

From ASRA  
Lester  
6:05 pm

HHS ASTHMA DELIVERABLES  
for 1/28/99 event

On paragraph number one, the public information campaign should not lead-off the summary of HHS asthma announcements; this is an EPA-funded activity which HHS is happy to support but which is not as high a priority for us as other activities. HHS plans to work closely with EPA to ensure that the campaign is most effective and that it does not duplicate outreach activities sponsored by NHLBI's National Asthma Education and Prevention Program. Since EPA has the lead on this campaign, they would be the best to draft the language.

On paragraph (2), HCFA has rewritten it as follows:

Educating patients and providers about new treatment guidelines. HHS will take a number of administrative action to encourage States to inform all providers who serve the Medicaid eligible population that the NIH guidelines are now available, including (1) HCFA will issue a State Medicaid Directors' letter to each State encourage the use of asthma best practice guidelines, (2) the initiative will be publicized at various provider (both fee-for service and managed care), State and beneficiary forums and conferences, and (3) ~~a Secretarial conference will be held with all stakeholders (need to discuss in Department - prefer it not part of the event)~~

On paragraph (3), we do not feel that the ideas proposed are something that HHS, specifically HCFA, should be doing. This includes the administrative action and the Secretarial summit. If you'd like to discuss this further, please call Liz or me.

In addition to these comments, we feel strongly that it would be a very good idea to incorporate the following AHCPR FY '2000 initiative.

In the year 2000, AHCPR is proposing a \$1.5 million initiative to improve health care practices for children with asthma, thus improving children's health quality and outcomes. This initiative focuses on two activities:

1. A research effort to rigorously test efforts to Translate Research into Practice, specifically in Pediatric Asthma. Pediatric asthma has well-established evidence-based clinical guidelines; nevertheless there continues to be evidence that many health care professionals do not follow the guidelines in their daily practice. Translating Research into Practice generates new knowledge about approaches that are effective and cost-effective in promoting the use of rigorously derived evidence in clinical settings and that lead to improved health care practice and sustained practitioner behavior change. These activities include Disease Management strategies.

(TRIP)

this makes no sense

2. Expansion of AHCPR's technical assistance activities to States to help them translate research into practice through disease management strategies. AHCPR will use activities, such as its User Liaison Program invitational regional seminars, to inform State policymakers about disease management programs in pediatric asthma and answer questions about research design. The User Liaison Program is a longstanding, highly popular program that brings State policymakers together in disparate regions of the country. The policymakers receive updates on high priority policy and research areas, and have an opportunity to discuss State-specific issues

From around the country

with each other and with national experts. This activity will help support the Department of Health and Human Services planned \$50 million support for competitive research grant awards to State-initiated research in disease management strategies for pediatric asthma.

We also feel strongly that a paragraph on research should be included which talks about research to prevent asthma from developing in the first place as well as research to better manage the disease for people who have it. This is currently being prepared by NIH. Funding for asthma research is as follows:

1998: \$100.675 million

1999: \$115.338 million (+\$14.663 million, +14.6% over 1998)

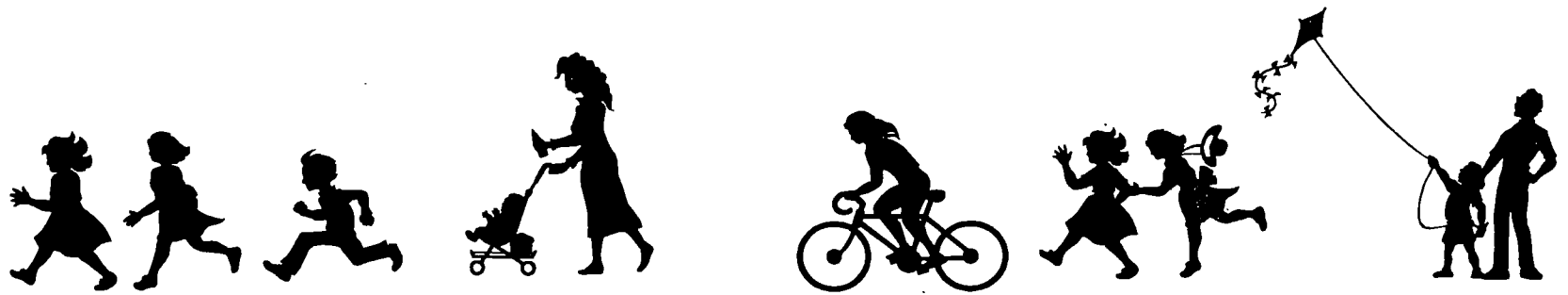
2000: \$117.911 million (+\$2.573 million, + 2.2% over 1999)

Finally, we would also strongly suggest a paragraph on the asthma initiative of the the President's Task Force on Environmental Health Risks and Safety Risks to Children, since a summary of the Task Force recommendations on asthma--"Asthma and the Environment: A Strategy to Protect Children"--will be released at the event. HHS has played a major role in developing this strategy and would be responsible for many of its components. Though the OMB pass-back includes only partial funding for the HHS components of this initiative, the Secretary has said that she intends to take the case to the Hill and hopes to secure funds by the time the budget process is complete. A paragraph detailing this is currently being drafted by ASPE.

How much  
larger that  
amt is than  
the one year  
savings in  
BBA

~~\$403~~

2 times  
amt in BBA  
savings in  
Q2

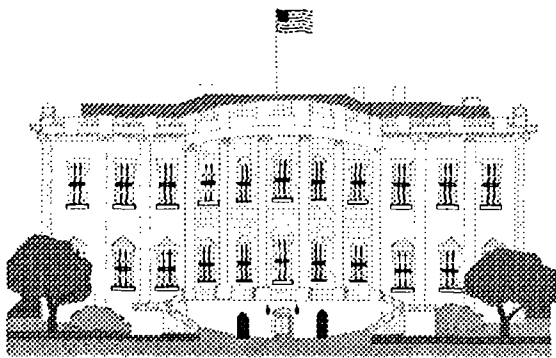


# **Protecting the Future:** ***Putting Children First***



# Executive Order 13045

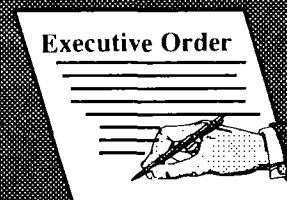
**In April 1997 President Clinton signed an Executive Order that requires federal agencies:**



**✓to make it a high priority to identify and assess environmental health risks and safety risks that may disproportionately affect children, and**

**✓ensure that its policies, programs, activities and standards address disproportionate risk to children**

# Implementing the Executive Order

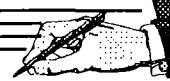


## Selected Accomplishments To Date

- ▲ Established 8 Centers of Excellence in Children's Environmental Health Research (EPA and NIEHS)
- ▲ Sponsored Conference on "Preventable Causes of Cancer in Children" and Research Agenda Published
- ▲ Fourth *National Health and Nutrition Examination Survey* to Measure Environmental Contaminants in Children's Body Fluids
- ▲ Established specific programs aimed at providing information and assistance to communities and parents (e.g., EPA's Child Health Champion Campaign and HUD's Healthy Homes initiative)
- ▲ Significant Progress in Protecting Children from Environmental Threats through Implementation of Environmental Standards
- ▲ An interagency web site highlighting children's environmental health and safety has been developed.

# E.O. 13045 Established an Interagency Task Force

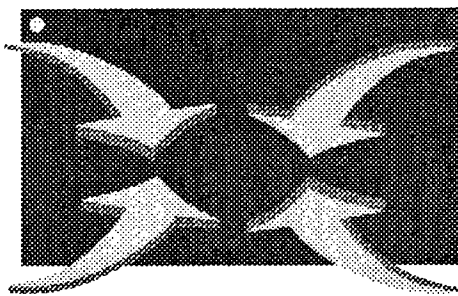
Executive Order



*The Task Force on Environmental Health Risks and Safety Risks to Children, Co-chaired by the DHHS Secretary and the EPA Administrator, includes 10 federal agencies and 6 White House offices*

**In April 1998, the Task Force identified 4 priority areas for immediate attention**

- ✓ **Asthma** - close to 6 million American children have asthma
- ✓ **Unintentional Injuries** - leading cause of death in children in the United States - leading causes are traumatic brain injury (TBI) and fires
- ✓ **Childhood Cancer** - Cancer among children is the most common cause of disease-related mortality for children 1-14 years old.
- ✓ **Developmental Disorders** - Birth defects are the leading cause of infant mortality



# **FY 2000 Initiatives: An Interagency Effort**

**U.S. Department of  
Health & Human Services**

**U.S. Environmental  
Protection Agency**

**U.S. Consumer Product  
Safety Commission**

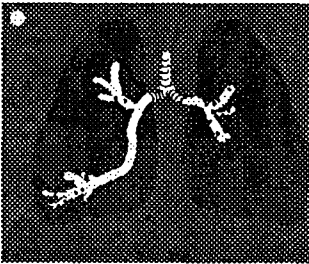
**U.S. Department  
of Transportation**

**U.S. Department  
of Housing & Urban  
Development**

**U.S. Department  
of Justice**

Other agencies represented on the Task Force are: DoED, DoL, State, DOE, Ag, OMB, CEQ, NEC, DPC, OSTP and CEA

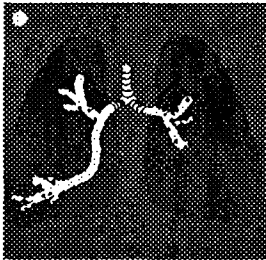




# **Asthma**

## **Why we care**

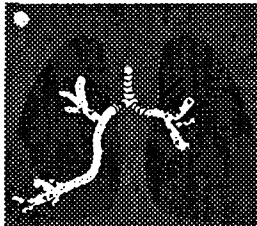
- ▲ The number of children with asthma has doubled in the past 15 years**
- ▲ 5,500,000 children are affected**
- ▲ 150,000 hospitalizations due to asthma each year**
- ▲ A 3-fold increase in the number of deaths in children from asthma from 84 in 1977 to 280 in 1995**
- ▲ Over 10 million missed school days per year.**
- ▲ Cost of asthma to the U.S. economy was estimated to be \$6.2 billion in 1990 and is projected to be more than \$14 billion in 1996 .**



# Asthma Proposal

**To address environmental aspects of asthma within the broader context of prevention and control the workgroup proposes to...**

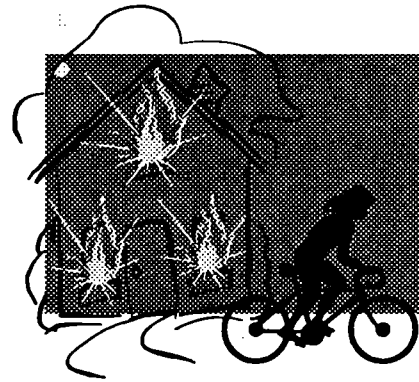
- ▲ Increase research on environmental factors that may cause or worsen asthma ,**
- ▲ implement public health programs to reduce environmental exposures to asthma triggers,**
- ▲ establish a nationwide system for collecting and analyzing asthma data**
- ▲ Reduce the disproportionate health burden of asthma in poor and minority children**



# Goals

***By the year 2010...***

- ▲ the increasing rate of asthma prevalence in children will be halted**
- ▲ asthma hospitalization rates in children will be reduced to no more than 15 hospitalizations per 10,000 people - *down from 18.1***
- ▲ the asthma death rate in children will be reduced to no more than 2 per million people - *down from 3.7***
- ▲ no more than 10% of people with asthma will experience activity limitations - *down from 22%***

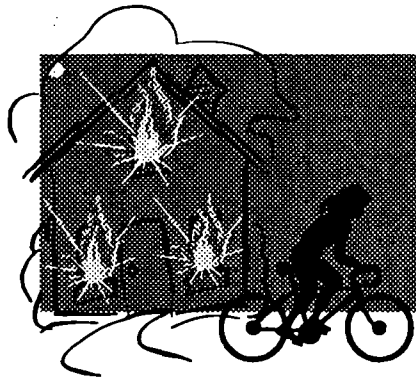


# Unintentional Injuries

## Why we care



- ▲ About 8,000 children and teens are killed in motor vehicle crashes and 1 million are injured each year. (62% were totally unrestrained)
- ▲ More than 250 children under 15 die and another 350,000 are injured in bicycle crashes annually, largely from brain injuries.
- ▲ about 1000 die in residential fires each year and another 5000 are injured



# Unintentional Injuries Proposal



- ▲ reduce motor vehicle-related brain injuries through education & information, and assistance to states on legislation and enforcement relating to children's car restraints,
- ▲ reduce bicycle-related brain injury by increased emphasis on the importance of and distribution of helmets, and
- ▲ reduce residential fire-related deaths by increasing public awareness, providing smoke alarms at reduced cost and insure proper installation

