Meeting of the
Pharmacy and Therapeutics Committee
June 18, 2003
Minutes
Draft

Members Present:	**DMAS Staff:**
Randy Axelrod	Patrick Finnerty, Director DMAS
Gill Abernathy	Cynthia Jones, Chief Deputy Director
Eleanor S. (Sue) Cantrell	Cheryl Roberts, Deputy Director of Programs and Operations
Avtar Dhillon	Manju Ganeriwala, Deputy Director of Finance and Administration
Arthur Garson, Jr.	Paige Fitzgerald, Counsel to the Board
Mariann Johnson	Bryan Tomlinson, Director of the Division of Health Care Services
Mark Oley	Craig Markva, Acting Director, Office of Communications & Legislative Affairs
James Reinhard	
Mark Szalwinski	Adrienne Fegans, Program Administration Specialist
Renita Warren	
Absent:	**Guests:**
Roy Beveridge*	Secretary of Health and Human Resources, Jane Woods, via phone
Christine Tully	Elmer E. Neil, M.D. Chair, Board of Medical Assistance Services
	Manikoth G. Kurup, M.D. Member, Board of Medical Assistance Services

*was to join in via conference call but unable to make connection

Call to Order

The meeting was called to order by Chairman Axelrod at 9:10 am. Director Patrick Finnerty addressed the Committee and indicated that the Preferred Drug List and Prior Authorization Programs are critical to DMAS and our clients. He provided an overview of today's meeting agenda to include PDL background information, actions taken, next steps, the roles of DMAS, the Committee and the contractor, review of procedural issues by the Attorney General's office, and public comment period.

Chairman Axelrod asked each of the members to introduce themselves and provide information on their background. Mr. Finnerty introduced Dr. Elmer Neil, Chairman of the Board of Medical Assistance Services. Dr. Neil thanked the members of the Committee for their service and noted that the Board is trying to take a more proactive role in the activities of the Department. He introduced Dr. Manikoth G. Kurup, a member of the Board who will serve as liaison between the Board and the Committee. Mr. Finnerty also introduced Steve Harms, Deputy Secretary from the Office of the Secretary of Health and Human Resources. A staff contact list has been provided to the members.

Overview and Status of the Medicaid PDL and Prior Authorization Programs

Ms. Cindi Jones, Chief Deputy Director, presented an overview of the PDL program, the actions the Department has taken to date, and next steps for implementation of the programs. The PDL programs will be implemented no later than January 2004. (See Ms. Jones' presentation entitled: Status Report on the Development of a Medicaid Preferred Drug List Program, June 18, 2003.)

The Virginia PDL program is being developed to meet Virginia's needs and will not duplicate the programs in other states. During the development of the Virginia request for proposal, the Department addressed many of the concerns noted in the Kaiser Commission reports on the Michigan and Florida's PDL programs. The Department has been reaching out to providers, consumer advocates, and pharmaceutical companies to get their input into the design of the program.

Roles of DMAS, P&T Committee, and Contractor

Director Finnerty discussed the roles of each of the parties involved in the PDL programs. (See Director Finnerty's presentation entitled: Roles of DMAS, Pharmacy and Therapeutics Committee, and Preferred Drug List Contractor, June 18, 2003.)

The Department wants to be responsive to the P&T Committee and wants the Committee to let DMAS know of anything they need.

In addition to the full-time members of the P&T Committee, Ms. Cindy Kirkwood (PharmD), a Board-Certified Psychiatric Pharmacist from Virginia Commonwealth University (one of 12 in the state), has agreed to serve as an ad- hoc consultant to the P&T Committee for the purpose of reviewing mental health drugs.

Procedural Issues for P&T Committee Meetings

Paige Fitzgerald, Esq., Special Counsel from the Attorney General's office, provided a freedom of information act summary to the Committee. The review included information on executive sessions, electronic communication meetings, public records, public comment, and meetings.

Remarks from Secretary Woods

Secretary of Health and Human Resources, Jane Woods joined the meeting via phone. She thanked all those who volunteered to serve on the P&T Committee. There has been a lot of concern regarding PDLs because they have not necessarily worked well in some states. The Committee will be helping to make sure Virginia does not make the same mistakes as other states have made along the way. She stated the most critical concern will be that Medicaid clients have access to the quality medications they need. She noted the expertise of the Virginia P&T Committee puts Virginia in an excellent position to establish a quality program. Secretary Woods mentioned that the development process will continue to open as we proceed.

Public Comment from Interested Parties

Chairman Axelrod opened the meeting to those parties who had requested to give public comment. Approximately 60 attendees were present. Public comments were categorized into oral presentations and written comments, and organized by interested party: consumer advocates, providers, and pharmaceutical companies. All comments have been posted to the DMAS website, along with the presentations.

Oral comments were presented by:

Consumer Advocates

Jill A. Hanken	Virginia Poverty Law Center
George Braunstein	Virginia Association of Community Services Boards
Val Marsh	Virginia Affiliate of the National Alliance of the Mentally Ill
Eldon James	Virginia Association of Area Agencies on Aging
Judy Castleman	Virginia Quality Healthcare Network
Rick Shinn	Virginia Primary Care Association
Sue Rowland	Virginia Organizations Responding to AIDS
Carter Harrison	Alzheimers Association
Cathleen Emhof	Allergy and Asthma Network Mothers of Asthmatics

Providers

Rebecca P. Snead	Virginia Pharmacists Association
Karen E. Sanders	American Psychiatric Association

Pharmaceutical Companies

Ashley Taylor	Pharmaceutical Research and Manufacturers of America (P*h*RMA)

Written comments were submitted by:

Consumer Advocates

Sandi Qualley	Hemophilia Association of the Capital Area

Providers

D. Calloway Whitehead, III	Psychiatric Society of Virginia and the Northern Virginia Chapter of the Washington Psychiatric Society

Pharmaceutical Companies

Jake Hansen	Barr Laboratories and the Generic Pharmaceutical Association
Gary M. Bolick	Pfizer, Inc.
Stuart Gordon	Plasma Protein Therapeutics Association (PPTA)

Future Committee Meeting Dates

Chairman Axelrod noted that the Committee is under a compressed time frame to meet the January 2004 implementation date. The Committee will need to work through data and therapeutic classes. He requested that members e-mail Patrick Finnerty or Cindi Jones with a particular day and time of day that works best for future meetings. From that information, members will be polled with specific dates to establish the next meeting.

Adjournment

There being no further business, the meeting was adjourned at 11:35 a.m.

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COMMENTS TO THE PHARMACY AND THERAPEUTICS COMMITTEE JUNE 18, 2003

I am Jill Hanken from the Virginia Poverty Law Center. I specialize in health law, and in my work I represent low income Virginians who are Medicaid and FAMIS enrollees.

Since last summer I have voiced my concerns about a PDL for fee-for-service Medicaid and FAMIS recipients. While the budget language addresses some of those concerns, I think it's important for the P & T committee to understand why many of us objected to the PDL in the first place. In addition, now that we're working towards actual implementation, it is critical for you to design and implement a program that works well and avoids the nightmares that have occurred in other states.*

A PDL – by definition – restricts access to prescription drugs as a way to save money. The state saves money in two ways – 1. by including on the Preferred Drug only the cheapest yet effective drug in each therapeutic category, and 2. by securing "Supplemental Rebates" from companies that want their drugs included on the Preferred Lists. When a drug is prescribed that is not on the PDL, a prior authorization mechanism is required.

A prior authorization process – no matter how well planned – is a barrier to pharmacy services. Indeed, that is precisely why the pharmaceutical companies have an incentive to pay supplemental rebates – They want to avoid the prior authorization process!

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*A prescription drug cost control program was implemented in Florida in October 2001. This program limits Medicaid recipients to 4 brand name prescriptions per month and to drugs on the state's PDL unless the provider receives prior authorization. Documents for one month - March 2002 - show that:

- Over 58,000 recipients were denied medications due to the four brand limit and PDL.
- Approximately 25,000, or less than half, of these recipients eventually received the drug. The length of the delay is unknown.
- Approximately 25% of recipients (13,681) received either a generic substitute or a different brand name.
- Over 20,000 recipients, or more than 1/3 of all denials, failed to receive any medication in the same therapeutic class as the prescription.

Documents filed in Hernandez v. Medows, Case No. 02-20964, U.S. District Court, S.D. FL, a case (now settled) which challenged the failure of Florida to provide recipients with written notice and an opportunity to appeal when coverage of their prescription drugs was terminated, suspended, delayed or reduced. Florida's Medicaid population is three times larger than Virginia.

Similar problems have occurred in Michigan. "Report on Prescription Access Hotline" (April 22-June 14 2002; "Final Statistical Report" (Mental Health Association in Michigan and Michigan Association for Children with Emotional Disorders), June 24, 2002.

The primary concern of consumers is that the Medicaid patient whose prescription is rejected at the pharmacy counter will often walk out, not only without the original prescribed drug, but also with no drug at all. This has serious consequences for the patient's health, as well as the state which may pay more for unnecessary emergency care, nursing home admissions or deteriorated health conditions.

Navigating or avoiding the prior authorization system may be difficult or impossible for the Medicaid patients who:

Have very low income. The basic monthly income limits for various Medicaid categories are:

- Individuals who are over 65, blind, and disabled – 80% of the poverty line - Individual $599, Couple $808, a couple on SSI $829
- Parents – Income under 33% of the federal poverty line (e.g. $342 – $435 per month for a family of 4, depending on region)
- Pregnant women – 133% of poverty line - $2040 for family of 4
- Children under 19 (through FAMIS) - 200% of poverty line - $3067 for family of 4

  Thus, in almost all cases, Medicaid enrollees lack the resources to pay up-front at the drug store to obtain a prescribed drug rejected for lack of prior authorization.

Are sicker than the general population, with a significantly higher incidence of chronic disease.

- More than 25% of adult non-elderly Medicaid beneficiaries have multiple chronic conditions, compared to less than 10% of such individuals with employer based coverage. Peter J. Cunningham, "Affording Prescription Drugs: Not Just a Problem for the Elderly", (Center for Studying Health System Change), Research Report No. 5 at 4,7 (April 2002), available online at www.hschange.org
- Studies have shown that restrictions on access to prescription drugs imposed by other states have resulted in increased emergency mental health services and increased institutionalization. Soumerai, "Effects of Medicaid Drug Payment Limits on Admission to Hospitals and Nursing Homes", New Eng. J. Med. 1991, 325:1072-1077.

Often face other obstacles.

- Literacy skills are disproportionately lower for Medicaid recipients than for the population at large.

- More likely to lack the resources needed to take affirmative steps to negotiate a complicated Prior Authorization process after a rejection at the pharmacy occurs.

- Limited access to telephones, or time during work hours at service jobs to make/receive/return phone calls.

- Lack of transportation – more Medicaid recipients lack private transportation and are physically disabled. They may have significant difficulties in simply returning to the pharmacy to obtain a non-PDL drug.

Thus, a prior authorization system for prescription drugs is inherently problematic for Medicaid patients. In your design of Virginia's PDL, please consider ways to

1. Reduce the necessity of Prior Authorization; and

2. Make sure the Prior Authorization system works so that medically necessary drugs are available quickly and efficiently, with a minimum amount of work for patients, doctors and pharmacies.

