend. Mean	Post-Expend. Mean	Difference in Expend.	% Difference in Expend.	% Distrib. of Expend.	% Distrib. of Expend.
		Pre (-5 mo. to 0 mo.)	Post (1 mo. to 6 mo.)	Post-$ less Pre-$	Diff./Pre-$	Pre (-5 mo. to 0 mo.)	Post (1 mo. to 6 mo.)
Expenditure per Recipient per Month							
Total Health Expenditures	77	$ 3,027.17	$ 3,270.80	$ 243.63	8.0%	100.0%	100.0%
Total Health Expenditures - MTM	77	$ 3,027.17	$ 3,247.65	$ 220.48	7.3%	100.0%	99.3%
Total Health Expend. - MTM & Prescriptions	77	$ 2,037.16	$ 2,017.00	$ (20.15)	-1.0%	67.3%	61.7%
Inpatient Hospital Care & Services	77	$ 720.05	$ 800.79	$ 80.74	11.2%	23.8%	24.5%
Home & Community Based Services	77	$ 707.47	$ 741.97	$ 34.50	4.9%	23.4%	22.7%
Extended & Residential Care Services	77	$ 22.80	$ 25.70	$ 2.90	12.7%	0.8%	0.8%
Prescribing Providers	77	$ 265.36	$ 240.55	$ (24.81)	-9.3%	8.8%	7.4%
Non Prescribing Providers	77	$ 247.10	$ 156.89	$ (90.21)	-36.5%	8.2%	4.8%
Ambulatory Care Services	77	$ 13.07	$ 10.38	$ (2.69)	-20.6%	0.4%	0.3%
Other Care & Services	77	$ 48.78	$ 36.92	$ (11.86)	-24.3%	1.6%	1.1%
Lab & Diagnostics Procedures	77	$ 12.52	$ 3.79	$ (8.73)	-69.7%	0.4%	0.1%
Prescriptions	77	$ 990.02	$ 1,230.65	$ 240.63	24.3%	32.7%	37.6%
MTM Services	77	$ -	$ 23.15	$ 23.15	0.0%	0.0%	0.7%
Total Expenditure for All Recipients							
Total Health Expenditures		$ 233,092.38	$ 251,851.94	$ 18,759.56	8.0%	100.0%	100.0%
Total Health Expenditures - MTM		$ 233,092.38	$ 248,286.84	$ 15,194.46	6.5%	100.0%	98.6%
Total Health Expend. - MTM & Prescriptions		$ 156,861.07	$ 155,309.34	$ (1,551.73)	-1.0%	67.3%	61.7%
Inpatient Hospital Care & Services	77	$ 55,443.76	$ 61,660.96	$ 6,217.20	11.2%	23.8%	24.5%
Home & Community Based Services	77	$ 54,475.30	$ 57,132.00	$ 2,656.70	4.9%	23.4%	22.7%
Extended & Residential Care Services	77	$ 1,755.85	$ 1,979.14	$ 223.29	12.7%	0.8%	0.8%
Prescribing Providers	77	$ 20,433.02	$ 18,522.63	$ (1,910.38)	-9.3%	8.8%	7.4%
Non Prescribing Providers	77	$ 19,026.33	$ 12,080.50	$ (6,945.83)	-36.5%	8.2%	4.8%
Ambulatory Care Services	77	$ 1,006.45	$ 799.21	$ (207.24)	-20.6%	0.4%	0.3%
Other Care & Services	77	$ 3,756.17	$ 2,842.99	$ (913.18)	-24.3%	1.6%	1.1%
Lab & Diagnostics Procedures	77	$ 964.19	$ 291.91	$ (672.28)	-69.7%	0.4%	0.1%
Prescriptions	77	$ 76,231.31	$ 94,760.05	$ 18,528.74	24.3%	32.7%	37.6%
MTM Services	77	$ -	$ 1,782.55	$ 1,782.55	0.0%	0.0%	0.7%

TABLE 10: Documentation Analysis by Chart Abstraction

Comparison of Chart Abstracts to MTMS Statutory and Regulatory Requirements
Chart Abstraction Data (n = 126 records)

1. Use of an electronic medical record – 126/126 (100%)
2. List of current and resolved conditions – 104/126 (82.4%)
3. List of drug allergies – 126/126 (100%)
4. Physician contact information – 124/126 (98.4%)
5. Date of visit 126/126 (100%)
6. Time spent with patient – 123/126 (97.6%)
7a. List of drugs in use by patient – 118/126 (93.7%)
7b. Drugs linked with corresponding indications for use – 75/126 (59.5%)
8. Doses/directions of medications – 126/126 (100%)
9. Medical devices – 92/126 (73.0%)
10a. Alcohol Use – 114/126 (90.5%)
10b. Tobacco Use– 117/126 (92.9%)
11. Environmental Factors – 126/126 (100%)
12. Drug Therapy Problems – 126/126 (100%)
13. Care Plan Description – 126/126 (100%)
14. Instructions to Patient – 126/126 (100%)

Val/Jim

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF DIRECTOR

ACTION REFERRAL

TO	DATE
Medical Services/ Giese	3-10-11

DIRECTOR'S USE ONLY	ACTION REQUESTED
1. LOG NUMBER 101404	[X] Prepare reply for the Director's signature DATE DUE 3-17-11
2. DATE SIGNED BY DIRECTOR cc: Mr. Keck, Deps,	[ ] Prepare reply for appropriate signature DATE DUE [ ] FOIA DATE DUE [ ] Necessary Action

APPROVALS (Only when prepared for director's signature)	APPROVE	* DISAPPROVE (Note reason for disapproval and return to preparer.)	COMMENT
1. Val Williams	4-4-11		
2.			
3.			
4.			