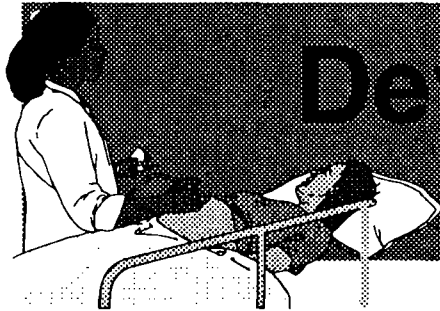
*Research and surveillance are also incorporated into the proposal for each area*





**By the year 2004...**

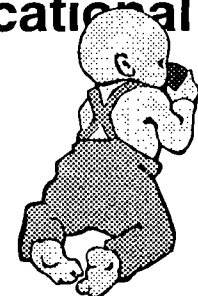
- ▲ **89% child safety seat use for children <5 years old** - *up from 63% currently*
- ▲ **50% car booster seat use** - *up from 6% in 1995*
- ▲ **89% seat belt use for youth 5-15 years old** - *up from 65% in 1996*
- ▲ **50% bicycle helmet use** - *up from 25% in 1994*
- ▲ **10% reduction in bicycle & pedestrian injuries & fatalities**
- ▲ **reduce residential fire death rate for children 0-5 to 1 per 100,000** - *down from current rate of 2.6*
- ▲ **working smoke alarms on every floor in 74% of households** - *up from 52% in 1995*

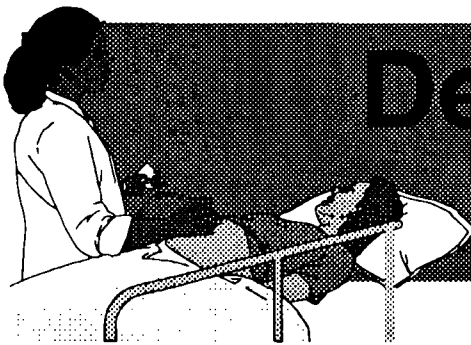


# Developmental Disorders

## Why we care

- ▲ More than 150,000 babies (4% of all live births) are born with significant birth defects each year
- ▲ Birth defects are the leading cause of infant mortality
- ▲ Estimated lifetime costs to care for children with the most common birth defects are more than \$8 billion
- ▲ About 17% of American school children have a developmental disability
- ▲ Services to children with developmental disorders cost states \$128M a year in health services & \$29B a year for educational programs
- ▲ Nearly 1 million children have elevated lead blood levels





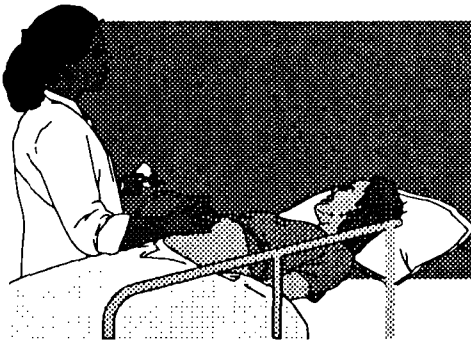
# Developmental Disorders Proposal

## ▲ Research to elucidate and prevent developmental disorders

- basic and etiologic studies on environmental factors and developmental disorders
- develop a National Information Database on Children's Health Risks

## ▲ Reduce the incidence of lead poisoning through enforcement of lead-based paint regulations

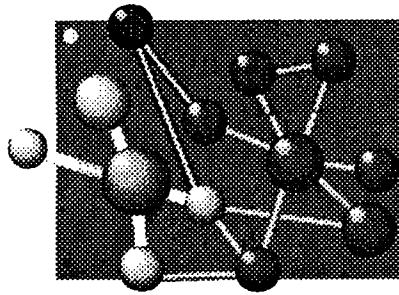




# Goals

***By the year 2010...***

- ▲ reduce the occurrence of neural tube defects to 3 per 10,000 live births- *down from 5 per 10,000***
- ▲ reduce the infant mortality rate to no more than 7 per 1,000 live births- - *down from 7.2 in 1000***
- ▲ reduce the prevalence of developmental disabilities to no more than 10% - *down from 17%***
- ▲ reduce the prevalence of blood lead levels (10 ug/dL or greater) among children 1-5 years to virtually zero- *down from 4.4%***

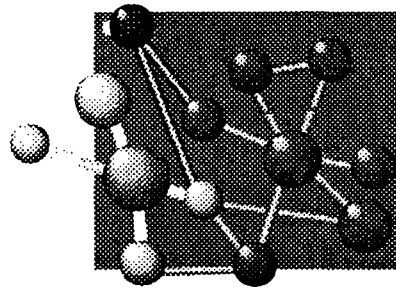


# Childhood Cancer

## Why we care

- ▲ 8000 new cases diagnosed annually
- ▲ About 1600 children under 15 die each year
- ▲ Childhood cancer incidence increased 6% from 1974 to 1995
- ▲ The causes of most cases of childhood cancers are not known





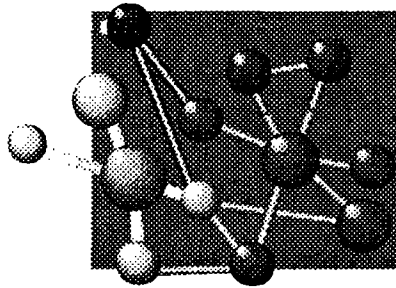
# Childhood Cancer Proposal

## ▲ National Network for Research on Cancer in Children, including:

- National Childhood Cancer Registry
- Childhood Cancer Tissue Bank

## ▲ Model Cancer Inquiry Response System

## ▲ Workshops to 1) identify research needs relating to causes of childhood cancer, and 2) develop predictive toxicological models for children's cancer



# Goals

*By the year 2010...*

- ▲ Identify environmental and other causes of childhood cancer
- ▲ Develop effective means of communicating with the public about associations between environmental factors and childhood cancers

# Resources



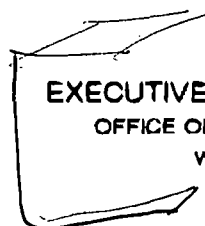
|                                |                                                                                       | FY1999              | FY2000               |
|--------------------------------|---------------------------------------------------------------------------------------|---------------------|----------------------|
| <b>Asthma</b>                  |    | \$95.5M             | \$38.3M <sup>1</sup> |
| <b>Unintentional Injuries</b>  |    | \$12.4M             | \$28M                |
| <b>Developmental Disorders</b> |   | \$191M <sup>2</sup> | \$25M                |
| <b>Childhood Cancer</b>        |  | \$85M <sup>3</sup>  | \$2.5M               |

<sup>1</sup>Does not include an additional \$17M for high priority asthma needs identified by EPA in it's OMB submission. For HHS represents an estimate of environmental aspects of asthma.

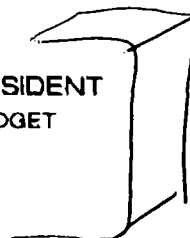
<sup>2</sup>Includes all research on developmental disorders

<sup>3</sup>Includes NCI research on childhood cancer

*base \$95.5M*  
*New \$38.3M*  
*\$5.5M*  
*\$29.5M HHS*  
*\$6.8M EPA*  
*\$2.5M HHS*  
*\$1.3M EPA*  
*\$1.0M HHS*  
*\$1.0M HHS*  
*\$5.5M agreement*  
*research indoor activity*



EXECUTIVE OFFICE OF THE PRESIDENT  
OFFICE OF MANAGEMENT AND BUDGET  
WASHINGTON, D.C. 20503



TRANSMISSION NUMBER: 202/395-5836  
VERIFICATION NUMBER: 202/395-6827

ENVIRONMENT BRANCH  
ROOM 8026  
NEW EXECUTIVE OFFICE BLDG.

Name

Fax #

To:

Devorah Adler

x 65557

From:

Candida

Message:

What was sent to Nere this morning

Historical means questionable section, but we  
are clear on rest of it w/ our editApparently a re-write by EPA's Administrative  
office is on its way to us...Number of Pages to Follow: 2

Date:

26 Jan '99

Time:

DRAFT**The Environmental Protection Agency's Children's Asthma Initiative**

Asthma is reaching epidemic proportions among American children today, especially in poor urban communities. Nearly 6 million children suffer from asthma ~~and many more children have the disease but simply have not been diagnosed~~. The number of children with asthma has doubled over the past fifteen years and is spreading most rapidly among young children. In fact, the incidence of asthma increased 160 percent for children under 5 years old from 1980 to 1994.

The health implications of asthma are significant. With 150,000 children being hospitalized each year, asthma is now the leading cause of hospitalization for children due to chronic illness. Even when asthma symptoms are not severe enough to cause hospitalization, they can still be severe enough to prevent an asthma sufferer from living a normal life. For example, children with asthma miss twice as many school days as other children and asthma has become the leading cause of school absenteeism due to chronic illness. In total, there are 10 million missed days of school as a result of asthma symptoms. The overall cost of asthma to the U.S. economy was estimated to be \$6.2 billion in 1990 (not just children). *Minority children & children living in poverty bear a disproportionate burden from asthma, suffering a much higher rate of hospitalization & death from asthma.* Scientists do not understand the reasons for the worsening trends in asthma or why lower socio-economic groups are more severely impacted. However, there is consensus that reducing children's exposure to known asthma triggers, such as secondhand smoke and indoor allergens, will reduce the frequency and severity of asthma attacks.

Recognizing the importance of asthma, the President's Task Force On Environmental Health Risks and Safety Risks to Children prepared a comprehensive and coordinated cross-government initiative to address environmental factors that play a crucial role in causing and worsening childhood asthma. The guiding principles of the initiative include an emphasis on: reducing the disproportionate burden of asthma on the poor and minorities; community-based programs; partnerships between government, non profits and the private sector, and evaluation of programs.

The Clinton Administration is committed to reducing the burden of asthma on children, their families and society. Over the next three months, EPA, HHS and other Federal partners will work with the private sector to develop a final ~~an~~ action plan that will prepare us to move expeditiously in FY 2000 to implement the initiative in close partnership with all interested government and non-government organizations.

EPA already has invested \$5 million in this fiscal year (FY99). EPA proposes to invest an additional \$17 million in FY2000 to address environmental factors that contribute to the worsening asthma trends. These investments will be a significant step toward reducing children's asthma. The focus of these investments is to reduce children's exposure in the home, schools, and day care facilities to known asthma triggers such as secondhand smoke and indoor allergens (e.g. dust mites, animal dander, insects, and mold). ~~These investments include:~~ *activities included in the FY2000 budget amount of \$22M:*

**Implementing School Based Programs.** EPA, in cooperation with DHHS and the Department of Education, will invest \$8.4 million to expand implementation of EPA's Indoor Air Quality Tools for Schools program, and to substantially expand the

availability of the "Open Airways" and "A is for Asthma" elementary and pre-school asthma management programs, developed by the American Lung Association. EPA's Indoor Air Quality Tools for Schools program provides practical information in a checklist format for school personnel to improve the quality of indoor ~~and make~~ <sup>air</sup> our schools safer for children with asthma by managing potential asthma triggers. With this investment, EPA hopes to help more than 2 million children breathe cleaner indoor air in their schools and to be better equipped to manage their asthma, for those children with the disease.

**Creation of a new national public information campaign--** EPA and DHHS will work together to conduct a national public information campaign to reduce children's exposure to environmental tobacco smoke and other indoor asthma triggers which will include:

--~~\$3~~ million in funding for a national public service campaign and community based programs.

[ --\$1 million to expand existing in-home education networks such as the USDA Extension Service's Healthy Indoor Air for America's Homes program to provide direct in-home assistance to parents in identifying asthma triggers and assisting parents in implementing effective intervention strategies. ] \*

--\$1.2 million to better equip health care providers, including managed care organizations, to educate children and their parents about ways to reduce exposure to asthma triggers.

**Improving our understanding of the link between environmental factors and asthma.** EPA will also spend ~~\$1~~ million to expand its research into the role which environmental pollutants (including chemicals, particles, ozone, diesel exhaust, pesticides, tobacco smoke and allergens) play in the onset of asthma in children and to develop better and more practical strategies for improving the quality of life of children with asthma. EPA will also invest \$1 million to conduct a pilot program to expand ambient ozone and particulate monitoring in 1-2 communities downwind of industrialized urban centers to better understand the relationship between ambient air pollution and asthma.

224  
07/98

[ 1120 brief president  
re: interview w/ Kennedy ]

Susie

# DRAFT

## A NATIONAL STRATEGY TO FIGHT CHILDHOOD ASTHMA

Today, the First Lady is unveiling the Clinton Administration's national strategy and the largest ever federal investment to fight childhood asthma. Building on the Administration's 6-year effort to protect children's health, the Clinton Administration is dedicating \$72 million in FY 2000 to address the growing asthma rates among the nation's children. This Administration-wide effort — to be lead by the U.S. Environmental Agency and the Department of Health and Human Services — will fund important efforts to determine the cause of childhood asthma, reduce children's exposure to pollutants in our environment that can exacerbate asthma, and implement initiatives for education, outreach and air monitoring in communities across the nation.