To reduce the necessity of prior authorization, you should include:

- Additional exceptions for therapeutic classes and categories of patients. While the General Assembly and DMAS have already enumerated several therapeutic classes to exclude from the PDL, more may be needed.

  A recent report recommends exemptions from prior authorization for (1) all psychotherapeutic, anti-viral and anti-convulsive medications; (2) all name-brand drugs with narrow therapeutic indices; (3) all name brand drugs for which side effects have been identified with the generic equivalent; and (4) all drugs related to organ transplants. Kaiser Commission on Medicaid and the Uninsured, "Model Prescription Drug Prior Authorization Process for State Medicaid Programs", p.22 (April 2003).

  Exclusions for certain patients should also be considered. The P & T Committee should survey all Medicaid providers for input on these issues.

- Establish a clear "Grandfather" provision for all existing complicated drug regimens that will continue until the treating physician initiates a change. The PDL will affect the Medicaid fee-for-service population, which is primarily composed of elderly and disabled recipients. This is a very vulnerable population. Many elderly and disabled have several chronic conditions that require ongoing drug therapy. It would be very dangerous to disrupt a stable, safe and beneficial drug regimen.

- Make clear that when a non-PDL drug is approved, subsequent prior authorization is unnecessary.

- Information, information, information – must be provided on an ongoing basis to patients, doctors, and pharmacies, using multiple methods in multiple languages. This is perhaps the most critical aspect of the system. It is the only way to help doctors select a PDL drug (or request prior authorization) at the front end. (Doctors are often not even aware of what insurance and what formulary applies to an individual patient.) The system should also track doctors with a high number of prior authorization requests for follow-up and additional training.

While the PDL contractor will be primarily responsible for the operation of the prior authorization system, the P & T Committee must assist that operation by:

- Establishing a clear objective standard for "medical necessity" that includes consideration of side effects, compliance issues, past experience, failure on previous drug therapy, documentation of benefits of new drugs, and whether alternate therapy is available. Moreover, when the physician's opinion is reasonably supportable, deference to treating physicians and other prescribers is appropriate.

- Establishing a clear objective standard for what constitutes an "emergency", requiring dispensing of a 72-hour supply of a non-PDL drug. I recommend that whenever a patient presents a prescription for a non-PDL drug, and prior authorization or a substitute drug can not be authorized <u>while the patient is waiting at the pharmacy</u>, the emergency 72-hour supply should be provided.

- Limiting changes to the PDL. To eliminate confusion, changes should not be made in the PDL more than twice a year. And whenever changes are made, extensive "advertising" should accompany it.

The P & T Committee also has an essential role to play in monitoring and evaluating the PDL system and making appropriate adjustments.

- Surveys of patients and doctors should be a part of this evaluation.

- In addition to tracking prior authorization requests, determinations, appeals, etc., you need to evaluate the impact of this system on patient health. We need to know how many patients present prescriptions that are rejected or filled with substitute drugs. What kind of time/delays are involved? Have return trips to the pharmacy been required? Can medical complications/ ER visits be traced to denied prescriptions?

I do believe that we all have the same goal in mind – assuring that medically necessary drugs are readily available to Medicaid and FAMIS enrollees. Making this goal a reality in a PDL system is a challenge that requires a great deal of work and ongoing evaluation.

I appreciate the opportunity to make these comments as you begin your deliberations.

PHARMACY AND THERAPEUTICS COMMITTEE
June 18, 2003
MEDICAID PREFERRED DRUG LIST PROGRAM

(Presentation Comments: George E. Braunstein, CSB Executive Director)

My comments will focus on two frameworks proposed by the Virginia Association of Community Services Boards (VACSB) to protect the rights of consumers we serve.

The first recommended framework concerns *Implementation Parameters:*

- Consumers with serious mental illness should not be required to experience a treatment failure because a less effective, but cheaper, medication must be used prior to authorizing a more expensive drug treatment. The results of this approach are devastating to the consumer, and costly to the system.
    - In addition to anti-psychotic medications, (including those classified as atypical and anti-convulsant), medications of all types need to be easily accessed by public sector MHMRSA consumers. Using some type of 'special category' to ensure ease of access will not only be responsive to consumer needs, but will also result in a decrease of unnecessary and long-term Medicaid costs.
    - The selected Management Contractor should be able to demonstrate both experience and sensitivity to the needs of MH/MR consumers. In addition, it is recommended that a time-limited advisory group of service providers review key protocols in order to provide improved service and decrease the number of complaints and grievances.

The second framework concerns *Guiding Principles for Committee Activities* that we believe will be helpful.

- We hope the committee will primarily focus on the efficacy of medications in each classification, and adopt a mission of reviewing provider practices on a regular basis
- As part of the review of medication efficacy, recommendations for prescribing ranges and length of medication treatment would be helpful
- To the best of your ability, we recommend that any contact with pharmaceutical companies by committee members occur in a public meeting and, if additional information needs to be shared outside the public spotlight, that it be done through the committee's administrative personnel.
- In order to ensure that data generated by the Management Company is useful in practice management, the VACSB asks that this data be regularly forwarded to each CSB for the purpose of combining it with our own peer review information to better guide input for preferred practices.

(GEB:vhachest)

VACSB RESPONSE TO PDL
March 28, 2003

SUGGESTED PRINCIPLES FOR PDL IMPLEMENTATION PARAMETERS AND PRACTICE MANAGEMENT

Keeping in mind that CSBs manage and/or provide services to those consumers who are severely disabled and at greatest risk for more expensive hospital care, extra care should be taken to assure that these consumers have access to the medications they need when they are needed. As we discussed when we met, polypharmacy is entirely appropriate for and needed by consumers with serious mental illness (SMI). Otherwise, either a hospital stay in a private general hospital may be necessary and will be billed to Medicaid or an extended stay in a state hospital may be needed, for which the state General Fund is used.

In other states that have implemented PDL/PA, when consumers of public community programs have not received special consideration, the process has been chaotic at best. VACSB recommends the following in order to assure consumer stability.

PDL IMPLEMENTATION PARAMETERS

1) For consumers with serious mental illness served by the MHMRSAS system, there should never be a "fail up" policy regarding medications for consumers with either "straight" Medicaid or through HMOs. The atypical medications should be considered front line meds.

2) Wherever possible, in addition to atypicals, anti-psychotics, and anti-convulsants, exclude public sector MHMRSA consumer medications of all types from the PDL and therefore prior authorization.
   - If not possible, establish a special category for those consumers with mental illness and mental retardation or both who are case-managed by CSBs for SSRIs and other psychoactive drugs. This special category would allow immediate authorization of prescribed medications.
   - Establish the special category as above for consumers case managed by CSBs for when over 9 unique prescriptions are written. Again, an immediate authorization should be in place.
3) Management Contractor:
   - Prior to contract award and in the review stage, potential management contractors should demonstrate a record of sensitivity in addressing the needs of consumers who are the most severely disabled. (SMI and MR) This may be accomplished by reviewing contractor protocols and other processes used for public systems in other states as well as by interviewing community programs treating consumers with SMI in that state.
   - After contract award, it is recommended that DMAS develop a mechanism for operational review by CSBs/other long-term care providers of any protocols, procedures, and processes involving prior authorization by that contractor.

4) Pharmacy and Therapeutics Committee:

- We would reiterate the need for practitioners who are skilled in public community services. At least one should have experience in treating consumers with mental retardation.
- The Committee should determine parameters early in the process. Committees of this type do not review provider practice. Instead they focus on the efficacy of the various medications in each classification, assuming appropriate provider practice.
- A general theme for the committee should be to provide some recommended prescribing ranges and some guidance as to how long a trial of medication should continue before it is determined to be ineffective.
- Appointments to a P&T Committee will be important so as to avoid making the meetings too political and therefore not focused on the best benefit to the patients/consumers.
- An administrative person should be the point person for all contacts by pharmaceutical companies. Such companies tend to put enormous pressure on P&T members if they can have direct access.
- Data generated by the Management Company may provide a view of prescribing practices of CSB psychiatrists and how they compare to private sector Medicaid providers. This will be useful if shared with CSBs, who can combine this data with local or regional outcome information to achieve a picture of preferred practice expectations.
- Unlike consumers who are case managed by CSBs, those consumers and/or consumer groups whose care is not managed but who appear to consume large amounts of services may need to be targeted for utilization review.

Department of Medical Assistance Services
P&T Committee
June 18, 2003
Testimony by Val Marsh, Executive Director
NAMI-VA

Thank you for this opportunity to share the views of families and mental health consumers coping with serious mental illnesses. I represent the Virginia Affiliate of the National Alliance of the Mentally Ill. There are over 220,000 members nationwide, and Virginia has nearly 6,000 members statewide.

Though people with brain disorders such as schizophrenia and major depression comprise a small portion of Virginia's Medicaid population, they are among the most ill and vulnerable. Nonetheless, they number in the thousands. Unfortunately, these individuals have experienced indescribable stigma and discrimination for more years than can be counted.

Psychotropic medication has been vitally important to NAMI since its inception. For nearly 25 years, families have advocated tirelessly for better treatments for their relatives. Long ago, NAMI members reminded national decision makers of this country's genuine commitment to treating other biologically based illnesses such as cancer, heart disease, and more. Advocating for better medication, as one of many key treatment modalities, is something to which NAMI members have always devoted themselves.

In recent years, NAMI's voice seemed to have been heard. Yet it is disheartening that psychotropic medications of all classes now appear to be slipping out our grasp - not due to efficacy, but due to cost.

Families and consumers are mindful that cost is a vital consideration in health care (though it is no more than 12% of the overall cost of care for mental illness). But we would like to remind you that it is not possible to place a price tag on bringing a family back to life who has been lost to a devastating illness.

We cannot engage in arguments debating the efficacy of new vs. old medications. We KNOW the newer ones help the people we love have a better chance to recover and lead more full, productive lives. . Wouldn't you want the same for your son, daughter, brother, nephew, mother, father, etc? Additionally, like other kinds of medications, psychiatrists and consumers need access to a number of options, because no one medication works for every single person.

As this committee meets, we at NAMI-VA have the following primary concerns.

- Atypical antipsychotics and anticonvulsants must remain exempt from the screening process of preferred drug lists. Additionally, we believe it is imperative that the full range of antidepressant and anti-anxiety medications be added to the protected class of medications for complete access. Many consumers have multiple illnesses. For example, schizophrenia occurs in combination with depression about 50% of the time, serious depression often co-occurs with crippling anxiety, etc. Why should a doctor be forced to treat only one out of two illnesses with the most effective medication available? Why should a consumer be forced to have any medical condition treated with outdated, less

effective medication for non-medical reasons?

- Other states' PDL programs have already proven that inserting barriers to accessing psychiatric medications results in people not receiving treatment. People with brain disorders, by definition, cannot withstand complicated measures, denial and appeal procedures, etc., even if someone else engages in the "paper/telephone battle" for access. It is cruel and unfair to expect a person with imbalanced brain chemistry to endure an appeal process/waiting period. Mental illnesses leave consumers vulnerable to confusion and hopelessness. This then leads to non-compliance, and the danger of severe symptoms arising. Isn't this what we are trying to avoid? There is simply no way to guarantee that bureaucratic problems will not manifest, especially when cost is paramount.