RECEIVED
Dept. of Health & Human Services
MAR 10 2011
Bureau of Health Services

BERRY, QUACKENBUSH & STUART
A PROFESSIONAL ASSOCIATION
Attorneys and Counselors at Law

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POST OFFICE BOX 394 (ZIP 29202-0394)
COLUMBIA, SC 29201

TELEPHONE
(803) 779-2650

TELECOPIER
(803) 255-0179

James H. Quackenbush, Jr.
E-mail: jk@bqslaw.com

March 8, 2011

SC Department of Health and Human Services
Title Anthony E. Keck, Director
Address Post Office Box 8206
City, State Zip Columbia, SC 29202

Re: Medicaid Reimbursement

Dear Director Keck,

We appreciate the opportunity to have met with you and your staff to discuss the current status of South Carolina Medicaid and to allow us the opportunity to present our cost savings proposals.

In overview, our proposals included:

1. A project to increase the dispensing of generics within community pharmacies for the SC Medicaid program.
    a. An increase of 2 percentage points to Georgia's 69.2 percent would raise at a minimum 14 Million dollars annually
    b. An increase to the nation's highest generic percent in a Medicaid program Massachusetts -79.3 percent would yield over 84.7Million annually.
    c. A program to mirror the current process in North Carolina that Secretary Cansler is very support of and their consultants, Mercer, monitors.
        i. The program yields for North Carolina a 20 Million dollar savings per percentage point
        ii. It provides quarterly reporting on all community pharmacies to allow the providers to benchmark vs. competitors and to improve geo-market outcomes

2. The utilization of Prior Authorization for the anticonvulsant and atypical antipsychotic medications

a. It appears that 8.5 percent of the SC Medicaid drug spend is for anticonvulsants. Therefore, prior authorization for that level of expenditure is appropriate.
b. It appears that 4.7 percent of the SC Medicaid drug spend is for atypical antipsychotic medication. The proper management of this expenditure, including prior authorization, is appropriate.

3. The utilization of e-prescribing tools in the highest prescribing Medicaid physician group to mirror the Florida Gold Standard Project. You requested information on the status of e-prescribing in South Carolina. The latest figures we could find indicated that, for the 2009 Safe Rx Awards by Surescript, South Carolina ranked 39th. For reference: NC -5th, FL -10th, GA -26th and AL- 27th.
    a. Provide the top 1000 SC Medicaid prescribers with a free e-prescribing tool.
    b. The state of Florida showed savings of $700 per patient per month based on the prevention of poly-physician, poly-pharmacy and formulary management.
    c. We will seek out vendors to meet with the Department to achieve this goal

4. To work to develop adherence and medication therapy management programs that provide a favorable return on investment and can achieve the best care per expended state dollar.
    a. We ask the Department while working towards this savings goal to provide all the community pharmacy partners with some high cost patient groups and outcome goals so we may assist the state in their goal to provide the best health care possible to the citizens in SC Medicaid.

We have attached additional policy detail on each proposal. Additionally, we request that the agency provide a key contact with which we can establish a series of meetings. It may also be collaborative to establish a pharmacy or provider group that will allow the continued exchange of high quality cost saving approaches to the department and align the goals of all involved. We seek to be a partner with your agency and the companies represented by the SC Association of Chain Drug Stores have a proven track record across the country.

Thank you again for your time. Please let us know who on your staff we should work closely with as we seek to bring these proposals to fruition.

Sincerely,

James H. Quackenbush, Jr.
SC Association of Chain Drug Stores

South Carolina Department of
Health & Human Services

Anthony E. Keck, Director
Nikki R. Haley, Governor

April 14, 2011

Mr. James H. Quackenbush, Jr.
SC Association of Chain Drug Stores
1122 Lady Street, Fifth Floor
Post Office Box 394
Columbia, South Carolina 29201

Dear Mr. Quackenbush:

Thank you for your letter regarding cost saving ideas that the South Carolina Department of Health and Human Services (SCDHHS) can pursue to assist in managing the $125 million dollars that we have committed to take out of the state system as expenditures in fiscal year 2012.

As we discussed during the March 23, 2011 meeting, the agency is interested in continuing a partnership with the South Carolina Association of Chain Drug Stores. The effort towards paying for health, instead of just health services is a primary goal at SCDHHS. As we continue to evaluate all of the ideas presented by our stakeholders, we look forward to working with you.

Thank you for your continued support and participation in the Medicaid program. If you have any questions or concerns please contact Ms. Valeria Williams at (803) 898-3477.

Sincerely,

Melanie "BZ" Giese, RN
Deputy Director

MG/ws

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