**A Dramatic Increase in Asthma Rates.** Recent reports have found an alarming rise of childhood asthma in the United States. Approximately five million children now suffer from asthma; even more troubling, the incidence of asthma in children under age five has increased 160 percent from 1980 to 1994. With 150,000 children being hospitalized each year from asthma, it is now the leading cause of hospitalization for children due to chronic illness, at a cost of \$1.9 billion in medical expenses every year. And children are hospitalized more than any other age group. Asthma is also the leading cause of school absenteeism among school children due to chronic illness, costing 10 million missed school days each year.

**A National Strategy.** Recognizing the importance of fighting childhood asthma, the President's Task Force on Children's Environmental Health and Safety Risks prepared a comprehensive, Administration-wide strategy to address environmental factors that play a crucial role in causing and worsening childhood asthma. This strategy calls on the U.S. Environmental Protection Agency, the Department of Health and Human Services and other agencies to work together to strengthen and accelerate research into the environmental factors that cause of worsen childhood asthma, implement public health programs to reduce environmental exposures to asthma triggering pollutants, and establish a coordinated nationwide asthma surveillance system to track asthma rates, identify high risk populations and environmental risk factors, and develop community-tailored plans to alleviate asthma risks.

**The Largest-Ever Federal Investment.** The President's FY2000 budget includes \$72 million to fight childhood asthma. This includes \$22 million for the U.S. Environmental Protection Agency to address environmental factors that contribute to the rising rates of asthma. These funds will help reduce children's exposure in the home, schools, and day care facilities to known asthma triggers such as secondhand smoke and indoor allergens (e.g. dust mites, animal dander, insects, and mold) by:

**Implementing School-based Programs:** The U.S. Environmental Protection Agency, in cooperation with the Departments of Health and Human Services and Education, will invest \$8.4 million to expand outreach and educational programs to inform parents, teachers, and children about how to improve indoor air quality for children with asthma and manage potential asthma triggers. With this investment, 2 million children across the nation will breathe cleaner air in their classrooms.

**Creating a New National Public Information Campaign:** The U.S. Environmental Protection Agency and the Department of Health and Human Services will work together to develop and implement a national public information campaign to reduce children's exposure to secondhand

$$5 + 1 + 6.2 + 8.4 = 20.6$$

$$12.2 + 8.4 = 20.6$$

20.6

22

assume  
\$50 in  
for the

50  
17  
1.5  
68.5

(7)

243  
smoke and other indoor asthma triggers. This campaign will include: a \$4 million dollar national public service campaign and expanded community-based outreach programs; a \$1 million dollar expansion of existing in-home education networks to provide direct in-home assistance to help parents identify asthma triggers and implement effective strategies to reduce health risks; and \$1.2 million dollars to better equip health care providers to educate children and their parents about ways to reduce exposure to asthma triggers.

**Researching the Link Between Environmental Factors and Asthma:** The U.S. Environmental Protection Agency will spend \$5 million to expand its research into the role that environmental hazards (including chemicals, particles, ozone, diesel exhaust, pesticides, tobacco smoke and allergens) play in the onset of childhood asthma and to develop better and more practical strategies for improving the quality of life of children with asthma. EPA will also invest \$1 million to conduct a pilot program to expand air pollution monitoring in up to two communities downwind of industrialized urban centers to better understand the relationship between air pollution and asthma.

(NEED INFO ON HHS BUDGET)



U.S. DEPARTMENT OF HOUSING  
AND URBAN DEVELOPMENT



OFFICE OF LEAD HAZARD CONTROL

David E. Jacobs, Office Director  
(202) 755-1785 Ext. 102  
Internet:david\_e. jacobs@hud.gov

# FAX TRANSMITTAL

RECEIVER'S NAME:

*Devona Ahluwalia*

RECEIVER'S FAX NO.:

*(202) 456-5557*

RECEIVER'S PHONE NO.:

*(202) 456-5101*

SENDER'S NAME:

*Chelline Hatchett*

SENDER'S PHONE NO.:

*(202) 755-1785 ext 114*

NUMBER OF PAGES, INCLUDING COVER SHEET:

*2*

DATE

*1/1/99*

IN REPLYING BY FAX, OUR NUMBER IS (202) 755-1000  
(COMMERCIAL AND FTS)

COMMENTS

*Please forgive the spelling of your name. If you have  
any questions please call me at (202) 755-1785 ext 114. Thank  
you.*

*Chelline*

6 CEOs

all members of Congress  
feds AID foundation

no Shalala

4pm

## **DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT'S HEALTHY HOMES INITIATIVE**

### **AMERICAN FAMILIES DESERVE BOTH SAFE AND AFFORDABLE HOMES FOR THEIR CHILDREN**

HUD is requesting funding in FY 2000 to continue the development of the Healthy Homes Initiative. In FY 2000, the Initiative will include a program to demonstrate and pilot-test new housing maintenance, renovation and construction methods, implement a new public education campaign to prevent both emerging and well-recognized diseases and injuries, conduct research and establish an interagency task force. This Initiative is an important part of the Administration's efforts to respond to the special environmental health and safety needs of children, including Executive Order 13045 on Protection of Children From Environmental Health, signed by President Clinton in 1997.

Each year, 2,500,00 children are killed or injured by dangers in the home. For example, asthma and other chronic lung diseases now cause more than 4,500 deaths per year and cost the nation \$6 billion annually. Its prevalence has increased 50 percent in the past 10 years and is now the number one cause of absenteeism in school-age children. Eighty percent of all fire deaths now occur in the home. Thousands of children die each year from exposure to pesticides, solvents and other chemicals improperly stored and used in the home. Housing-based solutions exist for all these issues which provide both affordable and healthy homes for America's children.

HUD's unique multi-disciplinary staff will enable the Nation to make progress in understanding and developing healthy homes. Only at HUD can the focus on housing be properly balanced with public health concerns to ensure that solutions are practical and capable of being replicated on a broad scale. The Department's experience with lead poisoning prevention shows that housing-based diseases can be conquered if housing-based expertise is brought to health and safety concerns.

December 17, 1998

Memo to: Gary Claxton, ASPE  
John Callahan, ASMB  
\* Bonnie Washington, HCFA \*  
Chris Jennings, DPC  
Jeanne Lambrew, DPC  
Devorah Adler, DPC  
Jennifer Klein, ~~OFF~~ DPC  
Sarah Bianchi, OVP

From: Mark Miller, OMB

Re: Medicaid Asthma Disease Management Proposal

Dan Mendelson asked that we provide you with the attached draft proposal to encourage the use of disease management to treat pediatric asthma in the Medicaid program.

The package includes a \$50 million incentive/start-up grant program targeted to fee-for service Medicaid programs. The proposal also includes ideas for increasing the use of asthma disease management in Medicaid nationally by distributing and encouraging the use of NIH asthma protocols, and reducing any regulatory barriers that might discourage states' disease management efforts.

We will schedule a meeting early next week to discuss the proposal.

Attachment

## Asthma Disease Management Initiative in Medicaid DRAFT FOR DISCUSSION

There is some evidence that asthma disease management programs in the private sector improve quality of life for asthma patients and reduce asthma related hospitalization and emergency room visits. (Plotcher, 1996) By encouraging the use of asthma disease management techniques in the Medicaid program, we could reduce the incidence of asthma episodes and improve the health of low-income children.

The Medicaid program is an ideal infrastructure through which to implement a low-income children's asthma initiative because:

- a) the Medicaid program targets low-income children;
- b) the Federal government shares in state costs for asthma related care for Medicaid patients, and;
- c) State Medicaid databases may provide demographic and epidemiological data to define the scope of the asthma problem in the state and assist in measuring state-specific outcomes of an asthma initiative.<sup>1</sup>

*What Is Disease Management?* Disease management is a new managed care technique designed to improve the care of certain chronic conditions, such as asthma. Disease management organizations are a growing trend in the private health care insurance industry. Revenues of companies who target and treat chronic illness is expected to double over the next year, to \$348 million. (Kilborne, 1998)

Through intensive case management and use of appropriate clinical practices, disease management programs have been shown to improve health outcomes, reduce inpatient hospitalization, lower total costs, and increase consumer and physician knowledge. (Plotcher) Asthma disease management programs in the private sector find reduced hospitalizations and emergency room visits by 50%, and improved functional status as measured by the ability to work and quality of sleep. (Plotcher)

Disease management combines the use of the most up-to-date treatment protocols (or "best practices") with a *prevention component* -- providing disease specific education programs and health screening; an *intensive case management component* -- close monitoring patient care and treatment compliance; and a *self-care component* -- empowering patients to identify symptoms and care for their own chronic disease. (Coons, 1996)

---

<sup>1</sup> States pursuing disease management in Medicaid in the fee for service environment have been successful in identifying asthma related claims from their Medicaid claims databases.

SENT BY FAX TELEPHONE 7020 112-17-90 1 4:19PM 333/2097 000071# 3

***Asthma Disease Management in Medicaid.*** Some states (including VA, TX, MS, MD, FL, MN) are embarking on Medicaid disease management programs. (Guiden, 1998) For example, Virginia significantly reduced hospitalizations and emergency room visits in its fee for service disease management pilot simply by identifying Medicaid physicians with asthma patients and providing six hours of training in appropriate asthma treatment. (Rossiter, 1998) Mississippi's new disease management program includes Medicaid payments for pharmacists to provide additional education, case management and drug therapy for patients with asthma. Once approved, Florida's "Invitation to Negotiate" program will contract with outside disease management organizations outside of the existing primary care case management system (PCCM) to provide case management and best clinical practice information. Florida intends to put the disease management organizations "at-risk" for improved patient outcomes, so that the contractors will only be paid out of savings from reduced asthma related hospitalizations and emergency visits.

***Barriers to Implementing Asthma Disease Management in Medicaid.*** While a documented success in the private sector, there are some barriers to implementing disease management in Medicaid. While savings may eventually result from decreased emergency room visits and hospitalization rates for chronically ill individuals, disease management may increase "up-front" costs by requiring physician and patient education and more intensive case management efforts. For example, appropriate asthma clinical protocols in Virginia's program increased benefit costs by increased use of inhalers and more frequent visits with a case manager to ensure patient compliance with treatment. (Rossiter)

Other barriers to implementing Medicaid disease management include the high cost of contracting with disease management organizations, lack of adequate data systems to identify and track individual patients (particularly managed care encounter data), and lack of documentation about disease management's effect on health outcomes and program savings. (Pinney, 1998) Medicaid MCOs may be reluctant to invest in disease management services for Medicaid patients because of the high caseload turnover. (Guiden)

The following paper proposes a range of policies that will assist and encourage states to explore the use of disease management techniques to focus on and improve health outcomes of low-income children with asthma.

## **Proposal for an Asthma Disease Management Demonstration**

**Summary.** HHS would conduct a demonstration to test the use of innovative asthma disease management techniques for children enrolled in the Medicaid program. HHS would provide \$50 million for competitive start-up grants to states who submit disease management programs to identify and treat asthmatic children with the most appropriate care. Participating states would be required to measure the success of the program in averting asthma related medical crisis -- such as the number of hospital stays or an emergency room visits. States would be encouraged to track other quality of life measures -- such as missed school days from asthma related illness.

**Scope.** Grants would be available for a minimum of 10 states. Programs can be statewide, or could target areas of the state with high asthma incidence among Medicaid beneficiaries. Grant funds would be available for new or expanded disease management efforts only. State with asthma disease management programs in place would be required to maintain their current efforts in order to access grant funds for a program expansion. Waivers may be required if states implement mandatory enrollment.

**Financing.** To assist states with the start-up costs of the demonstration, \$50 million in mandatory Medicaid funds would be made available to the Secretary of HHS in FY2000. Alternative proposals include:

*Alternative Option A.* Withhold \$20 million in grant funds for distribution once participating states establish a asthma baseline approved by HCFA.

*Alternative Option B.* Withhold \$10 million in grant funds as a reward for states who have reached certain level of improvement against their asthma baseline.

**Proposal Requirements.** To qualify for the grant funds, states would be required to submit a proposal that includes the following:

- *Asthma Treatment Baseline.* Participating states would be required to establish a "current practices" asthma baseline from existing Medicaid data against which it can measure the success of the disease management intervention. States should plan to provide HCFA with quarterly and yearly outcome measurements against the baseline. The baseline should track, at a minimum,
  - number of Medicaid eligible children with asthma in the area of the demonstration
  - number and cost of asthma related office visits,
  - number and cost of hospital stays and emergency room visits from asthma-related incidents.
  - other quality of life factors for which the state can produce a baseline, such as missed school days and beneficiary compliance with treatments.