- We know that the charge of this committee is to help the state save money. But these cost savings measures must not cause unnecessary suffering or sacrifice of human lives. Virginians should not have to fail repeatedly on less expensive medications for non-medical reasons before having access to what their own doctors recommend.

- Finally, we at NAMI-VA have been asking the state for many years to examine its "silo funding structure." This committee's charge of reducing medication expenditures, if disaffiliated with some means of considering inpatient and physician costs, recidivism rates, etc., means that your cost saving recommendations are far less likely to succeed, because they will be made in a vacuum. While your "official charge" of reducing costs is narrow, we urge you to recommend the need for a more broad psychopharmacological examination of psychiatric care. Other states have found that blending the funding for medication with funding for inpatient care, etc., in fact reduces the overall cost of care, because fewer people wind up needing hospitalization.

Thank you for your time today. We wish you well in the deliberations ahead of you.

NAMI Policy Research Institute

March 2003

Prior Authorization Threatens Consumers' Health

To control pharmaceutical spending and to attempt to control their budget expenses, a number of states have adopted or are considering restrictions on access to certain types of expensive medications, including psychotropic medications, in their Medicaid programs. States will be attempting to control drug costs in several ways such as placing certain drugs on a list requiring prior authorization before dispensing -- and requiring as a prerequisite for authorization of a specific, often non-formulary medication - that the patient fail on at least one other medication.

These prior authorization initiatives pose significant threats for Medicaid recipients with serious mental illnesses trying to access medications prescribed by their treating physician. While NAMI understands that states must make tough decisions in the face of the current budget crisis, these programs will jeopardize consumer health if they restrict access to needed medications.

Based on data from Florida and Michigan thousands of Medicaid recipients have left the pharmacy without filling their prescriptions due to the prior authorization programs.

It is clear to the NAMI Policy Research Institute that the consequences for people with serious mental illness will be devastating if Medicaid prior authorization programs and other cost control initiatives become more commonplace. Based on costs rather than health and safety, prior authorization programs, preferred drug lists and fail first procedures often force physicians and consumers to choose medications that they would otherwise not prescribe. Restrictions on access to psychotropic, medications not only jeopardize consumer health, but they fail to reduce overall health costs. Multiple studies have shown that in the long run, such policies actually increase costs in hospitalization as well as emergency and primary care.

NAMI Policy Research Institute's Prescription to Ensure Access to Medications

In response to the developing threats to access to medications for people with serious mental illness, the NAMI Policy Research Institute's Access to Medications Task Force was created and charged by the Board of Directors to examine the available evidence and provide policy guidance on this issue to the NAMI Board, NAMI's grassroots' advocates, and policymakers.

Based on the task force deliberations, NAM I recommends the following 10-point program to ensure open access to medications in the current budget deficit environment. This program is an integrated, comprehensive approach to addressing the needs and interests of the people with serious mental illnesses who need access to medications for recovery.

Federal Strategies

1. NAMI supports an increase in the "Federal Medical Assistance Percentage," or FMAP to get states through these difficult financial times. Cutting back on Medicaid spending by states will result in severe service, infrastructure and community impacts due to the loss of federal funds. We are supporting efforts of the National Governors Association and other groups to increase the Medicaid matching rates.

2. NAMI supports appropriate, emerging legislative initiatives to expand prescription drug coverage for Medicare beneficiaries. We believe that state pressure to control prescription drag spending will mount in the absence of a Medicare drug benefit.
3. NAMI supports system-wide health care reform to reduce fragmentation in the delivery of mental health services and to ensure access to the most effective treatments.
4. NAMI supports increased funding allocations to the National Institute for Mental Health (NIMH) to gain better insights on access to new medications and supports increased funding for research on evidence-based practices.

State Strategies

1. When it comes to medications, particularly for mental illnesses, one size clearly does not fit all. Each person can react differently to anti-psychotic or anti-depressant medications both in terms of efficacy and potentially dangerous side effects. NAMI opposes the use of Medicaid prior authorization programs to control prescription drug costs and utilization. NAMI believes that Medicaid prior authorization programs are high-risk cost containment strategies and they are not an effective cost-management strategy based on private sector experience. The most cost effective and humane solution is to respect the roles of the practitioner, and consumer to select the treatment that works best.
2. **If prior authorization programs are in place or being strongly considered, NAMI supports carve-outs for anti-psy(:hotic, anti-depressant, anti-anxiety and anti-convulsant medications from restrictive cost control programs in order to ensure that people with mental illness have open access to medications that maintain recovery.**
3. NAMI supports research efforts by pharmaceutical companies to develop new medications but opposes pricing practices that make these medications unaffordable.
4. NAMI supports the development of notification, grievance and appeals procedures to protect Medicaid recipients with serious mental illness.
5. NAMI will participate, as appropriate, in class-action suits, and file amicus briefs, that would oppose restricting Medicaid clients' access to prescription drugs through prior authorization programs.
6. NAMI supports "Polypharmacy Education Programs" that are aimed at reducing the over prescribing of medications as an alternative to restrictive cost containment programs and the development of explicit treatment protocols with rigorous follow-up assessments.

Conclusion

NAMI remains opposed to state policy changes that put costs ahead of consumer health care and stands ready to work with states to find real solutions to current budget problems. NAMI looks for every opportunity to work with state and federal policymakers and to ensure that limited public dollars are used in the most effective way to protect access to the most effective treatments for people with serious mental illnesses. We encourage policymakers to consider a comprehensive and coordinated effort to address the needs of people with serious mental illness to prevent long-term damage to an already inadequate system of care.

For further information, please contact Mike Fitzpatrick at mfitzpatrick@nami.org or (207) 353-9311 or Joel Miller at joel@nami.org or (703) 524-7600.

Good Morning. My name is Eldon James and I am Executive Director of the Virginia Association of Area Agencies on Aging (V4A). V4A serves as the coordinating organization for Virginia's 25 Area Agencies on Aging (The triple A's). The Triple A's have been designated since the 1970s, jointly by the federal government, the Commonwealth of Virginia and by local governments to serve older Virginias. Services include preparing and implementing Area Plans for services to older Virginians, serving as an advocate and focal point for aging issues and services, and ensuring, in cooperation with other agencies and organizations, the availability and accessibility of a comprehensive, coordinated system of services to older people.

With that in mind, we offer the following comments to you as you embark on your very important journey. In order not to be repetitive of what other speakers are offering today, I will focus on only three issues. These issues may be repeated by others but they are so very important to what you are undertaking that they warrant repeating.

1) The long lead time for preauthorization for 9 unique medications. 180 days (for non-institutionalized beneficiaries) may be necessary for DMAS to do its job but let's not create a situation where we cause havoc in people's lives in order to think we are saving money. For many reasons, our elderly who are Medicaid beneficiaries generally do not deal well with significant changes in their daily or weekly or monthly routine. Disruption of prescriptions may have devastating human consequences on these Virginians. Such health consequences often translate into significantly more expensive health care costs such as emergency room visits. Speed in turnaround times for preauthorization and in the handling of appeals of denials will be critical to the health maintenance of these individuals and in meeting the bottom line savings that the Medicaid program must meet – not merely shifting the cost from prescriptions to other areas within the Medicaid budget.

2) Effective beneficiary and provider training and education will be critical to avoiding barriers that will occur from misunderstanding of the new program and its new rules and procedures. Let me say this again - our elderly who are Medicaid beneficiaries generally do not deal smoothly with significant changes in their daily or weekly or monthly routine. Disruption of prescriptions may have devastating human consequences on these Virginians. Poor information, untimely information and misperceived information can have devastating impacts on these often frail

Virginians.

3) Monitoring the impact of the program changes that will be implemented will allow Committee members and policymakers to understand the impacts of the steps taken to save drug costs. Unintended consequences, which you will be working hard to prevent but which always occur in new and complex program changes, will lead to painful health impacts for these individuals and their families and will negatively impact the bottom line.

Thank you very much for the opportunity to share our concerns with you and let me leave you with one summary thought – We appreciate that what you have to accomplish is a positive impact on the bottom line of the cost of prescription drugs, we wish you Godspeed in the journey you are embarking on, and we pray (and offer our help) for your success in paying for that savings with increased efficiency and not in human costs of frail, elderly Virginians or in costs to other aspects of the Medicaid budget.

Comments to P& T Committee 6/18/03

Judith S. Castleman, Executive Director
Virginia Quality Healthcare Network

The Va. Quality Healthcare Network (VQHN) is a statewide coalition of nearly 50 voluntary health associations and patient advocacy groups formed to ensure access to quality health care for all Virginians. We worked hard to place the numerous patient protections into the budget language that directed the establishment of a Medicaid Preferred Drug List and Prior Authorization process. I feel certain that your background materials include this protective language.

Since many of the other speakers today will address the particular needs of mental health patients, I would like to speak about those patients with other medical conditions. My particular concern is for those patients with multiple concurrent medical conditions and the medications required to treat those conditions. It would be the exception rather than the rule that an elderly patient, or a patient with serious mental illness, did not have other chronic physical diagnoses, such as diabetes, cardiovascular and gastrointestinal problems, etc. Each of these requires a different drug regime, and often it is through an arduous trial and error process of benefits and side effects that the exact regime that works best for the patient is agreed upon. It is critical that this PDL process not jeopardize those carefully crafted drug combinations for these patients. So please keep this in mind when you look at individual classes of drugs and consider that the vast majority of clients who will be subject to this process will fall into the above described illnesses.

One suggestion that has been discussed for your consideration is some type of "rolling grandfathering" process. The healthcare provider who is treating a patient with multiple prescription drugs that are not listed on the DMAS formulary, could change one drug at a time, over a specified period of time. Only after a time sufficient to see if the new drug fits well with the others in the patient's prescription plan, would he then try to change another of the drugs. While this might seem complicated, it would prevent requiring a patient to change to an entirely new set of drugs without the ability to discover what will work best.

I want to reinforce to you that fee-for-service Medicaid patients, which will be the clients of this new PDL program, are not "just like any other patient" in a physician's practice. These patients will not be like the child Medicaid patients whose income eligibility rates are far higher. They will have incomes far below $10,000 per year. These are usually the sickest of the sick, the poorest of the poor, without someone to look out for them and see that they follow through with prescribed medical and pharmacological recommendations. They often do not have transportation to take them back to the doctor or pharmacy on a later date. Anything that makes compliance more difficult will often result in poor health outcomes. It would certainly not be cost effective to cut the cost of providing prescription drugs, only to drive up the costs of emergency room visits, hospital admissions, and surgery.

I urge you to learn from the mistakes of some of the other states that have gone through this process before you. One state found that there were no oral diabetic agents on the list that were appropriate for children. Similar patient horror stories have come from other states. Please consider all the patients who might need a drug in a particular class.

Finally, I have brought for your consideration a copy of the recent legal settlement between Medicaid patients and state of Florida. Perhaps this will be useful in avoiding some of the mistakes that they apparently made in developing their prior authorization process. You can put such protections in place at the outset of the Virginia program.

Thank you for your time and attention and good luck on the arduous task that you have before you.