- *Appropriate Care Protocols.* States would develop, or contract with a disease management organization to develop, an intervention model that includes appropriate disease treatment protocols (i.e. clinical pathways or best practices). The protocols should be consistent with NIH's recent asthma treatment guidelines.
- *Patient and Physician Outreach and Education.* The proposal should include a plan for the dissemination of asthma treatment guidelines to Medicaid physicians. Plans should include a beneficiary education component that focuses on self-care -- such as ways to avoid attacks, and the proper use of inhalers.
- *Leveraging Medicaid Funds.* Grant funds are targeted for start-up costs, not to offset the state share of traditional Medicaid benefits. States are encouraged to design programs so that outreach, case management and benefit and treatment costs are claimable under the current law Medicaid program (or through a waiver or state plan amendment). For example, states may use grant funds to evaluate asthma data to construct a baseline or evaluation. States may not use the grant funds to offset state match for increased pharmaceutical expenditures under the demonstration.
- *Partnerships.* States who partner with pharmaceutical companies, physicians, pharmacists in designing the demonstration will be favorably considered.
- *Concentrate Grant Awards for Fee For Service Programs.* Grant awards would be targeted to disease management proposals in Medicaid fee-for-service, or managed care carve-out programs. [We do not recommend providing incentive grant funds for states to pass-through to Medicaid managed care organizations. Based on our conversations with states implementing disease management in Medicaid, managed care encounter data is often insufficient to establish a baseline. The state and federal government would not share in the savings achieved by MCOs, so it may not be an appropriate place to provide start-up cost assistance. (See managed care options below).]

### **Proposal for National Asthma Treatment Strategies.**

In addition to the state-specific focus, we recommend the following initiatives to improve the treatment of asthma in Medicaid programs nationwide:

1) *Asthma Disease Management Guidelines.* Similar to the AIDS treatment guidelines issued last year, HHS will issue a State Medicaid Director's letter to encourage the use of asthma best practice guidelines as issued by NIH and private sector organizations. (See attached.)

2) *AHCPR Asthma User Liaison Program.* AHCPR will work with HHS to identify and provide states with "best practices" in asthma disease management. AHCPR will disseminate this information by designing a User Liaison Program (ULP) for asthma disease management, which will train state and local governments in the understanding and use of asthma disease management guidelines.

3) *Identifying and Eliminating Federal Barriers.* To remove any unnecessary roadblocks to the use of best practices in asthma treatment, HHS will review and wherever possible, reduce any federal barriers that might exist in HHS regulations, or state Medicaid manual. HHS will report to the Secretary in one year with its recommendations.

HHS will also review current Medicaid law and provide states with guidance as to what waivers of law or changes in state plan amendments are required in order for states to implement certain disease management techniques in Medicaid -- such as physician education programs or additional case management from non-traditional providers, such as pharmacists.

4) *Improving Asthma Treatment within Medicaid Managed Care.* As the incidence of asthma grows predominantly in low-income populations, it is important that Medicaid providers provide the highest quality care based on HHS guidelines:

- Through their contracts with managed care organizations, HCFA and the States should ensure that all providers who serve the Medicaid population are aware of and adhere to these guidelines.
- HHS could increase awareness about disease management techniques by requiring states to report on their MCOs disease management efforts as part of the 1915b managed care waiver process, or as part of the managed care contract between the state and the MCO.
- HCFA could require that states collect data on the care provided to asthma patients in MCOs. (This could also be required of FFS states not participating in the demonstration.)

5) *Evaluation and Technical Assistance Funding.* States might benefit from the experience of existing disease management programs in pioneering states such as Virginia Florida and

Mississippi. HHS would evaluate existing Medicaid disease management programs and submit a report to OMB. The evaluation would be jointly performed and funded by HCFA and ASPE.

### Sources

Stephen Joel Coons, Ph.D, "Disease Management: Definitions and Exploration of Issues"; *Clinical Therapeutics*, Vol. 18, No. 6, 1996.

Mary Guiden, "Educating Patients May Mean Savings for States"; *State Health Notes*, Volume 19, No. 286, Oct. 12, 1998.

Peter Kilborne, "Moving Beyond Cost-Cutting, H.M.O.'s Look to Manage Chronic"; *New York Times*, December 7, 1998.

Medical Alliances, Inc.; "Disease Management Shows Great Promise" [www//medsource.com](http://www.medscape.com).

W.P. Munroe, K. Kuz, C. Dalmady-Israel, L. Potter, W.H. Schonfeld (MedOutcomes Inc. Richmond VA), "Economic Evaluation of Pharmacist Involvement in Disease Management in a Community Pharmacy Setting" *Clinical Therapy*, 19(1):113-23, January 1997.

Pinney Associates, Inc. "Barriers to Implementing Disease Management Programs," Bethesda MD, [www.medscape.com](http://www.medscape.com).

David W. Plotcher and Peter Kongstvedt, "Disease Management"; The Managed Health Care Handbook, Ernst and Young LLP, Gaithersburg, MD, 1996.

Louis Rossiter, Ph.D, "The Impact of Disease Management on Outcomes and Cost of Care: A Study of Low-Income Asthma Patients"; *Williamson Institute for Health Studies*, Virginia Commonwealth University, 1998.

Paul Wynn, "The Role of Physicians in Disease Management"; *Managed Care Magazine*, October 1996.

# President's Task Force on Environmental Health Risks and Safety Risks to Children

## Proposed FY2000 Interagency Budget Overview

| ASTHMA                                      |                                                  |  |                          |             |
|---------------------------------------------|--------------------------------------------------|--|--------------------------|-------------|
|                                             | Base<br>(\$\$ in FY99 Pres. Budget) <sup>1</sup> |  | FY2000 OMB<br>Submission |             |
| DHHS                                        | \$80 M                                           |  | \$29.5 M                 |             |
| Research                                    |                                                  |  | \$12 M                   |             |
| Public Health Practice <sup>2</sup>         |                                                  |  | \$7.5 M                  |             |
| Surveillance                                |                                                  |  | \$6 M                    |             |
| Reducing impacts on minorities              |                                                  |  | \$4 M                    |             |
| EPA                                         | \$5.5 M                                          |  | \$23.8 M <sup>3</sup>    |             |
|                                             |                                                  |  | \$6.8 M                  | plus \$17 M |
| Research                                    | \$4 M                                            |  | \$1.3 M                  | \$6 M       |
| Public Health Practice                      | \$1.5 M                                          |  | \$5.5 M                  | \$7.5 M     |
| Surveillance                                |                                                  |  |                          | \$3.5 M     |
| Reducing impacts on minorities <sup>4</sup> |                                                  |  | (\$4 M)                  | (\$10 M)    |
| HUD                                         | \$10 M                                           |  | \$2M                     |             |
| Research                                    |                                                  |  |                          |             |
| Public Health Practice                      |                                                  |  |                          |             |
| Surveillance                                |                                                  |  |                          |             |
| Reducing impacts on minorities              |                                                  |  |                          |             |
| <b>TOTALS</b>                               | <b>\$ 95.5 M</b>                                 |  | <b>\$ 55.3 M</b>         |             |

<sup>1</sup> Estimated \$\$ attributable to environmental aspects of asthma prevention and management in children.

<sup>2</sup> Includes guidance, education, and training activities as well as traditional public health programs.

<sup>3</sup> \$6.8 M included in budget submission plus an additional \$17 M in high priority needs identified by Administrator Browner in her budget transmittal letter.

<sup>4</sup> Estimated. \$\$ already counted in research, public health practice and surveillance.

Dan --

Thanks for the opportunity to review the OMB proposal to promote disease management strategies for pediatric asthma patients enrolled in the Medicaid program.

Although I share your concerns about the constraints of the discretionary budget, we believe that limiting the asthma initiative to competitive grant program for the segment of the Medicaid population enrolled in fee for service delivery systems would result in a number of critical issues remaining unaddressed.

Most importantly, only 20 percent of children with asthma are enrolled in the Medicaid program. To limit the focus of the asthma initiative to the Medicaid program would effectively exclude the vast majority of children with this disease. In addition, only Medicaid fee for service programs would be able to qualify for competitive grant funds, further limiting the number of children that would be reached by the initiative.

In addition, if the asthma initiative consisted solely of disease management strategies, it would not be able to support the community based educational efforts that are integral to effective asthma management. Grant funds supporting community based programs can be used to remove environmental triggers in community buildings, develop supportive medication policies in schools, and educate teachers, school nurses and other individuals that deal with children on a regular basis about the disease.

As you know, both EPA and HHS have submitted requests for funds to address the asthma epidemic using traditional public health strategies. There are some important differences between the activities conducted by the two agencies. The HHS initiative deals with asthma in both children and adults and includes but is not limited to environmental issues. Examples of areas that are addressed by HHS and not EPA include the development of new medical therapies, improving compliance with guidelines for medical management among both health care providers and persons with asthma, and management of asthma in pregnancy. The EPA initiative places much greater emphasis on controlling and reducing environmental triggers that cause asthma, including enforcement of regulatory standards for outdoor pollutants.

It is important to note that there are several activities that EPA is conducting that need to be supplemented by HHS activities. For instance, EPA's emphasis on public outreach is to encourage efforts to reduce exposure to environmental pollutants that trigger asthma attacks. This is an important component of asthma management, but ignores the critical role of medical management that HHS is seeking to provide. Insuring appropriate medical management and the dissemination of health education messages are not within the purview of EPA's proposed activities.

## CONTROLLING ASTHMA THROUGH COMMUNITY LEVEL INTERVENTIONS

### Disease Management (\$27 million total)

- **Implementing new disease management strategies.** Grant funds will be provided to States who submit disease management programs to identify and treat asthmatic children in their Medicaid fee for service programs in accordance with the new NIH guidelines. Participating States would be required to measure the success of the program in averting asthma related medical crisis, such as the number of hospital stays or emergency room visits. States would also be encouraged to track other quality of life measures, such as missed school days from asthma related illness. (\$25 million in mandatory funds)
- **Educating patients and providers about new treatment guidelines.** HHS would develop partnerships with managed care organizations to integrate asthma prevention programs into existing health education programs. HHS will take administrative action to ensure that all providers (not just those in fee for service delivery arrangements) who serve the Medicaid population are aware of and adhere to these guidelines, such as requiring States to collect data on the care provided to asthma patients in MCOs, or issuing a State Medicaid Director's letter to encourage the use of asthma best practice guidelines. The Secretary will also hold a managed care conference to highlight the new NIH guidelines. (\$2 million in discretionary funds)

### Implementing Public Health Programs (\$15 million in discretionary funds)

- **Developing asthma education and prevention programs.** CDC would provide grant funds to State health departments for community education about asthma control. Examples of activities that could be funded by these grants include school based programs and special clinics held at churches, community centers, and libraries that identify children suffering from asthma and educate their parents and other adults about the importance of receiving treatment.
- **Conducting a national asthma awareness campaign.** CDC would fund a national asthma awareness campaign, targeted to parents and emphasizing the importance of early diagnosis and effective management, as well as avoidable asthma triggers such as environmental tobacco smoke, indoor allergens, and outdoor pollution episodes.

### Surveillance and Evaluation (\$8 million in discretionary funds)

- **Establishing a disease baseline.** CDC would develop a new national surveillance system to establish a disease baseline and identify populations with significantly high or low prevalence of asthma. This system will be supplemented by a national telephone survey that will provide State level data on the impact of the new grant programs. This baseline will be used to evaluate the success of the new grant programs, to allocate limited resources, and target and evaluate health education and disease management efforts.

## Issue Paper E: Disease Management in Medicaid

**Issue.** In recent years, the managed care industry reaped savings and increased quality of care by treating chronic illness through a technique known as "disease management." Based on evidence of success in the private sector, it may be beneficial to adopt disease management techniques in states with fee-for service Medicaid programs, and encourage the use of disease management by Medicaid managed care organizations.

This section describes disease management, and recommends administrative actions that could encourage its use in the Medicaid program.

**Background.** Disease management may increase efficiency of health care delivery by targeting expensive, chronic illness -- such as hypertension, diabetes, asthma, AIDS, and hemophilia -- and integrating treatment and reimbursement. Disease management can include a *prevention component* -- providing disease specific education programs or health screening; a *case management component* -- monitoring patient care and establishing treatment regimens; and a *personal care component* -- empowering patients to identify symptoms or care for their own chronic disease.

Some disease management programs in the private sector show cost savings as a result of more efficient delivery of care. Savings may result from decreased emergency room visits and hospitalization rates for chronically ill individuals. MedOutcomes evaluated three small community retail pharmacy disease management programs for patients with hypertension, diabetes, hypercholesterolemia, and asthma. The study showed a decrease in monthly costs per patient between \$150 and \$300.<sup>1</sup> Harvard Community Health Plan found that implementation of an asthma management program reduced hospital admissions for pediatric asthmatics by 25% and adult disease management admissions by 10%.<sup>2</sup> The Diabetes Treatment Centers of America estimate 15-35% savings in diabetes care through aggressive education and self-care disease management programs.<sup>3</sup> While programs for certain diseases have been cost-effective, a Medicare FFS case management demonstration for heart disease not show savings or improved patient outcomes. In order for it to be cost effective, HCFA determined that payment controls would be required to give incentives to physicians to decrease utilization.

<sup>1</sup> W.P. Munroe, K. Kuz, C. Dalmady-Israel, L. Potter, W.H. Schonfeld (MedOutcomes Inc. Richmond VA), "Economic Evaluation of Pharmacist Involvement in Disease Management in a Community Pharmacy Setting" *Clinical Therapy*, 19(1):113-23, January 1997.

<sup>2</sup> Medical Alliances, Inc.; "Disease Management Shows Great Promise" [www.medsource.com](http://www.medsource.com).

<sup>3</sup> Ibid.

V R 1

*Disease Management In Medicaid.* States (including TX, MS, MD, FL, MN) are embarking on Medicaid disease management programs. Mississippi's Medicaid program includes Medicaid payments for pharmacists to provide education, case management and drug therapy for patients asthma, diabetes, and coagulations disorders. Florida's "Invitation to Negotiate" program will contract with disease management organizations to serve individuals with AIDS, diabetes and hemophilia. Florida plans to test whether disease management improves care, improves health outcomes, reduces inpatient hospitalization, lowers total costs, and increases consumer knowlege.

Barriers to implementing disease management include the high cost of contracting with disease mangement organizations, lack of adequate data systems, and lack of health outcome and savings information. <sup>4</sup> State FFS Medicaid programs, as well as Medicaid MCOs, may also be reluctant to invest in disease management services for Medicaid patients because of the high caseload turnover.<sup>5</sup>

*Administrative Actions and Grants.* As part of our management pass-back, we will encourage HCFA to explore the potential use of disease management in the Medicaid program. The following are some ideas for encouraging disease management in Medicaid:

- *Evaluation and Technical Assistance Funding.* States might benefit from the experience of pioneering states such as Florida and Mississippi. We <sup>will</sup> could ask HHS to evaluate <sup>the feasibility</sup> existing Medicaid disease management programs and submit a report to OMB. This <sup>or</sup> funding could come from HCFA's existing research and demonstration budget for <sup>EXPAND</sup> research on vulnerable populations or it could be conducted within ASPE.
- *Identifying and Eliminating Federal Barriers.* We do not know if states perceive any federal barriers to experimenting with disease management. To remove any unnecessary roadblocks, HHS could develop a disease management working group to:
  - Reduce any federal barriers that might exist in HHS regulations, or state Medicaid manual.
  - Review current law and provide states with guidance as to what waivers of law are required in order to provide preventative services, such as disease educational programs or provision of diabetes, in a managed care or FFS environment.
  - Identify and provide states with "best practices" in disease management,
  - Develop disease management partnerships between Medicaid and public health service.

---

<sup>4</sup>Pinney Associates, Inc. "Barriers to Implementing Disease Management Programs," Bethesda MD, [www.medscape.com](http://www.medscape.com).

<sup>5</sup> Mary Guiden, "Disease Management: Educating Patients May Mean Savings for States," *State Health Notes*, Vol. 19, Oct. 12, 1998.

- *Incentive Grants.* HHS could solicit Medicaid disease management proposals from states, and provide a limited amount of funding for states to launch pilot projects. Programs could be targeted to diseases for which Medicaid beneficiaries are most at-risk - such as hypertension screening in inner cities. We recommend grant awards are focused to states who are interested in working with Medicaid fee-for-service or the uninsured population. We do not recommend providing disease management funding for states to work with Medicaid managed care organizations, since MCOs have a natural incentive to implement cost effective managed care techniques.
- *1915b Waivers.* We could encourage disease management by requiring states to report on their MCOs disease management efforts as part of the 1915b managed care waiver process, or as part of the managed care contract between the state and the MCO.
- *1115 Waivers.* HHS could encourage states to apply for 1115 waivers for disease management programs that include services not typically provided by Medicaid. These waivers could be combined with the incentive grants in option 3.

For example, New Jersey was granted an 1115 waiver to redirect Medicaid DSH funds for its chronically ill or substance dependent uninsured population. Within its existing DSH budget, New Jersey directed hospitals to contract with out-patient clinics to provide less costly non-emergency care to patients with diabetes, hypertension, and alcoholism. The program was unsuccessful, in part, because the hospitals felt too constrained by their existing DSH funding to finance the new partnerships with outpatient clinics. A grant might have helped offset the start up costs until the program became cost-effective on its own.

EXAMINER/PHONE: Cindy Smith/5-7816

# FLORIDA

## APPENDIX J.

### DISEASE MANAGEMENT AGREEMENT WITH ITG (ASTHMA)

#### Florida's DM Asthma Program in Medicaid

Contract w/ a DM organization  
who provides doctors w/ info  
on best practices, provides education-  
case management for beneficiaries. —

Program is paid for entirely  
by savings to Medicaid. — even  
though patients are getting more &  
better care.

## ASTHMA DISEASE MANAGEMENT AGREEMENT

This Asthma Disease Management Agreement ("Agreement") is made by and between The State of Florida Agency for Health Care Administration ("The Agency"), with offices located at 2727 Mahan Drive, Tallahassee, Florida 32308, and Integrated Therapeutics Group, Inc. ("ITG"), a wholly-owned subsidiary of Schering-Plough Corporation, with offices located at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033. (The Agency and ITG are sometimes collectively referred to as the "Parties" and individually as "Party.")

### OVERVIEW

The Agency desires to implement a disease management program ("Program", as defined in Article 3 of this Agreement) for the benefit of Asthmatics, as defined in Section 1.1, with the advice of, and in consultation with, ITG. ITG desires to work with The Agency to implement the Program for the benefit of Asthmatics on the terms and conditions set forth herein.

### 1. DEFINITIONS

1.1 "Asthmatic" shall mean a MediPass Recipient or Eligible Non-MediPass Recipient who is an asthmatic as defined in Exhibit A.

1.2 "Children's Medical Services (CMS) Network" shall mean a comprehensive, continuous and coordinated system of health care that links community-based health care with multidisciplinary, regional and tertiary care to serve Medicaid-eligible children with special health care needs.

1.3 "Disease Management" shall mean an integrated, systematic health care management approach to improve patient outcomes and lower medical costs for patients living with specific chronic health conditions.

1.4 "Effective Date" shall mean the date on which the last signatory of this Agreement has signed the Agreement.

1.5 "Eligible Non-MediPass Recipient" shall mean individuals receiving SSI with Medicare coverage and Medicaid eligible Recipients whose Medicaid eligibility has been determined through the medically needy program, where appropriate, and for whom The Agency is responsible for the cost of medical care, including pharmaceutical products.

1.6 "Medicaid" shall mean the Florida Medicaid Program.

1.7 "MediPass" shall mean the Medicaid Provider Access System ("MediPass"), which is a primary care patient management system implemented pursuant to a waiver granted by the Secretary, Department of Health and Human Services, in

accordance with Title XIX of the Social Security Act and subject to provisions of Florida Statutes and the Florida Administrative Code.

1.8 "MediPass Recipients" shall mean eligible MediPass Recipients receiving assistance under the Work and Gain Economic Self-sufficiency ("WAGES") program, also referred to as Aid to Families with Dependent Children ("AFDC"); individuals receiving AFDC-related Medical Assistance Only ("MAO"); Sixth Omnibus Budget Reconciliation Act ("SOBRA") children; individuals receiving Supplemental Security Income ("SSI") without Medicare coverage; and children in foster care or subsidized adoption arrangements, and for whom The Agency is responsible for the cost of medical care, including pharmaceutical products.

1.9 "Program Initiation Date" shall mean the date on which the Program is first made available to Asthmatics.

1.10 "Provider Service Network ("PSN") shall mean an organized health system operated by health care providers offering integrated systems of care to Medicaid recipients. Under a demonstration project initiative, The Agency intends to contract with PSNs in four regions of the state.

1.11 "Recipient" shall mean an individual who has been determined to be eligible to receive Medicaid benefits.

1.12 "Specialist" shall mean a provider whose practice is limited to a particular branch of medicine or surgery, including one who, by virtue of advanced training, is certified by a specialty board as being a qualified expert in that area of medicine.

## 2. TREATMENT GUIDELINES

ITG shall assist The Agency in the development of an intervention model which includes mutually agreed upon treatment guidelines (clinical pathways or best practices) ("Guidelines"). These Guidelines shall be protocols that have been developed by experts in the field and which ensure high-quality, cost-effective care delivery. The Guidelines are for medical education purposes and shall be based on the asthma treatment guidelines developed and published by the National Heart, Lung and Blood Institute ("NHLBI") of the U.S. National Institutes of Health, the International Consensus Guidelines or other mutually acceptable asthma treatment guidelines. The final selection of the Treatment Guidelines will be made by The Agency. ITG's obligations under this Agreement shall be subject to ITG's review and determination that the Guidelines can be supported through its intervention programs. ITG shall review the agreed upon Guidelines and shall meet with The Agency to develop the specifics of the Program. As outlined in Exhibit B, The Agency shall cause the products to be used in the implementation of the Guidelines to be listed on the state's formulary with an open and unrestricted status.

If The Agency alters the Treatment Guidelines which have been previously accepted by the parties, then ITG has sixty (60) days from the date of its receipt of such

revised Treatment Guidelines to review the change and incorporate the change into this Agreement. If ITG believes that the Guidelines, as altered, cannot be supported or administered by ITG, then the parties shall attempt to reach a mutually satisfactory agreement on the Guidelines to be used, or either party may terminate this Agreement. The Agency shall provide ITG with thirty (30) days' written prior notice of any changes in the Guidelines.

### 3. PROGRAM DESIGN

**3.1 Intent of Program.** A key intent of the Program is to provide and test an innovative Disease Management model for Asthmatics. The priority of this Disease Management initiative is to meet the patient's comprehensive needs early before they reach a medical crisis in terms of compounding complications and thereby causing the patient needless suffering and costly medical treatments.

**3.2 Design of Program.** ITG's disease management system will use customized individual care management plans for identified individuals following appropriate disease intervention protocols (clinical pathways). The care management initiative stresses prevention and education, promotes lifestyle changes, improves medical self-management and increases patient and family satisfaction. Specialist referral guidelines, recipient education activities, clinical practice guidelines and intensive case management focusing on preventative health care will be utilized as part of this initiative.

**3.3 Program Objectives.** The Program will measure the outcomes among Asthmatics. The objectives of this Program include the following:

To encourage the organization and delivery of services for Asthmatics that will result in:

- improved care;
- improved health outcomes;
- reduced inpatient hospitalizations and emergency care visits;
- lower costs;
- better educated providers and consumers;

and will include the following components:

- specialist referral guidelines;
- intensive care management;
- provider education;
- recipient education;
- clinical practice guidelines;
- provider and Recipient profiling; and
- quarterly and yearly outcome measurements and reporting.

Specifics of the above components are contained in Exhibit C.

A description of the responsibilities of the Parties may be found in Exhibit D and the reporting requirements may be found in Exhibit E.

#### 4. ENROLLMENT SOURCES AND DISENROLLMENT

**4.1 Identification and Enrollment of Asthmatics.** The Agency will conduct claims analyses to identify those Recipients having the characteristics of a diagnosis of asthma. The Agency will provide ITG with the list of physicians who have the identified Asthmatics under their care along with contact information including their addresses and phone numbers. The providers will receive information regarding this Program and how their Asthmatics can voluntarily enroll into it. The providers will also receive a list of the identified Asthmatics that are under their care who may be eligible to enroll into the Program. ITG will be responsible for contacting these providers to voluntarily enroll their identified Asthmatics into the Program. ITG may also voluntarily enroll Recipients who have been referred by their Medicaid provider independent of the list of Asthmatics previously identified from claims data. Disease management services will be provided only to those Asthmatics enrolled in Medicaid who have been identified in the specified manner or who have been referred to this Program by their Medicaid provider.

#### 4.2 Eligibility.

**4.2.1** All Asthmatics are eligible to be enrolled in the Program. Medicaid Recipients participating in Health Maintenance Organizations ("HMOs") and PSNs are excluded from this disease management initiative. However, ITG may contract separately with HMOs and/or PSNs to provide disease management services to those managed care entities.