Date: June 10, 2003

TO: Cindy Jones, Chief Deputy
Department of Medical Assistance Services
600 E. Broad St. Suite 1300
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FR: Richard D. Shinn
Director of Public Affairs
Virginia Primary Care Association
10800 Midlothian Turnpike / Suite 265
Richmond, VA 23235
Office: (804) 378-8801 ext: 19
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RE: **Issues to Address on the Development and Implementation of a Medicaid Preferred Drug List in Virginia; Comments for the Pharmacy and Therapeutics Committee to Consider**

Dear Chief Deputy Jones:

Virginia Primary Care Association, as the association of Community Health Centers in Virginia, is charged with providing our members with information on legislation and policies that will impact their patients and the operations of Community Health Centers in Virginia.

Community Health Centers are non-profit health organizations providing services in medically underserved areas. These programs provide primary care, pharmaceutical services, dental care, behavioral health services, and preventive health services to over 165,000 Virginians in 67 locations across the Commonwealth. Community Health Centers had over 520,000 patient encounters during FY 2001. Of this population, approximately 18.4 % are recipients of Medicaid, and may be directly impacted by the development and implementation of a Preferred Drug List for Medicaid.

We understand the need to allocate resources in the most effective manner as to maximize the value, quality and quantity of services received by Medicaid consumers. Our concern is that, as the Preferred Drug list is developed and implemented, certain issues be considered that will protect the integrity and clinical efficacy of medical care provided to Medicaid patients. These issues include:

1) Provide the option for patients who have been stabilized on specific medications to be able to continue on that particular treatment regimen, rather than requiring that they be placed on the medications on the PDL.

2) For medications not specified in the PDL, make the prior authorization process as simple as possible, and prevent additional barriers to access for the physician as well as the patient.

- Our concern is that the provider be able to have easy and adequate access to written criteria required to establish medically necessity for prior authorization approval.

- Once a prior authorization has been obtained, make the time frame for which that authorization is effective to be as long as possible.
- One concern here is that the more frequently authorization must be established, the higher the administrative costs for staff, the physicians' time, as well as time away from actual treatment of patients, etc.

3) Ensure that an adequate number of medications be available for each therapeutic class, rather than limiting to only 1 or 2 medications per class.

4) Provide timely and efficient access for physicians to be able to access information as the PDL is phased in.

- Provide an efficient and easy to navigate website for information access, or a list serve.
- Ensure that authorization staff is available and accessible 24 hours a day.
- Will this be provided by the Pharmacy Benefits Management vendor, or from DMAS?

5) A concern we have is on who will have the final authority on approval for specific medications.

- For example, once a physician has determined that a specific medication is the most appropriate treatment, and that particular medication is not on the PDL, who will assume responsibility for the final medical decision?
- If the PBM has the final decision, what type of appeals process will be available to contest that decision?

6) In developing and implementing a PDL, we ask that the Virginia team review what has been therapeutically and administratively effective in other states

- As an example, the state of Vermont has implemented a PDL that provides provider access to comprehensive information on prior authorization criteria for specific drugs by therapeutic classification, as part of their web based information system.
- Refer to the Vermont website at: http://www.path.state.vt.us/
- With a direct link to their PDL at: http://www.path.state.vt.us/districts/ovha/ovha49.htm

7) As currently written, the Pharmacy and Therapeutics team is to be comprised of 8 to 12 members, including physicians and pharmacists.

- No mention is made of whether these persons are to be compensated or are volunteers;
- Or whether they are able to have ties to the pharmaceutical industry.
- A concern could develop as to how independent these persons will be,
- And how much influence could be exerted by the pharmaceutical industry on the team members' decisions as to which drugs should be included on the PDL.

8) Provide for timely updates to therapeutic classes, and timely notification to providers of any updates.

9) We are not clear on what will occur if there is a shortage or recall of a specific medication on the PDL.

- Will physicians be able to prescribe another drug in lieu of the one on the PDL, without having to go through a prior authorization process?

10) In developing and maintaining the PDL, the cost effectiveness of any given drug is to be considered only after it is determined to be safe and clinically effective.

- How will the decision be weighted for drugs in each class, to determine which drug is clinically most effective, and then weighted for cost-effectiveness?

11) An issue that has been raised is the potential for the PDL to become age or gender biased.

- For example, most chronic illnesses appear in the elderly population. Our concern would be that decisions to place drugs on the PDL be as free as possible from any bias reflecting age or gender, so that all classes of consumers would benefit from the PDL.

I look forward to continuing to work with you in the future. If I can be of service, please call me at (804) 378-8801 Ext: 19.

Sincerely,

Richard D. Shinn
Director of Public Affairs
Virginia Primary Care Association

Good morning. I am Sue Rowland, Director of Public Advocacy for a grassroots consumer group, the Virginia Organizations Responding to AIDS. Called VORA for short, this group is made up of agencies, organizations, and individuals who have an interest in strong public policy that serves to reduce the spread of HIV and to allow for effective treatment and supportive services for persons living with the disease in our state.

Over 15,500 people are living with HIV/AIDS in our state[1]. VORA works to assure that comprehensive prevention and treatment services are available throughout the state, in both rural and urban areas, where federally funded programs seem to be rich in funding, and where the funding is more limited.

We thank you for the opportunity to speak today, and especially thank Jill Hanken, who coordinated the consumer advocates for today's public hearing.

And we'd be remiss for not also thanking the General Assembly for the directive that this committee make recommendations to the Department about the appropriate exclusions for medications used for the treatment of HIV-related conditions. We appreciate that the antiretroviral medications are among those key therapeutic classes of drugs to be excluded from the PDL program according to recent DMAS' presentations. We trust that you all aware that these medications are critical to the health and well being of persons living with this virus (PWA's) -- and that any barriers to these medications, real or perceived, can result in consequences that are potentially life threatening, yet easily avoidable.

DMAS has recently reported that on November 30th of last year, 316 persons were enrolled in the HIV/AIDS Waiver program. (Some additional number of persons living with HIV/AIDS (PWA's) are also Medicaid eligible and may be receiving assistance for treatment services through Medicaid's other programs.) The strict income requirements for adults to qualify for Medicaid and Virginia's strict criteria for assessing nursing home eligibility (a requirement to become enrolled in any waiver program) serves to limit the number of PWA's that can qualify for this program.

However, for the over 300 persons enrolled, the waiver program is critical to achieving any improvement in disease condition because it provides access to skilled physicians and to the medications.

Today, we are asking that as you examine the responsibilities that you hold as members of the PTC, that you consider three issues in particular:

- The importance of the PWA (consumer or beneficiary) & provider training & education component of the PDL, particularly as it impacts your decisions;
- Using the AIDS Drug Assistance Program Formulary in your consideration of medications other than antiretroviral therapies which are as important to PWA's; and
- The processes that will be used to provide you with information on how your decisions may or may not be impacting upon health outcomes of the Medicaid clients included in the program.

[1] Virginia Department of Health reports that 15,449 persons are living with HIV/AIDS in March 2003. CDC estimates that in the U.S., as many as another third of that number may be living with the virus but are undiagnosed and unreported to health officials.

Consumer / provider training and education

While the direct responsibility for the training & education rests with the firm that will administer the program, the effectiveness of this component will have a direct impact upon the access to medicines by beneficiaries covered by the new plan. For PWA's, life is commonly complicated by multiple diagnosis (substance abuse, mental illness, hepatitis, and other HIV-related diseases). Of course, PWA's who qualify for these programs also have very low incomes – so that all the challenges of poverty are also at hand.

We already know that when Medicaid clients are shifted from one payment system to another, disruptions occur as clients make mistakes in acting within the new systems. The same kinds of disruptions can be expected in a new program for medications. Even though Antivirals will be excluded from the PDL, other medications commonly used by PWA's may not be. Other medications may not be included, are not exempt, and will require pre-authorization.

AIDS Drug Assistance Program's Formulary

We suggest that when looking at the other classes of medications that are also commonly used to treat HIV and HIV-related conditions the ADAP Formulary be used. "ADAP" is the AIDS Drug Assistance Program, and provides a formulary of medications used for HIV-related illnesses. PWA's who do not qualify for Medicaid and have an income of up to 250% of poverty can qualify for ADAP assistance. The Formulary is created by an Advisory Committee whose members are appointed by the State Health Commissioner. That Committee is also charged with selecting medications that are safe and clinically effective, as well as cost effective since the medications on the Formulary are paid for with a combination of state general funds and Ryan White Title II dollars. The funding is limited, and the Advisory Committee's decisions must not result in a growth in the rate of expenditures that would limit the number of eligible PWA's enrolled in the program. The ADAP Advisory Committee is made up of physicians and other clinicians with expertise in HIV treatment along with PWA's. The Formulary should be an appropriate tool for the Pharmacy & Therapeutics Committee to use when considering the other classes of drugs used by PWA's.

Monitoring the Effects of the PDL

The PDL program has grown out of the need to produce savings in the escalating costs of medications in the overall Medicaid program, as such must respond. However, the decisions that will be made by the Committee must also be evaluated in the context of the impacts upon the health status of the impacted beneficiaries. Particularly among people that must rely upon Medicaid programs for assistance in financing their health care services, late or inconsistent treatments due to access barriers are known to lead to more serious and more costly care. Virginia should take the lead in constructing a monitoring program that will assess the impacts of your decisions, assuring the cost of medications is not held in check at the expense of the health of its beneficiaries.

Thank you very much for this opportunity. We look forward to working with you further as you embark upon your tasks.

Alzheimer's Association

Comments to the Pharmacy and Therapeutics Committee on Virginia's Preferred Drug List (PDL)

The Alzheimer's Association appreciates the open process used by the Department of Medical Assistance Services (DMAS) in the development of the provisions of the Preferred Drug List (PDL). The Association is especially pleased with the current exemption provided for cholinesterase inhibitors and we look forward to working with DMAS to make the PDL easy to use for people with Alzheimer's disease and their caregivers.

The Association would like to point out a few issues that should be taken into consideration when developing the list in order to minimize negative effects on people with Alzheimer's disease.

1. Most people with Alzheimer's disease have co-morbid conditions, which often requires medications in addition to cholinesterase inhibitors. It is important that a grandfather clause exist for these individuals since a change in medication might exacerbate the symptoms of Alzheimer's disease, such as combativeness, confusion and aggression.
2. The PDL should be changed only once or twice a year to reduce the risk of adverse reactions due to the shifting of medications. Fewer changes to the PDL will also reduce confusion for consumers, doctors and pharmacists about which drugs are on the list.
3. A drug that adversely reacts with cholinesterase inhibitors should not be the only drug available, without prior authorization, in a therapeutic class.

Thank you for the opportunity to present our concerns. We look forward to working with you as the PDL is developed.

6/12/2003

Good morning/afternoon. My name is Cathy Emhof. I am speaking on behalf of Allergy & Asthma Network Mothers of Asthmatics, a national nonprofit patient education organization serving over 100,000 families throughout the United States. I am a community Outreach Service Coordinator for this organization; however, I am also the mother of two children. My oldest child Mikey has asthma. I currently live in Alexandria, Virginia. I received no payment from Allergy & Asthma Network Mothers of Asthmatics or anyone else to be here today.