**4.2.2** The following categories describe Medicaid Recipients who are not eligible for enrollment in this program:

- a) Medicaid eligible Recipients who, at the time of application for enrollment and/or at the time of enrollment, are domiciled or residing in an institution, including mental hospitals, skilled nursing facilities, intermediate care facilities for persons with developmental disabilities, state hospitals, correctional institutions, residential group care facilities operated through the Department of Juvenile Justice, or Regional Perinatal Intensive Care Centers (RPICCs);
- b) Medicaid eligible Recipients who are receiving services through a hospice program;
- c) Medicaid eligible children who are in the custody of the Department of Children and Families and are residing in an emergency shelter;

- d) Medicaid eligible children with special health care needs who are enrolled in the CMS Network;
- e) Medicaid eligible women who, due to pregnancy, change eligibility categories to the SOBRA eligibility category; and
- f) Medicaid eligible children who receive Prescribed Pediatric Extended Care Services.

**4.3 Initial Work Plan.** The Agency will provide a list of the eligible Recipients to ITG, in a format acceptable to ITG, formatted by county, utilization and cost. After ITG receives the data, ITG shall review the data and submit, within a period of four (4) weeks from the signing date of this Agreement, an initial plan ("Initial Work Plan") to demonstrate adequate staffing to fully implement the components of this Program. The Initial Work Plan shall illustrate ITG's ability to provide individualized care to those Recipients categorized as "high risk" or "severe" and the distribution of staff shall reflect the distribution of Asthmatics throughout Florida. The Initial Work Plan must include a description of the number of staff and their distribution throughout Florida.

**4.4 Disenrollment.** ITG may not disenroll a Recipient from this Program unless requested by the Recipient or required by The Agency due to eligibility changes. There are currently no lock-in requirements for enrollees in MediPass.

## **5. CONFIDENTIALITY**

ITG shall safeguard the use and disclosure of information pertaining to current or former Medicaid Recipients and comply with all state and federal laws pertaining to confidentiality of patient information. Recipient information is strictly confidential and under no circumstances shall this information be duplicated and/or provided to anyone for any purpose other than as set forth in this Agreement; *provided, however*, that ITG may use the data provided to it by The Agency so long as no such data is identified to any third party as The Agency's data without the consent of The Agency.

ITG agrees, throughout the Term and for three (3) years thereafter, to retain in confidence, and cause its directors, officers employees, agents and consultants (collectively, "representatives") to retain in confidence, all concepts, structures, issues and data related to the Program, including the terms of this Agreement (collectively, the "Information") disclosed to it by or on behalf of The Agency and that it will not, without the written consent of The Agency, use Information supplied hereunder for any purpose other than for purposes of analysis and explanation of utilization, costs and patterns of care, and for other purposes indicated herein; provided, that ITG may disclose Information to its agents and consultants in order to perform its obligations under this Agreement. The Agency agrees, throughout the Term and for three (3) years thereafter, to retain in confidence, and cause any of its employees or representatives to retain in confidence all Information disclosed to it by or on behalf of ITG. The restrictions shall

not apply to Information: (a) which is or becomes public knowledge; or (b) which is made lawfully available to the receiving party by an independent third party; or (c) which is already in the receiving party's possession at the time of receipt from the disclosing party; or (d) which is independently developed by employees of the receiving party and/or affiliates of its parent corporation where appropriate; or (e) which is required by law, regulation, rule, act or order of any governmental authority or agency to be disclosed by the receiving party; provided however, that such receiving party gives the other party hereto sufficient advance written notice to permit it to seek a protective order or other similar order with respect to such Information and thereafter discloses only the minimum Information required to be disclosed in order to comply.

## 6. TERM OF AGREEMENT

The term of this Agreement shall commence as of the Effective Date and, unless sooner terminated, shall remain in effect until the third anniversary of the Program Initiation Date (the "Initial Term"). This Agreement shall be automatically renewed for successive one year periods (each a "Renewal Term" and together with the Initial Term, the "Term"). At least six (6) months prior to the end of the Initial Term and each Renewal Term, the parties shall meet to discuss the continuation of this Agreement. This Agreement may be terminated by either party without cause, effective thirty (30) days after the provision of written notice to the other party.

## 7. SPECIFIC USE

Any items which may be provided by ITG to The Agency, its providers and/or Asthmatics in connection with the Program or this Agreement shall be used by The Agency solely in connection with the implementation of the Program and shall not be used by The Agency for any other purpose whatsoever.

## 8. INTELLECTUAL PROPERTY

All concepts, structures, ideas, patents, trade secrets, trade names, trademarks, services marks, materials or property (collectively "Intellectual Property") of ITG utilized in connection with the Program pursuant to this Agreement shall remain the property of ITG, and The Agency shall have rights to use such Intellectual Property to the extent permitted by this Agreement or as otherwise agreed to in writing by the parties.

All Intellectual Property of The Agency utilized in connection with the Program pursuant to this Agreement shall remain the property of The Agency, and ITG's rights to use such Intellectual Property shall be limited to those permitted by this Agreement or as otherwise agreed to in writing by the parties.

## 9. LEGAL AUTHORITY

The Agency represents and warrants that it has the authority to enter into this Agreement and that by doing so, it does not cause either party to violate any laws, including any applicable fraud and abuse or privacy statutes.

## 10. GENERAL PROVISIONS

### 10.1 Notices

All notices or other communications required or permitted hereunder shall be in writing and shall be delivered personally, by commercial overnight delivery service, by facsimile or sent by certified, registered or express air mail, postage prepaid, and shall be deemed given when so delivered personally, by overnight delivery service or by facsimile, or if mailed, five (5) days after the date of mailing, addressed as follows:

To ITG

Integrated Therapeutics Group, Inc.  
2000 Galloping Hill Road K-6-2, 2385  
Kenilworth, New Jersey 07033  
Attention: C. Dutch,  
Manager Health Management Operations

To The Agency

Agency for Health Care Administration  
Medicaid Program Development  
2727 Mahan Drive  
Bldg. 3, Room 2223B  
Tallahassee, Florida 32308  
Attention: Charles Kight  
AHCA Administrator

or to such other address as either party shall designate by like notice to the other party.

### 10.2 Force Majeure

Noncompliance with the obligations of this Agreement due to force majeure, laws or regulations of any government, war, civil commotion, destruction of production facilities and materials, fire earthquake or storm, labor disturbances, shortage of materials, failure of public utilities or common carriers, and any other causes beyond the reasonable control of the applicable party, shall not constitute breach of contract.

### **10.3 Non-Assignment**

Neither Party shall have the right to assign this Agreement to a third party without the prior written consent of the other party, which consent shall not be unreasonably withheld; provided, however, that ITG may assign this Agreement to its subsidiaries or affiliates. Any permitted assignee shall assume all obligations of its assignor under this Agreement. No assignment shall relieve either Party of responsibility for the performance of any obligations which have already accrued. This Agreement shall inure to the benefit of and be binding upon each Party, its respective successors and permitted assigns.

### **10.4 Invalidity/Governing Law**

If any provision of this Agreement is finally declared or found to be illegal or unenforceable by a court of competent jurisdiction, both Parties shall be relieved of all obligations arising under such provision, but if capable of performance, the remainder of this Agreement shall not be affected by such declaration or finding. This Agreement shall be governed by applicable laws of the State of New Jersey.

### **10.5 Indemnification**

ITG agrees to indemnify and hold The Agency, its officers, directors, agents and employees harmless from and against any and all liabilities, losses, proceedings, actions, damages, claims or expenses of any kind, including reasonable attorney's fees which result from the negligence or willful acts or omissions by ITG, its agents, directors, officers, or employees in connection with the representations, duties and obligations of ITG set forth in section 5 of this Agreement regarding confidentiality of patient information.

### **10.6 Counterparts/Entire Agreement**

This Agreement may be executed in counterparts, each of which shall be deemed to be an original, but all of which together shall constitute one and the same Agreement. This Agreement states the entire agreement and understanding of the parties with respect to the subject matter set forth herein, all prior and contemporaneous oral and written agreements and discussions being merged herein.

### **10.7 Rules of Construction**

Unless the context of use indicates another or different meaning or intent, the following rules shall apply to the construction of this Agreement: (i) words importing the singular number shall include the plural number and vice versa; (ii) the words "hereof," "herein," "hereto" and other words of similar import refer to this Agreement as a whole; and (iii) unless otherwise defined therein, all terms defined in this Agreement shall have the meanings assigned to such terms herein when used in any certificate, document or other instrument made or delivered in connection herewith or pursuant hereto.

## 11. FEES AND CLAIMS

ITG will not charge a fee to provide disease management services to Asthmatics. The Agency will continue to pay submitted Medicaid fee-for-service claims through its fiscal agent for ITG-enrolled Recipients at no risk to ITG. The Agency will reimburse Medicaid providers only for those services identified as compensable in the program specific Coverage and Service Limitations Handbook.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date last set forth below.

The Agency for Health Care Administration

By: Richard T. Lutz  
Name: Richard T. Lutz  
Title: Director State Health Purchasing  
Date:

Integrated Therapeutics Group, Inc.

By: Roch Doliveux  
Name: Roch Doliveux  
Title: CEO  
Date:



**Exhibit A**  
**to Asthma Disease Management Agreement**

**ASTHMATIC DEFINITION**

An Asthmatic is defined as a MediPass Recipient or an Eligible Non-MediPass Recipient if his/her primary or secondary diagnosis is ICD-9 codes 493.0-493.9 (493.0 Extrinsic asthma, 493.1 Intrinsic asthma, 493.2 Chronic obstructive asthma, 493.9 asthma, unspecified), or the applicable asthma codes in future coding standards, as appears in the claim utilization data for that person. If any such Asthmatics have claims indicating Chronic Obstructive Pulmonary Disease, Bronchiectasis, Chronic Adult Bronchitis, Cystic Fibrosis and/or other serious non-asthma respiratory conditions, then starting in the year the diagnosis is made, such individuals will be permanently deemed excluded from the definition of "Asthmatic."

**Exhibit B**  
**to Asthma Disease Management Agreement**

**RECOMMENDED TREATMENTS AND FORMULARY**

The Agency shall define and deliver to ITG a copy of the Guidelines within thirty (30) days after the Effective Date of this Agreement.

The Agency shall cause the products to be used in the implementation of the Guidelines to be listed on the state's formulary with an open and unrestricted status. The formulary will directly reflect the recommended interventions noted in the Guidelines. The formulary shall include the following therapy classes: anti-inflammatory, beta agonist, antihistamine, antihistamine decongestant and antibiotics.

**Exhibit C**  
**to Asthma Disease Management Agreement**

**PROGRAM COMPONENTS**

The Program components will include severity and risk assessments of the patient and interventions designed to improve compliance and prevent acute events. Baseline assessments should consist of identifying patients with asthma from claims data, stratification of patients into severity levels (for example, mild, moderate or severe), and verification of the diagnosis of asthma for patients in the severe category.

Interventions will include implementation of standard clinical guidelines for recommended treatments for asthma, specific to that patient's severity and/or risk level. These interventions will also include patient and provider education focusing on self-management by the patient. Also included will be outcome measures with feedback to providers and patients on a scheduled basis.

ITG's intervention model will include a method for:

- defining patient severity/acuity levels;
- disseminating treatment protocols to providers, and educational materials to recipients and providers;
- demonstrating improvement in provider compliance in delivering care congruent with the protocols;
- demonstrating improvement in compliance with receiving care congruent with the protocols;
- monitoring patient outcomes and patient satisfaction associated with the protocol driven care;
- providing reports to targeted providers and patients for continuous compliance improvement; and
- providing reports to The Agency.

**Physician Services**

In order to ensure high-quality and cost effective care, ITG shall provide Florida Medicaid providers and specialty physicians with educational information regarding treatment guidelines (best practices).

Physician services will include:

- education on treatment guidelines to all targeted physicians and specialists;
- assistance in developing appropriate recipient care plans; and
- feedback on monitoring of recipient participation.

The Agency is currently developing several advanced multi-media tools to aid in physician and recipient education regarding best practices and compliance with a plan of care that reflects these guidelines. ITG will examine these tools upon their completion and testing in both individualized and group learning situations and determine whether such tools can be incorporated into the Program. One example of the tools being developed is an interactive CD-ROM program that is designed for use with asthmatics and their providers.

#### Patient Services

Most intervention efforts will be targeted to those who are identified as high utilizers or potential high utilizers as predicted with ITG's FutureMetrics analytical tool. Care management shall begin with an initial assessment and risk screening. Based on the findings of the assessment, the patient will be categorized by severity level. The Agency is expecting that the majority of individualized interventions and outreach ventures will be focused on those Asthmatics who are in the moderate to severe levels or the "high utilizers". Care plan development will be done for those targeted Asthmatics categorized as "severe" and will be accomplished through a coordinated effort involving the patient and/or the patient's family, ITG's care management team, and the Medicaid primary care provider and specialty provider(s), and will include face to face interaction where appropriate. Individualized patient education is a necessary component of disease management and should be derived from the care plan. ITG will use care managers with experience and training in asthma for targeted or selected Asthmatics. These are managers who will coordinate services across the full continuum of care. This Program will be physician driven and nurse or pharmacist managed.