Allergy & Asthma Network Mothers of Asthmatics respects the Virginia Medicaid P&T committee's efforts on behalf of tax payers, a quarter of whom have asthma, to curtail soaring costs of asthma medications provided to Medicaid patients. Our organization has a similar goal but different methods to reduce health care costs associated with asthma. We teach patients ways to reduce or eliminate symptoms through comprehensive care that includes judicious use of medications, trigger avoidance, proper nutrition and exercise, and of course, patient education.

Another example; we teach patients the importance of taking a proactive rather than reactionary approach to asthma management. Bronchodilators used before recess or running through an airport and at the first sensation of an asthma episode usually prevents emergency or rescue situations.

Finally, not all molecules are created equal even within a class of medications. Like an artist blends basic colors to paint a landscape of many hues, physicians and patients today have a spectrum of medications from which to choose based upon the delivery system, patient/family age, work-life, school day, side effect profile, taste, and experience.

Teaching these and other patient-friendly concepts pays off, however, in Medicaid populations where access to medical care and medication includes additional hurdles for patients and physicians by default, the compounded results run counterproductive to your cost containment goals and the family's desire to eliminate emergency department visits, hospitalizations, missed work and school days, and sleepless nights caused by symptoms.

We urge you to take a proactive approach to asthma. Asthma is serious. The difference between a mild asthma episode and a deadly attack can be moments. For example my son Mikey … (I will talk about my son's experiences with the disease of asthma.)

Since my son's diagnosis, I have dedicated my life to helping other families know that asthma does kill and we need to respect its power to control our lives if we do not take a proactive approach.

I urge you to consider not adopting prior authorization restrictions from asthma medications and look at other creative and comprehensive ways to reduce medication costs. We would be delighted to work with you to win the war against asthma and the rising costs of asthma care in our state and country.

Thank you for this opportunity to speak to you today.

Comments from the Pharmacy Community for
Medicaid Preferred Drug List (PDL) Program
Pharmacy and Therapeutics Committee
Wednesday, June 18, 2003

Good morning, my name is Rebecca Snead and I am a pharmacist and the Executive Director of the Virginia Pharmacists Association. Thank you for the opportunity to offer comments from the pharmacy community regarding the implementation of a Preferred Drug List in Virginia and the work of the Pharmacy and Therapeutics Committee. I will be brief.

Pharmacy's main concerns regarding the implementation of the Preferred Drug List are:

- Provider access to information on the PDL and PA programs,
- The level of administrative burden placed on pharmacists by the PA process,
- Recipient access to needed medications, and
- Ability of the Commonwealth to reach budgeted savings goals.

As you proceed forward in your work, please feel free to contact us if we can be of assistance in any way.

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Virginia Medicaid Pharmacy Benefits
and the
Mentally Ill

Testimony of the American Psychiatric Association at the Pharmacy & Therapeutics Committee
Department of Medical Assistance Services
Commonwealth of Virginia
For June 18, 2003

Virginia Medicaid plays a fundamental role in providing outpatient pharmacy services to the low-income population, and the seriously and persistently mentally ill are more often than not members of this population. If the mentally ill are to be maintained within the community and kept out of hospitals, access to appropriate medications is essential. For this reason the American Psychiatric Association (APA) is particularly concerned about any decisions that will limit access to the most appropriate medications under state-funded programs.

The APA understands that pharmacy costs are the fastest growing component of healthcare costs and that for this reason they have been specifically targeted for containment. It is aware that the increased average cost of drugs coupled with the increased volume is straining the budgets of the states. However, medications comprise a relatively minor part of the total costs of treating persons with mental illness, but have a major impact on the likelihood of successful treatment outcomes.

The APA's concern is that if all the facts are not taken into account when steps are taken to manage pharmacy costs, although pharmacy costs may go down, there will be a net increase in overall medical expenses created because patients have been denied access to necessary medication. The challenge is to find a way to manage prescription drug costs that will not prove counterproductive; to find a way to manage drug costs that will not merely shift expenses to another sector of the healthcare system and provide patients with less than optimal care.

In the case of psychotropic drugs, the most cost-effective path and most appropriate clinical policy is to entirely exempt these medications from limitations to access. The way to keep expenses down is to make sure that patients receive whatever medications they need to treat their particular symptoms in the most efficient manner.

The Fact Is That Psychotropic Drugs Are not Like Other Drugs:

- The normal patient response time for psychotropic drugs is from three to six weeks. And the time it takes to eliminate the effects of these drugs is similarly lengthy. Most other medications have a response time of hours or even minutes.
- Psychotropic drugs are far more likely to induce idiosyncratic treatment responses in patients than are other medications. They also may differ in the way they affect a patient's particular symptoms. All schizophrenics are not alike in the way their disease manifests itself.
- Psychotropic drugs are associated with a considerable number of adverse side effects, especially when medical comorbidities, treated or untreated, are present. Although two drugs may be judged to have the same effectiveness in treating the patient's particular psychosis, they may have different reactions with other medications the patient is taking.
- Compliance is a significant issue when treating the mentally ill with drugs, and all of the preceding factors contribute to making compliance more difficult.

Restriction of Access to Medications Discriminates Against the Mentally Ill:

- Because of the unique nature of psychotropic drugs, the burden placed on the mentally ill will be disproportionately large if access to the appropriate medication is delayed or denied.
- This inequitable burden is arguably discrimination and creates the potential for challenges to the system that has created it.

Restriction of Access to Medications Impairs Clinical Decision Making and Patient Care:

- The special complications for clinical decision making created by psychotropic drugs demand that interference with physician choice be minimized.
- Restrictions imposed by formulary management will interfere with clinical choices necessary to provide the most appropriate medical care, i.e., the most tolerable and effective treatment for each individual patient.

Effective Psychotropic Drugs Are Essential to Maintaining the Mentally Ill in the Community

- Patients who do not receive the appropriate psychotropic drugs are often unable to function as members of the general community and may require hospitalization.
- Failure to provide adequate access to psychotropic drugs may create an ADA issue (Olmstead) because the state will not be providing the necessary services for all individuals that will keep them from unnecessary institutionalization.

Negative Fiscal Impact Created by Restriction of Access to Medications

- Studies have shown that restricting access to drugs often fails to achieve the intended goal of cost containment because unanticipated problems are created that necessitate greater utilization of the overall health system. [*]

  In fact, comprehensive analyses have clearly shown that:

  - There is a strong relationship between formulary restrictions and increased resource use;

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[*] Lewin Group: "Health Plan Benefit Barriers to Access to Pharmaceutical Therapies for Behavioral Health: Findings" *SAMHSA Managed Care Tracking System*, October 6, 1998. Soumerai, McLaughlin, Ross-Degnan, et al: "Effects of a Limit on Medicaid Drug-Reimbursement Benefits on the Use of Psychotropic Agents and Acute Mental Health Services by Patients With Schizophrenia." *New England Journal of Medicine* 194;331:650-655.

    - Restrictive formularies are often associated with as much as twice the utilization of health care services as nonrestrictive formularies; and
    - Nonrestrictive formularies are almost always associated with the lowest use of overall health care resources.
- Initiatives to reduce Medicaid pharmacy expenditures must take into account the effect of 1) reduced federal financial participation for decreased state expenditures on pharmaceuticals and 2) increased federal and state expenditures for more costly hospitalizations, emergency room visits, and physician/clinic visits.

For a combination of all of the reasons given above, many states have already concluded that exempting psychotropic medications from restrictions is the clinically responsible, cost-effective route to take.

Alternative Management Strategies

The Pharmacy & Therapeutics Committee is vested with the authority to identify exclusions to the prior authorization process. With this in mind, there are a number of alternatives to restricted formularies that are appropriate and responsible pharmacy management strategies for the mentally ill. These approaches are rooted in data analyses that suggest prescribing practices that are less than optimal may be one of the causes of the current financial squeeze.

Several states are exploring the refinement of prescribing practice through provider education projects and the use of best-practice guidelines and expect significant savings in behavioral health pharmacy costs as a result of these strategies. The areas that have been targeted for intervention include:

- Concurrent use of more than one drug from a given class;
- Excessive dosage;
- Evidence of patient noncompliance; and
- Duplication of therapy resulting from multiple prescribers, or lack of coordination of care.

For example, the state of Missouri's Division of Medical Services, its Medicaid agency, has recently undertaken a fourteen-month study to assist the implementation of a Behavioral Pharmacy Education and Outlier Management Initiative for the state's Medicaid program. This program has potentially significant national implications because it will assess the benefits-versus-costs of certain prescribing utilization practices. Missouri is one of the first states to have initiated an effort to improve its Medicaid behavioral health pharmacy services by targeting problem trends in prescribing practices and patient drug utilization.

Conclusion

In conclusion, the APA suggests that there are alternatives available for managing costs other than crudely restricting access to medications; alternatives that provide intelligent and responsible methods of cost-containment. These alternatives include the exemption of psychotropic medications from any access restrictions and the deployment of management techniques based on drug-utilization-review data, provider educations, and prescriber outlier management. They use current information technology to specifically target those physicians who seem to be prescribing in a manner that is not cost-effective, or evidence-based, and avoid the blunt tool of a restricted formulary that often denies appropriate treatment to the most needy patients.

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June 12, 2003

Mr. Patrick W. Finnerty
Director
Department of Medical
Assistance Services
600 East Broad Street, Suite 1300
Richmond, VA 23219

Dear Pat:

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the nation's leading research-based pharmaceutical and biotechnology companies, which discover and develop the majority of new medicines used in the United States and around the world. PhRMA appreciates the opportunity to address, both orally and in writing, the Pharmacy and Therapeutics Committee. As demonstrated in Michigan and Florida, the design process and implementation of a state's preferred drug list program is critical.

The Kaiser Commission on Medicaid and the Uninsured issued a report in January on the Michigan Pharmaceutical Product List (MPPL). The study found numerous deficiencies in Michigan's preferred drug list program including exceedingly restrictive preferred drug lists for certain categories of drugs; a burdensome prior authorization process; and a lack of communication with providers and beneficiaries.

In Florida, the Agency for Health Care Administration (AHCA) recently settled a class action law suit brought by Medicaid patients concerning the implementation of Florida's preferred drug list. The Settlement Agreement requires, among other things, increased notice to patients of their rights under the program. Specifically, a pharmacy must provide written notice to a beneficiary for a claim rejection. If the rejection is maintained, the beneficiary is entitled to a fair hearing. Further, where a claim is rejected for an "ongoing or continuing drug therapy" the beneficiary is entitled to reimbursement from the date he or she requests a hearing until the date of the hearing.

The Department of Medical Assistance Services ("the Department") has assured stakeholders that Virginia's preferred drug list program will not suffer similar shortcomings despite the rapid timetable for implementation by the January 1, 2004 deadline imposed by the General Assembly. Accordingly, P*h*RMA would like to offer the Pharmacy and Therapeutics Committee several procedural proposals to ensure an open and just process.

The Pharmacy and Therapeutics Committee ("the Committee") should make certain all of its meetings are open to the public and that ample notice is provided to all interested parties. The notice of committee hearings should be published on the Virginia Regulatory Town Hall and on the Department's website well in advance of a scheduled meeting. To facilitate the Committee's initial selection of preferred drugs, it is imperative that the Committee provide the pharmaceutical manufacturers and other interested parties with detailed information on the Committee's review process including but not limited to hearing dates with the corresponding therapeutic classes up for review. In addition, P*h*RMA urges the Committee to permit both oral and written testimony concerning the specific drugs under review in each therapeutic class. Finally, it is important the Committee establish an ongoing appeals process for drugs rejected from the preferred drug list. Procedures such as these will give rise to a more palatable program.