Patient services will include:

- Individualized patient care plans that describe care delivery options, interventions, and methods across the entire care continuum which are to be utilized by the entire multidisciplinary team. Care plans will be prepared for those targeted Asthmatics in the "severe" categories when the baseline assessment is performed.
- Individualized patient education and monitoring in which care managers will teach targeted patients and/or their caregivers about the special needs brought about by their disease. In addition, qualified staff will be available to answer the questions of Asthmatics and their physicians. Targeted Asthmatics and their physicians shall have access twenty-four (24) hours a day, seven (7) days

a week through a toll-free telephone number set up to handle these situations. The staff used shall be culturally sensitive and have multi-lingual capabilities when necessary. ITG may also utilize a translator service.

- The utilization of the Patient Learning System with Asthmatics, including the INSPIRE and SUPERCHAMPS education programs.
- Community outreach efforts which employ the use of the Asthma Fiestas. The Asthmatics enrolled in the Program will be specifically invited to these Asthma Fiestas when held in a location near the individual.
- Patient newsletters and/or supplementary educational materials specific to the asthma disease process, current treatments and other relevant information. Written materials shall be at or near the fourth grade comprehension level and designed so that at least 90 percent (90%) of the affected population can be expected to understand the materials presented. The materials provided will therefore need to be printed in Spanish and/or Haitian Creole for some areas of the state.
- Routine phone follow-up to monitor the status of targeted Asthmatics. The frequency of contact will be driven by the severity or acuity of the patient's medical status as described as follows: (a) *acute* - weekly contacts, (b) *moderate* - driven largely on an individual basis, it is suggested that it be done no less than once per month, but not required, and (c) *mild/stable* - monthly to quarterly contacts are suggested but not required.
- Support during hospitalization: ITG will make every effort to learn about hospitalization of Asthmatics stratified in the "severe" category. When notified of an admission of an individual in the "severe" category, care managers will work with hospital staff to review all hospital medical records, modify and update patients' individualized care plans, and facilitate appropriate and timely discharge planning. Care management staff will make on-site visits with patients and the hospital support team as indicated.
- Additional face-to-face visits with patients or their caregivers as needed.

The following descriptions are of the tools and interventions to be made available to Asthmatics through this Program. A brief description of each component developed by ITG follows:

♦ Analytics

- FutureMetrics
- CareMetrics
- Patient Needs Assessment
- Outcomes Measurements
- Program Performance Reporting

- ◆ Asthma Adventure Fiestas
  - INSPIRE
  - SUPERCHAMPS
- ◆ Health Management Program Coordinators

### Analytics

ITG will analyze the most current 24 months of pharmacy and medical claims level data to provide The Agency an in-depth understanding of the provider and patient-specific factors, which influence asthma utilization/costs. The analysis will target patients, as well as providers, and specific treatment profiles.

- FutureMetrics (Predictive Model) - A multivariate regression model which predicts patients who will be the high utilizers in the coming year, thereby allowing the intervention efforts to be focused more efficiently.
- CareMetrics - This flexible analytic tool is designed to identify subgroups of Asthmatics who have one or more issues with their care. The process facilitates the design and implementation of interventions to fit specific needs of various patient clusters identified in CareMetrics. The benefit for The Agency is greater efficiency in the implementation of the Program.
- Patient Needs Assessment - The Patient Needs Assessment is a survey instrument used for certain patients who have a high probability of having significant utilization in the coming year and/or fall into selected CareMetrics Patterns. This survey tool helps clarify the asthma-related needs of the high-risk patients and allows for more accurate targeting of interventions.
- Outcomes Measurements - Outcomes Measurement encompasses economic, clinical, satisfaction, and quality of life ("QOL") measures across the enrolled population. The strategy for assessing health in the enrolled population is designed to capture trended demographic data from both administrative (medical and pharmacy claims data) as well as self-reported information and disease specific content areas including health status and health risk exposures or behaviors.

Among the methodologies used for non-financial information is ITG's proprietary Quality Assessment System ("QAS"). A critical aspect of measuring quality revolves around patients' experiences and their perception of their health related quality of life, their satisfaction with access to and the provision of care, and their attitudes and knowledge about their disease and treatment. These validated measurement tools establish baselines and monitor patient perceptions of health-related quality of life, satisfaction with care, knowledge of the disease, and adherence to management plans.

When combined with the financial and clinical measurement, QAS provides a longitudinal profile for performance measurement that helps address the NCQA/HEDIS quality improvement requirements.

QAS provides the ability to obtain patient centered outcomes and quality indicators through a seamless data collection and reporting system for both adults and/or children. The system is designed to provide aggregate reports for population based assessments of programs or individual patient level reports as desired. QAS is offered to complement The Agency's ongoing efforts in this area.

### Asthma Adventure Fiestas

An Asthma Adventure Fiesta is similar to an open-house carnival only this carnival is for allergy/asthma patients, their family and friends. The fiesta is designed to provide an environment where attendees will learn about proper asthma management in a fun, interactive manner. The success of the fiestas, based on ITG's existing template and process, is a proven approach to maximizing attendance.

Adventure Fiestas will be held in community centers, church halls, school gymnasiums and hospitals. All those who enter will be known as Asthma Adventurers. Asthma educators will be known as Asthma Guides. Being an open house, Asthma Adventurers can come at any time between the opening and closing hours.

The first thing Asthma Adventurers will see as they enter a Fiesta is an opening video explaining the Adventure Fiesta. Those ages 13 and older will fill out a baseline questionnaire about their or their child's asthma. Children ages 12 and under will receive an activity book and crayons in the Funzone while the adults fill out the questionnaire. After completing the questionnaire, adults will pick up the children in the Funzone to go to the Asthma Adventure Starting Point where they will meet their Asthma Guide. Once approximately eight (8) Adventurers (max. 5 adults) have gathered, the Asthma Guide will start the Asthma Adventure at Site #1.

There are eight (8) Adventure sites, and approximately 10 minutes will be spent at each site learning something new about proper asthma management. At each site there are interactive demonstrations allowing the Asthma Adventurers to participate. Before moving on to the next site, the Asthma Guide will punch a hole in each Asthma Adventurer's "passport". After all eight (8) sites are visited, the Asthma Adventurers will be asked to fill out a survey about the Fiestas. Participants receive an Asthma Adventurer Certificate from their Asthma Guide and turn in their passports to receive gifts. Participants can sit down for the Fiesta finale and get food and drinks. A physician is present at the Doctor's Booth to answer attendees' questions about allergy, asthma and/or get and Inspirease spacer.

The Patient Learning System used in Asthma Adventure Fiestas contains multiple components including interactive patient education and extensive educational support materials. ITG will provide The Agency extensive support material and interventions

designed to achieve the goals of the program. Intervention materials will be developed for patients as well as for targeted providers.

INSPIRE and SUPERCHAMPS are comprehensive education programs that empower patients to manage their own asthma.

- Using integrated print and video materials that feature real patient success stories, the INSPIRE Program motivates and encourages the adolescent or adult patient to accept responsibility for the management of their own disease. Patients are instructed on use of such aids as peak flow monitoring, inhaler administration, and trigger avoidance to better help them manage their asthma. Adult patients may receive the following from attending an Asthma Adventure Fiesta session:

- ◊ Asthma Patient Guide
- ◊ Asthma Co-Management Booklet
- ◊ Peak Flow Meter
- ◊ Asthma Diary
- ◊ List of Asthma Resources
- ◊ Chart Recording Form
- ◊ Pre and Post Seminar Test

- SUPERCHAMPS is a unique comprehensive pediatric learning system that has been built upon the body of evidence surrounding child development patterns and learning techniques. The Program has been designed and written with the support and review of a broadly experienced advisory group that includes physicians, educators, child development specialists, and parents of children with asthma. SUPERCHAMPS sets specific goals to make asthma education a process whereby the child is taught to gradually accept responsibility for self-management of their disease. It is age/development appropriate curriculum that makes use of multimedia educational tools to provide the education and health management skills for the 2-6 year old patient, the 7-12 year old, and the 13-16 year old patient. SUPERCHAMPS recognizes successful asthma education should focus on behavior change, be experiential, be active, and engage the whole person. Each pediatric patient attending an Asthma Adventure Fiesta session may receive:

- ◊ Asthma STUFF home asthma center Asthma INFO - diary, personal plan, Barriers to Success, Emergency Card
- ◊ Rory, The Lion puppet and storybook for young children
- ◊ Asthma Kit personal organizer for school age children and preteens
- ◊ Age appropriate Asthma Home Video

### Health Management Program Coordinators

A key element of a successful Disease Management initiative is direct, frequent communication with physicians. The most effective method of impacting physician behavior is through one on one consultation on a routine basis. ITG will commit a group of highly trained Health Management Program Coordinators ("HMPCs") to deliver one on one consultation with targeted Medicaid physicians. ITG's HMPCs are accredited by the University of Wisconsin School of Medicine on the NIH/NHLBI Asthma Guidelines. HMPCs will deliver an Agency approved "best clinical pathway" message to targeted providers. The specific role of the field coordinators in the asthma program may include the following:

1. Provide an overview to targeted physicians of the Program for Asthmatics living with asthma on the first visits, including a review of the goals, strategies, action steps and interventions/resources.
2. Reinforce the "best practice" guidelines selected by The Agency via a Guidelines Visual Aid.
3. Provide physicians with educational resources for Asthmatics that have had an ER visit or hospitalization.
4. Provide physicians with data analysis results including medication utilization information and ER/hospitalizations utilization. Patient confidentiality is ensured throughout the process.
5. Review educational resources with provider and staff.
6. Provide the Asthma Lifestyle Video Series for targeted providers/sites.
7. Encourage the provider to refer appropriate patients for enrollment into the program and to the Asthma Adventure Fiestas.
8. Survey providers for their input/thoughts on the program. Survey results will be shared with The Agency.
9. The HMPCs will be trained in a two-day meeting reinforcing the program direction. Agency staff is encouraged to attend this meeting.
10. Quarterly direction meeting will be held with the HMPCs. The Agency will receive quarterly reporting on the percentage of providers and staff seen as well as comments on the Program

**Exhibit D**  
**to Asthma Disease Management Agreement**

**RESPONSIBILITIES OF THE PARTIES**

The responsibilities of the parties under the Program will include, without limitation, the following:

**AGENCY RESPONSIBILITIES**

1. Approval of asthma Disease Management treatment guidelines.
2. Ongoing communication to physician providers related to the availability of the program to their Asthmatics.
3. Provide and periodically revise a suggested list of appropriate sites that may be used for provider and/or patient education.
4. Other responsibilities will be mutually agreed upon as needed.

**ITG RESPONSIBILITIES**

1. Provision of Program presentations to targeted physicians.
2. Ongoing analysis to target intervention opportunities.
3. Provision of feedback reports to The Agency on ITG contacts with targeted physicians.
4. Timely, accurate reporting.
5. Case management services for targeted patients categorized as "severe" or "high risk".
6. Provision of tools and resources for the Program, which would include the following:
  - Treatment Guidelines to all targeted physicians.
  - ITG's validated analytical tools: FutureMetrics used in identifying future high risk patients for interventions and CareMetrics used in aligning program interventions to individual patient care issues.

- Outcomes measurement tool to measure the improvement in patients' symptoms, quality of life and satisfaction with care and ongoing analysis and feedback of the measurements.
- Asthma patient education brochures.
- Asthma education materials.

7. Provision of "Asthma Adventure Fiestas" for the education of all Asthmatics:

- Community based education setting for asthmatics and their families.
- Patient education materials: Asthma Control Kits and Peak Flow Meters.
- Training and education materials for adult and pediatric Asthmatics.
- Age specific interventions including INSPIRE and SUPERCHAMPS.

8. Commitment of appropriate professional field staff to consult with The Agency's providers on the Program, including education of NHLBI's asthma treatment guidelines, and insurance of comprehensive training of those consultants delivering the Program message.

9. Other responsibilities as mutually agreed upon.

**Exhibit E**  
**to Asthma Disease Management Agreement**

**REPORTING REQUIREMENTS**

Within seven (7) days of executing this Agreement, ITG and The Agency shall designate contact persons for management information issues ("ITG MIS Contact Person" and "Agency MIS Contact Person", respectively). The ITG MIS Contact Person and The Agency MIS Contact Person shall confer to finalize file types and file layouts for transmission of data prior to initiating work under this Agreement.