Thank you for the opportunity to comment on the first stage of the development of Virginia's preferred drug list program. Ashley Taylor will represent P*h*RMA at next week's Pharmacy and Therapeutics Committee meeting. We would appreciate your setting aside time for him to speak. Please do not hesitate to call me if you have any questions.

With kindest regards, I am

Very truly yours,

Anne Leigh Kerr

2541/2968/1166319

Hemophilia Association of the Capital Area

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June 12, 2003

Patrick W. Finnerty, Director
Virginia Department of Medical Assistance Services
600 East Broad Street
Suite 1300
Richmond, VA 23219

RE: HACA Comments on Request for Proposals for Medicaid Preferred Drug List (PDL) and Prior Authorization Program for Fee-For-Service Clients

Dear Director Finnerty,

The Hemophilia Association of the Capital Area ("HACA") is a not-for-profit organization established in 1964 that seeks to improve the quality of life for persons with bleeding disorders and their families within the northern Virginia region. HACA appreciates this opportunity to comment on the request for proposals (RFP) for a Medicaid PDL and prior authorization program for fee-for-service clients being developed by the Virginia Department of Medical Assistance Services.

Plasma derived products and recombinant factor products are life saving therapies for persons with a bleeding disorder. They must be available and infused promptly to decrease morbidity and mortality. These therapies replace the person's missing clotting components and immediate hemostatis is begun. We have reviewed the RFP for a Medicaid PDL and prior authorization program and are concerned that therapies for hemophilia and von Willebrand's disease are not on the list of excluded drug classes. We also noted that bleeding disorder therapies are apparently not listed as such on the PDL. We request that bleeding disorder therapies be included as an excepted class or that all plasma derived and recombinant analog products be included in the PDL. HACA has always been a proponent of the need for unfettered access to the full range of treatments available to meet unique patient needs.

It is no secret that the bleeding disorders community has been devastated over the past twenty years with one viral disaster after another. The HIV/AIDS onset in the early 1980s has been followed by the complications of hepatitis C and all of its manifestations. CJD, Parvovirus B-19, West Nile Virus and Hepatitis G have also all been causes of anguish.

The Medical and Scientific Advisory Councils of both the National Hemophilia Foundation and the Hemophilia Federation of America have advocated for recombinant product availability and access because these products do not contain blood and its inherent risks to health. The Health and Human Services Advisory Committee on Blood Safety and Availability, on two occasions, has recommended there be no barrier to access to recombinant therapies. In conversations

with members of our chapter, we have realized that individuals respond differently to different products. Product costs in dollars must not be the deciding factor is assessing safety for the users of factor concentrates. While treatment with plasma derived products may on the surface appear more cost effective, fewer infections from such pathogens as HIV and hepatitis C will reduce expenditures for treatment regimens to correct the effects of viral agents. There will be less need for liver transplants, reduced pain, fewer missed days from work or school and less drain on family finances resulting in fewer families being forced onto public welfare support.

We also request that you would exempt persons with bleeding disorders from the requirement for prior authorization. When a person has a bleed, it is imperative that the bleed be treated first and questions asked later. Bleeding from trauma to the head or abdomen is extremely life threatening. The bleeding must be put under control to prevent swelling of the brain and damage to or hemorrhaging of the internal organs. An individual with a bleeding disorder will not clot properly until the missing component is given. When a person with a clotting disorder bleeds into a joint, the joint capsule swells. Enzymes in the body will eventually break that blood down, but the enzymes don't distinguish between the blood and the cartilage on the ends of the bone. They destroy the cartilage on the ends of the bone and the lining of the joint capsule becomes thicker. If this process continues for a prolonged time, the result is decreased range of motion, pain, and permanent damage to the joint.

These are not therapies that can wait for authorization. There are no generic drugs, there are no alternative therapies. Physicians must have immediate access to these drugs and no barriers to their administration.

In conclusion, HACA strongly urges your committee to be sensitive to the unique needs of the community of patients that depend upon lifesaving plasma derived and recombinant analog therapies. Freedom of choice among therapies is a principle that all patients and healthcare professionals hold dear; it is contrary to good public policy to espouse any principle that could limit choice or impede access to a needed treatment.

Sincerely,

Susan Yamamoto
Susan Yamamoto
President

Sandi Qualley
Sandi Qualley
Executive Director

From the Psychiatric Society of Virginia and the Northern Virginia Chapter of the Washington Psychiatric Society

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June 12, 2003

Randall Axelrod, M.D.
Chairman, P&T Committee
Department Of Medical Assistance Services
600 East Broad Street, Suite 1300
Richmond, VA 23219

Dear Dr. Axelrod:

On behalf of the Psychiatric Society of Virginia (PSV) and the Northern Virginia Chapter of the Washington Psychiatric Society (WPS), we are eager to serve as resources to the Department of Medical Assistance Services (DMAS) and the Pharmacy & Therapeutic (P&T) as you develop and manage the "Preferred Drug List" (PDL). For public record and your first meeting, I respectfully submit to the P&T Committee a brief overview of our positions and recommendations with regard to a PDL for Medicaid patients.

Preserving Access to Psychotropic Medicine
It is PSV's position that the General Assembly intended that the PDL provide a broad exemption from prior authorization for medications used in the treatment of serious mental illness. Item 325 #4c of the 2003 Budget Conference Committee Report states:

"The Pharmacy and Therapeutics Committee shall recommend to the Department appropriate exclusions for medications, including atypical anti-psychotics, used for the treatment of serious mental illnesses such as bi-polar disorders, schizophrenia, and depression."

The legislature has provided the Committee members with clear, instructive language that empowers it members to make medically-based decisions as healthcare professionals. For example, depression is a serious and treatable mental illness. We know that successful treatment of depression requires the earliest identification of the most efficacious drug for an individual patient and uninterrupted administration of that medication. By failing to exempt drugs for depression from prior authorization, not only will the PDL program delay initial treatment for patients, but will likely result in stretching untreated illness into weeks and months while the physician identifies the most effective drug.

Pharmacy & Therapeutic Committee's Role
The P&T Committee should have a primary role in determining the medical policy of the PDL program and exemptions from the prior authorization process. The physicians and pharmacists on the Committee should be free from political or economic pressures and conflicts in their policy development. The committee should have unfettered input from professional and advocacy organizations.

We urge you to be guided by the General Assembly's intent to preserve patient access to mental health medication. Using your professional judgment will enable participating physicians to provide a high standard of care for Medicaid patients. Effective treatment will reduce the likelihood of the mentally ill winding up in our community emergency rooms, jails, and on the street.

Finally, we are concerned about the functioning relationship between the chosen PDL contractor and the P&T Committee. While DMAS documents include language that suggests the Committee will determine medications to include or exempt from PDL and prior authorization requirements, it appears that final action depends on the contractor's ability to negotiate a discount or supplemental rebate with manufacturers. Sections of the Request for Proposal (RFP) seem to conflict regarding the relationship between cost and effectiveness of medications. Like you, we want quality care and professional decisions to outweigh cost-savings on the front end.

Cost Savings Won't Come from Compromised Care
PSV members understand that Virginia is attempting to control the rapidly increasing cost of pharmaceuticals prescribed to the Medicaid community. Organized psychiatry appreciates the time and effort put forth by the P&T Committee members and the administrators at DMAS to develop and implement this complex program. We urge you to give special consideration to the most vulnerable among us to ensure that implementation measures will not result in substandard care and increased costs in other social service areas.

Please contact us if we can answer questions or provide additional information.

Sincerely,

Gregory Fisher, MD, FAPA
President

Cc: The Honorable Jane Woods
Secretary of Health and Human Resources
Irvin Muszynski
American Psychiatric Association

Laboratories, Inc.
444 North Capitol St, Washington, DC 20001

Presentation to the
Virginia Pharmacy and Therapeutics Committee
June 18, 2003

From
Barr Laboratories and the Generic Pharmaceutical Association

Jake Hansen

Vice President, Government Affairs

Barr Laboratories, Inc.

Chairman Axelrod and Members of the Committee, we regret that we are unable to attend the Committee's most important meeting: its introduction to an extremely important and difficult task of producing a PDL. However, we thank you for the opportunity to reflect upon the role of Virginia's Pharmacy and Therapeutics Committee and certain aspects of its Preferred Drug List and we look forward to assisting the Committee in any way.

As an introduction to who we are, Barr is a leading developer, manufacturer and marketer of generic and proprietary pharmaceutical products manufacturing cancer agents, cardiovascular drugs, and hormone replacement therapies used in the treatment of a number of female health care disorders. The positions taken in this paper also represent more than 140 member companies of the Generic Pharmaceutical Association. GPhA represents manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. Generic pharmaceutical products are used to fill more than one billion prescriptions every year.

Several issues are critical to formulating a sound Preferred Drug List (PDL) while lowering healthcare costs, and increasing access to affordable medicines. This paper will focus on the safety and savings of generic pharmaceutical products; PDLs - the importance of using a therapeutic consultation service and cautious discrimination in excluding certain drug categories;elements of PDLs that are being utilized in a number of states; and the importance of education.

Consumer Health -Generic Sameness and Safety

It is critically important to note that the only difference between brand pharmaceuticals and their generic equivalents is cost. For nearly two decades, America's generic pharmaceutical industry has been developing, manufacturing and marketing generic versions of brand prescription drugs. These generic products have been used by millions of consumers, and offer the same safety and effectiveness as their brand counterparts.

In ground-breaking consumer education ads being sponsored by the FDA, the Agency states that, "FDA makes it tough to become a generic drug in America so you can feel confident about taking generic drugs. All generic drugs are put through a rigorous, multi-step review process that includes a review of the scientific data on the generic drug's ingredients and performance. FDA also conducts periodic inspections of the manufacturing plan, and monitors drug quality – even after the generic drug has been approved."

To be approved, a generic must have the same active ingredients, same dosage form, same standards for purity and quality, same standards for manufacturing, same amount of drug absorbed over the same time, and same clinical effect as the brand product.

The generic manufacturer must conduct bioavailability and/or bioequivalence studies of its version of the branded drug to prove that it is the same as the brand drug.

Generic drugs can look different because certain inactive ingredients such as colors and flavorings may be different. But according to FDA, "these ingredients do not affect the performance, safety or effectiveness of the generic drug. They look different because trademark laws in the U.S. do not allow a generic drug to look exactly like other drugs already on the market."

Since the generic industry was founded in 1984, parties who were seeking to prevent more affordable generics from eroding brand drug market share and profits, have attempted to suggest to consumers that generic drugs are not the same, or may not work as well as the brand product. Repeatedly and emphatically, the FDA has responded to these efforts with a strong endorsement of the use of generic drugs. In 1997, 1998 and 1999, the FDA repeatedly confirmed that no clinical data exists that would support the restriction of generic substitution.

In April 1997, Roger L. Williams, M.D., Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, responded to a request from the National Association of Boards of Pharmacy to clarify FDA's position on generic substitution. Dr. Williams wrote, "If one therapeutically equivalent drug is substituted for another, the physician, pharmacist, and patient have FDA's assurance that the physician should see the same clinical results and safety profile. Any differences that could exist should be no greater than one would expect if one lot of the innovator's product was substituted for another."

In January 1998, Stuart L. Nightingale, M.D., FDA's Associate Commissioner for Health Affairs, issued a "Dear Colleague" letter reaffirming the substitutability of generic drugs. In his letter, which was sent to all healthcare professionals in the United States, Dr. Nightingale wrote, "Additional clinical tests or examinations by the health care provider are not needed when a generic drug product is substituted for the brand-name product. As noted in the 'Orange Book'... products evaluated as therapeutically equivalent can be expected to have equivalent clinical effect whether the product is a brand name or generic drug product."

In December 1999, then FDA Commissioner Dr. Jane Henney addressed the issue of generic safety and sameness in a letter published in the *Journal of the American Medical Association (JAMA).* Dr. Henney wrote, "Practitioners and the public may be assured that if the FDA declares a generic drug to be therapeutically equivalent to an innovator drug, the two products will provide the same intended clinical effect."

In October 2002, during his Senate confirmation hearings, Dr. Mark McClellan, (current FDA Commissioner) reaffirmed FDA support for the sameness and safety of America's generic

pharmaceuticals. Dr. McClellan said, “The quality, strength, and purity standards for approval of drugs sold in the United States are uniform, whether they are for generic or brand name drugs. Generic drugs contain the same active ingredients as the brand name drug and are just as safe and effective.”

Also in October 2002, in a Rose Garden address announcing an initiative to increase the timely approval of generic drugs, President George W. Bush noted that “generic drugs, which are just as safe and effective as the brand name drug… make American health care far more affordable.”

Consumer Savings

Every day, the use of generic products saves millions of dollars for consumers: those with insurance and those who must pay for their drugs out of their own pocket. This daily savings amounts to more than $10 billion dollars in lower health care costs each year.

Physicians are increasingly aware of the impact that rising drug prices are having on their patients. The American Medical Association has a policy statement that "supports programs whose purpose is to contain the rising cost of prescription drugs." The policy specifically encourages physicians to be aware of prescription drug prices and the availability of generic versions of brand name drugs.

Last year, 47% of all prescriptions were filled with generic drugs. So while nearly one in every two prescriptions was filled with a generic drug, only approximately 8% of all dollars spent on drugs were spent on generic medicines. Brand name prescription drugs, conversely, represented 53% of all prescriptions but consumed approximately 92% of all drug therapy dollars spent. These numbers reveal a stark reality: brand name prescription drugs exceed the cost of generics by almost ten-fold.

It is well documented that the high cost of prescription medicines has a direct effect on patient usage. A recent survey of 1,010 adults by Harris Interactive revealed some very disturbing drug trends. Of surveyed patients, 22% did not purchase at least one prescription issued by their doctor in the previous year because of cost. Additionally, 14% of patients reported taking a drug in smaller doses than prescribed and 16% reported taking their prescribed medication less frequently than prescribed to save money. Such statistics can hardly be consistent with our

society's goal of adequate health care. Clearly, cost is central to the issue of compliance.

A survey conducted by ChangeWave Research, an investment research firm, demonstrated the increasing acceptance of generic pharmaceuticals. More than half of consumers surveyed - 59 percent - said they currently ask their doctor if a generic drug is available at the time they get a prescription. And 67 percent said their insurance companies either advise or require them to accept generics. Meanwhile, some 76 percent of health-care professionals said physicians are more willing to prescribe generics now than they were a year ago.

This observation is confirmed by an AARP study released in the fall of 2002. The survey found that two-thirds of those surveyed usually choose generics over brand names when available, and 90 percent are willing to accept generic drugs as a way to reduce their drug costs. Nearly a quarter (24 percent) of the survey respondents said they have not been able to afford a prescription medication when there was no generic available. AARP noted that with 40 states currently grappling with Medicaid shortfalls driven by unsustainable drug costs, lowering the cost of prescription drugs has become an imperative.

Consumer Benefits and Potential Roadblocks

There are many examples of how access to generic medicines has benefited consumers. Perhaps the most visible, and recent example, involves Prozac. In August 2001, Barr successfully concluded a patent challenge as prescribed under Hatch-Waxman, and introduced a generic version of this blockbuster drug. The company enjoyed six months of exclusivity. On January 29, 2002, Barr's period of exclusivity ended, and multiple generic versions of Prozac entered the marketplace. Rapidly and predictably, the price of Prozac dropped from approximately $2.70 per dose for the brand to less than ten cents per dose for generic versions at the wholesale level. Prozac is only one example of the savings that generic drugs create.

Within the next three years, 27 brand pharmaceuticals with annual sales of more than $37 billion will go off patent, allowing the introduction of more affordable generic versions of these blockbuster products. The timely introduction of generic versions of these popular products will create new opportunities for consumer savings.

Despite these repeated assurances, a number of initiatives have taken place over the past five years in states across the nation that attempt to raise barriers to the substitution of affordable generic drugs by raising doubts about their safety and efficacy. These efforts have taken a number of forms – from attempts to impose restrictions on generic drugs to modifications to rebates, to changes in Medicaid formularies, to modifications to prescription regulations that can lock out generic substitution. These attempts, should they succeed, would cause unattainable healthcare for many.

PDL Development and Clinical Experts

Preferred Drug Lists, or PDLs, are effective ways to promote the appropriate utilization of quality pharmaceuticals in cost-effective ways. While not a new concept, PDLs are just recently finding their way into state-funded Medicaid and pharmaceutical assistance programs as state officials realize the significant savings that can result. Currently, PDLs are used extensively by Medicaid programs in 11 states including Tennessee, New Jersey, Arizona, Michigan, Maryland, and Pennsylvania. At least seven other states are in the process of implementing a PDL program. Virginia's PDL will significantly reduce Medicaid expenditure when the list of preferred drugs is created.

The Commonwealth's PDL should be developed according to national medical best practice standards. The Committee, with the assistance of clinical experts, should evaluate drugs according to therapeutic indications, clinical effectiveness, cost and if a generic version exists. Advice from other states indicate that when a P&T Committee has access to clinical experts to advise on drug selection, then the task of the P&T Committee can be more effectively focused on the practice of medicine. The preferred drug list and several drugs from each class, should come from the Committee's review and selection of the therapeutic action, safety, clinical outcome and cost data made available by this group.

Reviewing the PDL at least quarterly for inclusion of new pharmaceutical products or changes in accepted clinical practice standards and updating the list to those standards is another imperative initiative of the Committee.

It is important to note that price alone does not preclude a drug from being included in a preferred list. If a less expensive version of a drug exists, but lacks "a significant, clinically

meaningful therapeutic advantage" over other drugs, the less expensive drug is excluded. Virginia's preferred drug list will thus become the physicians' guide to prescribing the best and most cost effective treatment for patients enrolled in Medicaid.

A good model is Illinois, which has maintained a list of preferred drugs that are available without prior authorization and operated a prior authorization process for non-preferred drugs since the early 1980's. Illinois attributes at least $100 million in reduced spending annually to their prior authorization and PDL program. Further, their current ratio (61% generic and 39% brand) is largely attributable to this approach.

Importantly, Illinois has recognized the need to effectively utilize pharmacist and physician expertise in the selection of drugs used in its PDL.

Exclusions

Regarding the issue of excluding drugs, it is important to note that the Commonwealth has recently established through legislation that the "AB" rating of generic drugs by the FDA assures their safety and efficacy, and therefore substitutable. The Committee's actions regarding exclusion of any generic medicine must be guided by this law.

The exclusion of drugs in such categories as mental health, oncology, diabetes, AIDS or other areas are often tied to the mistaken position, frequently promoted by patient groups and manufacturers, that generic versions of therapies in these categories may not offer the same safety and efficacy as the brand counterparts. This issue has been repeatedly addressed by the FDA, which has confirmed the substitution of all brand name drugs where an equivalent generic version is available.

For example, products associated with the treatment of mental health and other neurological conditions, such as epilepsy, are often considered for exclusion. It is important to note that of the top 15 drugs used to treat mental illness, generic versions are currently available for five, and five additional brand drugs are expected to soon have generic competition. There are currently over 60 major drugs available to treat a variety of mental health issues. The potential for exclusion of drugs in this one category could have significant impact on opportunities to lower

health care expenditures.

In considering the issue of exclusions, Massachusetts recently concluded that as much as 47% of prescription drugs covered under Medicaid could be classified as mental health therapies.

Similar arguments have previously been made about other cancer and Cardio-vascular drugs, where no scientific data supports their exclusion. As a result Barr and GPhA would recommend that the exclusion of any prescription drug product be based solely on conclusive, sound scientific and clinical data, and that the FDA Orange Book, as expressed in Commonwealth law, govern the decision to exclude any generic therapy. This is critical for ensuring that PDL decisions are not susceptible to efforts by special interests to exploit loopholes in the PDL structure and P& T Committee process, as prescribed under the law.

Other State Examples

In 2000, Georgia's state Drug Utilization Review Board enacted a preferred drug list to be used in the following state-funded programs: Medicaid, PeachCare for Kids, Board of Regents for higher education health insurance benefits and State Health Benefit Plan for state employees. The list was created by the Drug Utilization Board and Express Scripts, the state's Pharmacy Benefit Manager (PBM) and is composed of both brand and generic drugs. But under Georgia's plan, all generic drugs are automatically considered preferred. And when a new generic equivalent becomes available for a brand on the preferred list, the brand version loses preferred status.

Georgia officials expect to achieve significant savings from the plan, which began in 2001 after the state suffered budget shortfalls in Georgia's Medicaid and State Health Benefit Plan due to a 20 percent increase in pharmaceutical spending.

Kansas Governor Bill Graves (R) signed a law in 2002 allowing the Department of Social and Rehabilitation Services to create and maintain a PDL. Similar to Georgia's program, Kansas limits reimbursement to generic drugs unless the physician indicates the brand or other drug is absolutely necessary.

In Massachusetts, where according to the state Division of Medical Assistance, Medicaid spent

about $968 million on prescription drugs last year for roughly 933,000 people - a 16.8 percent increase over the previous year - state lawmakers enacted legislation that will now require Medicaid patients to fill prescriptions with generic medicines. The program, which went into effect August 2002, institutes a preferred drug list of generic medicines and physicians are given the authority to override the list when medically necessary. While too early to quantify actual savings, officials predict significant returns.

Michigan Governor John Engler (R) signed legislation in 2001, creating the Michigan Pharmaceutical Best Practices Initiative to develop a PDL. Under the plan, the Michigan Therapeutics Committee was appointed to compile a list of drugs that are "best in class." "Preferred drug lists are the most effective tools available to states" to control spending on prescription drugs, said Gov. Engler. "Michigan's new program saves $800,000 each week -- or $42 million this year," he continued.

Consumer Education Initiatives

Research has indicated that most consumers have a positive view of generic drugs. This is good news for states seeking to lower their prescription drug costs by encouraging the use of generic drugs. But with brand companies hammering consumers with $23 billion in ads, free samples and direct-to-consumer marketing campaigns, many Americans are being falsely convinced that brand drugs are superior to less expensive, yet equally effective generic alternatives.

Generic companies spend no money advertising their products and have limited funding available when compared to brand companies to provide educational programs for consumers. With generics offering the same safety and effectiveness as brand drugs but at a cost that is up to 80% less, states could see significant returns from an investment in consumer education.

States such as Florida and Arkansas have adopted an educational program that sends representatives to inform doctors of the safety, efficacy and cost efficiency of generic drugs. Arkansas Director of Medicaid Ray Hanley, "Much of the information that physicians get on drugs comes from salesmen who are on commission. Our research shows that most people do not need those drugs that are advertised excessively."

In Michigan, where 27 cents of every tax dollar goes to Medicaid and its pharmacy costs have

doubled over four years, officials recently teamed up with Blue Cross Blue Shield of Michigan (BCBSM), the state's largest health care provider, to initiate a Generic education program called Generics First.

Under the Generics First program, BCBSM mailed 7,000 coupons to its members, created a comprehensive consumer web site, published various brochures and enrolled 1,100 pharmacies, including 10 major chains, to encourage generic usage. BCBSM also developed a pledge card, downloadable from the web site that can either be carried in a wallet or placed in medical records to state consumer preference for generic medicines. So far, the savings have been dramatic: Michigan's Generic Drug Dispensing Rate (GDR) rose 1%, saving BCBSM nearly $13 million and nearly $25 million in statewide savings.

In the State of Nebraska, where recent statistics indicated that the rate of brand drug usage was 63%, five points above the national average of 58%, Blue Cross Blue Shield Nebraska recently launched radio spots encouraging consumers to use generic drugs. BCBS officials predict savings of $1.1 million for every 1% increase in generic drug use. While too early to quantify savings, the campaign, which began in May, has been very successful, dropping Nebraska's brand drug usage rate to 62% in only six months.

Summary

America's generic pharmaceutical developers and manufacturers encourage this Committee to embrace opportunities to increase the usage of generic drugs. GPhA and Barr Labs are willing to assist the Committee with any request that will help physicians treat patients while maintaining quality healthcare and real savings. It is our hope, that we can build a partnership allowing you to take available Medicaid dollars and provide more affordable prescription drugs, while diverting savings to other critical programs.

We have heard consumers and their need to have access to the medicines they need to live longer and healthier lives. We are committed to lowering drug costs. The generic pharmaceutical industry already saves $10 billion a year for Americans, and more savings are possible.

We look forward to working with you.

Corporate Affairs Division
Pfizer Inc
325 7th Street, NW, Suite 1200
Washington, DC 20004
Tel 202 783 7070 Fax 202 347 2044

Gary M. Bolick
Director
Government Relations

Attention: Adrienne; Fegans

June 12, 2003

Mr. Pat Finnerty
Director
Virginia Department of Medical Assistance
600 East Broad Street
Richmond, Virginia 23219

Dear Mr. Finnerty,

Thank you for the opportunity to provide comments on the preferred drug list currently being implemented JFor Virginia fee-for-service Medicaid. Pfizer believes that certain principles should be considered when preferred drug lists and prior authorization programs are implemented. We hope that you will view these principles as patient protections and as ways of ensuring that quality care is prioritized over cost and not compromised.

First and foremost we believe in the ultimate authority of the prescriber. Since the patient's physician or other health care provider has the most intimate knowledge of a patient or consumer's medical condition and needs, that health care provider must ultimately have the final say in what medication is appropriate for a patient. A Virginia Department of Medical Assistance Services' status report issued April 1, 2003 states that: "non-preferred drugs are approved for coverage if the prescribing physician provides medical justification, that meets the clinical criteria recommended by the P&T Committee and established by the state" (page 7). It is our hope that `medical justification' will include the knowledge each health care provider has about his/her individual patient. If physicians are bound only by clinical criteria established by the state and P&T Committee, it may compromise the quality of care delivered and received by not allowing the provider to take into consideration factors relating to tolerance and subsequent compliance. Each medication must be judged, not in the abstract, but on how safe and effective they are for individual patients.

While individual prescribers should have the ultimate authority on medications for their patients, we do appreciate the state's need to contain costs through appropriate utilization management techniques. We do however feel that the P&T Committee should be

composed of actively practicing physicians and pharmacists with the objective of considering the clinical and logistical implications of proposed restrictions. Actively practicing providers will have the most up to date knowledge on current practices, trends and needs of patients today.

We are pleased to see that particular exemptions to the PDL are being considered, especially in the area of Epilepsy, HIV/AIDS and cancer. Pfizer believes that certain types of medications should never be subjected to prior authorization restrictions due to the complexity of the condition being treated and the higher potential for adverse events from medication switches. This is particularly true with mental health medications. While your cost saving analysis shows a fiscal impact to the state of $11 million for exclusions of SSRIs and $5 million for grandfathering for consumers stabilized on an SSRI or other mental health drug (excluding atypicals), we would argue that the emotional, physical and financial cost of relapse to both the individual and the state will be far greater. In the October issue of *Psychiatric Services*, State Medicaid officials note that states that have imposed prior authorization for psychiatric medications on the basis of cost alone have actually seen increases in healthcare costs as a result of adverse events and relapses.

In light of this, we support preferred drug list decisions based on comprehensive clinical reviews. Prior authorization programs and related decisions made with regard to medication use must be based on a comprehensive review of medical compendia, peer reviewed literature, information from the medication's originator, other sources of expert information, and the; individual patient in consultation with his/her doctor. Decisions should also be based on data in the subpopulations in question. The National Medical Association recently released a report in partnership with the National Pharmaceutical Council entitled, *Racial and Ethnic Differences in Response to Medicines: Toward Individualized Pharmaceutical Treatment.* The report states that pharmacogenetic research has shown differences exist among racial and ethnic groups. East Asians, for example require higher doses of codeine than whites to achieve effective pain relief. The report also discusses differences in body mass, genetic structure, nutritional status, co-morbidity profiles, smoking and cultural factors among racially and ethnically diverse populations. These factors can lead to varying responses to medications. It is therefore essential to consider these populations and such differences when making formulary and prior authorization determinations.

Prior Authorization decisions should be timely. Before a prior authorization program is implemented, an adequate infrastructure must be in place to respond to physician requests in a timely manner. Requests should be decided within the minimum 24 hours as required by OBRA-90.

While the hope is that all appropriate medications will be approved for each patient, there will be those that are denied and result in adverse events. A system should be established that monitors the impact of prior authorization systems on patient care and requires reporting of adverse; events. If these problems arise from the restrictions, the program should be suspended until appropriate corrective action can be taken. Other groups have expressed concern about this issue. The Kaiser Commission, in a recent policy brief

stated that "there is scant evidence that states are actively evaluating the beneficiary level impact of their benefit management approaches on the vulnerable population served by Medicaid." We applaud states such as Maryland that included a requirement for the benefit manager administering the PDL, to monitor and report adverse events and other patient impacts.

In your April 1 Status Report, you highlight the importance of public comment in the development of the preferred drug list and the P&T Committee. We hope that all decisions pertaining to access restrictions are pursued using an open public forum that encourages input from outside experts and interested parties. A process should therefore be developed to provide guidelines for meeting this need.

To ensure that patients and consumers in Virginia Medicaid have sufficient choice, we recommend that within a therapeutic class there should be a minimum of three medications before prior authorization is allowed. Sufficient choice among medications that are not subjected to prior authorization should be ensured to recognize the complexity of treating patients and the medical needs of individuals.

As Dr. McKinnell stated in his letter to Governor Warner in February 2003, Pfizer opposes the implementation of a preferred drug list that is linked to supplemental rebates. While we appreciate the financial circumstances faced by the state, we do not support programs that prioritize cost over quality of patient care. Thus, while Virginia has decided to move forward with a preferred drug list, it is our hope that the above principles will be considered and implemented and that ultimately the health and well being of Virginia citizens, the doctor/patient relationship and the most appropriate medical care for the individual patient will considered first and foremost over all else.

Thank you for the opportunity to comment. We welcome the opportunity to discuss these principles with you further.

Sincerely,

Gary M. Bolick

Plasma Protein Therapeutics Association

PPTA Reference No.: HPSC03032

Comments by the Plasma Protein Therapeutics Association (PPTA) on Virginia DMAS P&T Committee Procedures

Submitted June 10, 2003
for the
June 18, 2003 Pharmacy & Therapeutics Committee Meeting

The Plasma Protein Therapeutics Association (PPTA) appreciates the opportunity to provide input into the Virginia Department of Medical Assistance Services' (DMAS') Pharmacy & Therapeutics (P&T) Committee procedures. While PPTA continues to be very impressed with DMAS' commitment to receiving stakeholder communications and input, we believe that consumer / patient input must be continually solicited throughout the prior authorization and preferred drug list (PDL) process to ensure that patient safety and effectiveness is protected. The P&T Committee's consideration of the issues of safety and effectiveness should always include a focus on whether the patient will be comfortable enough with the therapies, medications, and treatments being added to the preferred drug list (PDL) to ensure patient compliance with prescribed regimens. Further, where the P&T Committee is reviewing orphan or unique and specialized therapies not dispensed at the corner pharmacy, the P&T Committee must ensure that it has all available, appropriate, and up-to-date medical data. The review of such therapies must be facilitated and assisted by consulting medical and pharmaceutical specialists familiar with the therapies, as well as the patients who will be potentially impacted by P&T Committee choices.

PPTA is the primary advocate for the world's leading producers of plasma-based and recombinant analog therapies (collectively, "plasma therapies"). Plasma therapies treat unique, life-threatening, and chronic diseases and disorders, such as hemophilia (clotting factor therapies), primary immune system deficiencies (intravenous immunoglobulin therapies), and Alpha-1 Antitrypsin Deficiency (Alpha-1 Therapy).

Patient Comfort Factor and Compliance With Medication Regimens

PPTA cannot stress enough the importance of obtaining consumer input into the prior authorization / PDL process. While most states that have adopted P&T committees have included at least one consumer member, Virginia's P&T Committee contains no consumer members to provide crucial patient input. This is unfortunate because, in many cases, a patient's continued health is likely to hinge on how compliant the patient is with the treatment regimen prescribed by his or her healthcare provider. If a patient is not comfortable with the treatment made available under the PDL, the patient's health and safety could be affected. For this reason, PPTA hopes that the P&T Committee will always welcome and provide adequate time for presentation by affected consumer groups.

Use of Medical and Pharmaceutical Specialists

In addition, it is important that DMAS contract to bring in knowledgeable medical and pharmaceutical experts to advise the P&T Committee on orphan or unique and specialized therapies for chronic diseases when those therapies are under review by the P&T Committee. While the membership of the P&T Committee is an impressive group of talented and knowledgeable physicians and pharmacists, there are going to be medications and therapies with which they are unfamiliar, or about which they have knowledge derived only from scholarly journals. It is important that, in such cases, the P&T Committee receive input from medical and pharmaceutical experts on the therapies, as well as on the characteristics of the patient group(s) to be affected. And here again, particularly with regard to orphan or unique and specialized therapies, patient input must be included in the formula for decision-making.

Thank you for your consideration of these PPTA's concerns. And again, thank you for this opportunity to provide input.

Stuart Yael Gordon
Director, State Affairs
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