**ITG Reporting Responsibilities**

Quarterly and annual reports that document disease management outcomes and process measures: Quarterly reports that depend on semi-annual data from The Agency will be submitted to The Agency semi-annually by quarter. These quarterly and annual reports will include:

- results of baseline patient satisfaction surveys for new enrollees and Asthma Fiesta participants
- enrollment/disenrollment data for patients in the care management program
- number of patients in each severity level
- migration of patients between severity levels
- number of emergency room visits by severity level
- number of inpatient hospital days by severity level
- number of hospital readmissions by severity level
- clinical outcome measures as described below
- summary of all Asthma Fiestas, including date, location, and number of participants
- schedule for Asthma Fiestas planned for the next quarter
- number of recipient contacts by method of contact for patients categorized as "severe"
- annual reports on case studies
- annual reports on the results of satisfaction surveys for recipients enrolled for at least six months

After the initial satisfaction survey, an Asthmatic must be enrolled in the Program a minimum of six (6) months to be included in the end of year satisfaction survey. The following four (4) clinical outcome measurements must also be included:

- The increase in the average number of prescriptions for inhaled corticosteroid use

- Inhaled corticosteroid use
- The increase in the distribution of peak flow meters and completion of action plans
- To the best extent possible, tracking the pulmonary function rates of asthma patients. ITG may use a sample or targeted population for this report if gathering the necessary information from the entire population proves unfeasible.

ITG may have additional outcome and process measures in place or develop measures beyond those required by The Agency. For example, ITG may also include outcome measurements which encompass economic, clinical, satisfaction, and quality of life measures across the enrolled population. ITG will measure the quality of care outcomes to ensure that identified intervention opportunities, specific protocols, treatment guidelines and critical pathways have been followed to the greatest extent possible. The Agency will also provide data to ITG to assist in tracking outcome and process measures as described below.

#### Agency Reporting Responsibilities

The Agency will provide the following information to ITG:

- monthly list of eligible MediPass Recipients, including their names and assigned MediPass providers' names and telephone numbers. This report will also include paid claims data for the MediPass Recipients on the list.
- monthly list of Eligible Non-MediPass Recipients including names and Medicaid providers' names and telephone numbers, when appropriate
- quarterly paid claims information on all ITG-enrolled recipients, including hospitalizations, rehospitalizations, length of stay and emergency room utilization.
- The Agency shall provide comprehensive medical and pharmacy claims data for Asthmatics for the most recent twenty-four (24) month period available followed by the most recent rolling twenty-four (24) month period every six (6) months during the term of the agreement. Periods shall be aligned with calendar quarters. The data should represent fairly complete utilization and cost information, i.e., at least ninety-five percent (95%) of the total incurred payments for the most recent quarter available.

### Data Use and Disclosure

1. The Agency shall maintain ownership of the datasets and all patient records used in this Project.
2. All datasets and reports shall be returned to The Agency upon request.
3. No data (such as utilization and trends) shall be disseminated or published without the expressed written consent of The Agency.
4. The Agency will be allowed to request and receive ad hoc reports and data samples for analysis, as needed.
5. ITG may not use patient level data for marketing purposes without the expressed written consent of The Agency.
6. The data are to be used solely for this Program, subject to the provisions set forth in Article 5.

### Cost and Utilization Reporting

The Agency shall provide to ITG comprehensive medical and pharmacy claims data for at least the twenty-four (24) month period prior to the Program Initiation Date, and no longer than each subsequent six (6) month anniversary thereof. Earlier twenty-four (24) month data sets will be provided to assist in the developing of baseline and targeting criteria. Since data is provided on a lagged basis due to claims adjudication, both parties will address the dates of data prior to transmission. At The Agency's request, ITG shall offer guidance to The Agency in providing such data. The Agency represents and warrants that, to the best of its knowledge, all past, present, and future data provided to ITG reflects, or will reflect, The Agency's actual experience with respect to the costs associated with asthma treatment for the applicable periods and The Agency will advise ITG of changes in claim processing or benefit design that impact such data.

Virginia

VA's

## Additional Background from ~~VA's~~ Medicaid Disease Management Programs

### Virginia's Asthma DM Pilot Project

- VA implemented a small pilot project two years ago to train 60 Medicaid primary care physicians in appropriate clinical pathways (ie best practices) for the treatment of asthma. Training sessions lasted 6 ½ hours. VA found that the pilot project reduced the number of emergency room visits, suggesting improved quality of care and life for patients. The pilot also saved money (actual results forthcoming).
- VA Implemented only in fee for service Medicaid, because the state was able to track historical FFS claims and target doctors who treated many Medicaid asthma patients. Managed care organizations were excluded because the state does not get sufficient encounter data to track disease specific treatment and claims.
- VA found that ~~FFS~~ Medicaid is an ideal place to implement DM programs because there is a high incidence of sick patients, and there is an abundance of demographic and epidemiological data for studies. State could also easily track expenditures for disease related claims through FFS Medicaid and measure hospitalization rates and DM savings results.
- VA use no state or Federal funds for the pilot. Program was paid for by "NPC" an association of pharmaceutical companies and the Medical College of VA.
- VA experienced encouragement from HCFA and advocacy organizations, and perceives no Federal barriers to implementing programs like this one in other states. VA had strong support of physicians who participated -- 95% reported to be pleased with the program. Believes that information dissemination about DM would be the best way to encourage other states to implement.
- Now contracting with "Health Information Systems" to implement statewide and for additional chronic diseases (cardiovascular, diabetes). Virginia will receive federal financial participation for the statewide program. VA expects to accomplish this through its state plan without a waiver of Medicaid.
- Georgia, West Virginia, and Alabama are interested in DM programs, and are meeting with VA to discuss its program.

Has HHS considered partnering w/ pharmaceutical cos to offset the cost of the initiative?

VA's

MISSISSIPPI

## News

*Continued from page 1236*

tious practice policy that allows individual health care providers to decline participation in assisted suicide, abortion, and withdrawal of life-sustaining measures.

The policy on assisted suicide gives attending faculty physicians the primary responsibility for coordinating and implementing the procedure. The physician must contact the OHSU patient advocate, who will coordinate patient

care and confidentiality needs but "shall not personally participate. . . ."

"These are outpatient events," said Roy Magnusson, M.D., OHSU director of medical services and residency training programs. If a hospitalized patient requested assisted suicide, the hospital would try to arrange for the patient's discharge to home or hospice care, Magnusson said. According to Ryan, "Assisted suicide has not yet occurred inside the hospital."

The procedure allows medication to be obtained from the hospital pharmacy. The OHSU patient advocate "contacts willing pharmacy/pharmacist to arrange for filling the prescription." The pharmacist "fills prescription without using online billing mechanism" and "dispenses medication to physician or physician's agent." The physician "dispenses medication to patient and provides instructions for use."

"Our policy and procedure

is actually more restrictive than what the law requires," said Ryan, "and it was intended that way so that confidentiality of all participants is maintained one from another. The pharmacist is the only person who knows everyone [involved]." She confirmed that the policy and procedure has been used.

—Nancy Tarleton Landis

## Medicaid to pay Mississippi pharmacists for disease management

### State board deliberates credentialing process

Mississippi has broken new ground by becoming the first state to pay pharmacists for disease management visits with Medicaid patients. Eligible pharmacists will receive \$20 for each 15–30 minute visit for the management of diabetes mellitus, asthma, hyperlipidemia, or coagulation disorders.

In March the Health Care Financing Administration (HCFA), which oversees Medicaid, approved an amendment to the state Medicaid plan to include payment for disease management services by "credentialled" pharmacists. The program was presented to HCFA as a way of achieving cost-effective, high-quality care—and will be closely watched by the state Medicaid program for evidence that it is cost-effective.

Pharmacists will provide disease management serv-

ices under protocol for patients referred by their physicians. The pharmacist will evaluate the patient, review drug therapy with the physician, and educate the patient about management of the disease and adherence to the drug regimen. According to the Medicaid plan, "The involvement with the patient and the education of the patient about lifestyle changes and improved drug regimen compliance are aimed at reduction of or avoidance of costly hospitalizations and emergency care."

Medicaid will pay pharmacists for a maximum of 12 visits per patient per year, including visits for any of the covered diseases the patient may have. There is no limit on the number of patients per pharmacist.

"Pharmacy care records" are to include progress notes and laboratory data.

These records must be provided to the physician and available to the state Medicaid plan. The pharmacist must have a private area for patients' disease management visits. Each qualified pharmacist will have a provider number for billing Medicaid.

To qualify, the pharmacist must have completed a disease-specific certification program approved by the state board of pharmacy. Graduates of six-year Pharm.D. degree programs are considered certified for two years but thereafter must—like the non-Pharm.D. pharmacists—become recertified every two years.

On May 4, Mississippi board of pharmacy and Medicaid officials met with representatives of national pharmacy associations (including ASHP), drugstore chains, pharmacy schools, and insurers to explain the

program and tackle questions about standards for disease-specific certification. H. Joseph Byrd, Pharm.D., FASHP, Chairman and Professor of Clinical Pharmacy Practice, School of Pharmacy, University of Mississippi, worked closely with Medicaid officials on the waiver for payment to pharmacists. At the meeting, Byrd outlined the approach taken to gain the waiver and the elements of pharmacist disease management described in the waiver. He noted that the new language about payment to pharmacists was added to a section of the state Medicaid plan that describes services by nonphysicians ("other practitioners' services") and drafted to specifically cover "disease management services" rather than "cognitive services."

William L. "Buck"

Stevens, executive director of the state board of pharmacy, told meeting attendees that pharmacist provider numbers were expected to be issued by July 1. Therefore, the state needed to quickly establish a procedure

more re-  
hat the law  
yan, "and  
that way so  
lity of all  
aintained  
er. The  
e only per-  
everyone  
confirmed  
nd proce-  
ed.

rleton Landis

ess through which a phar-  
macist can obtain the dis-  
ease-specific certifications.  
Stevens said the process  
should be accessible (e.g.,  
should involve home study

and use of the Internet), af-  
fordable (costing no more  
than \$150), and portable—  
for potential use in other  
states.

Certification for each of

the four diseases would in-  
volve an exam and a skills  
workshop. The National As-  
sociation of Boards of Phar-  
macy was represented at  
the May 4 meeting and

proposed to provide Missis-  
sippi with an assessment  
mechanism within one  
month. ■

## FDA proposes rules for health claims on dietary supplements

A proposed rule from  
FDA attempts to differ-  
entiate the types of health  
claims allowable for herbal  
products, vitamins, and  
other types of dietary sup-  
plements from those per-  
mitted drug manufacturers.  
According to FDA, the in-  
tent is to make the labeling  
of dietary supplements  
more informative, reliable,  
and uniform. The rule  
would not affect the avail-  
ability of dietary supple-  
ments or consumers' access  
to them.

The distinction between  
a drug and a dietary supple-  
ment became blurred after  
the Dietary Supplement  
Health and Education Act of  
1994 was passed. This  
Act permitted manufactur-  
ers of dietary supplements  
to make claims about their  
products that had previous-  
ly been allowed only for  
drugs. They were author-  
ized to describe how the in-  
gredients of their products  
affect the structure and  
functioning of the body  
but were prohibited from  
claiming that their prod-  
ucts could treat, diagnose,  
cure, or prevent disease.

The proposed FDA rule is  
an attempt to draw a line  
between "disease" claims  
and "structure or function"  
claims. Because diseases af-  
fect the structure or func-  
tion of the body and the  
products (drugs) given to  
treat or prevent disease can  
be described in terms of

their effects on structure  
and function, the act au-  
thorizes dietary supplement  
manufacturers to make

only those structure and  
function claims that are  
not also disease claims. The  
distinction is more than a

matter of semantics, since  
dietary supplements can be  
brought to market more  
easily than drugs and they

### Examples of Claims That Would and Would Not Be Permitted for Dietary Supplements, Along with FDA's Reasoning

#### Not Permitted

"This supplement improves the structure and function of the heart, thereby reducing the risk of heart disease." (The claim is a disease claim because it states that the supplement can prevent or cure a disease.)

"This supplement improves the structure and function of the heart, thereby reducing the risk of heart disease." (The claim is a disease claim because it states that the supplement can prevent or cure a disease.)

"This supplement improves the structure and function of the heart, thereby reducing the risk of heart disease." (The claim is a disease claim because it states that the supplement can prevent or cure a disease.)

"This supplement improves the structure and function of the heart, thereby reducing the risk of heart disease." (The claim is a disease claim because it states that the supplement can prevent or cure a disease.)

"This supplement improves the structure and function of the heart, thereby reducing the risk of heart disease." (The claim is a disease claim because it states that the supplement can prevent or cure a disease.)

"This supplement improves the structure and function of the heart, thereby reducing the risk of heart disease." (The claim is a disease claim because it states that the supplement can prevent or cure a disease.)

#### Permitted

"This supplement improves the structure and function of the heart, thereby reducing the risk of heart disease." (The claim is a structure or function claim because it states that the supplement can improve the structure and function of the heart.)

"This supplement improves the structure and function of the heart, thereby reducing the risk of heart disease." (The claim is a structure or function claim because it states that the supplement can improve the structure and function of the heart.)

"This supplement improves the structure and function of the heart, thereby reducing the risk of heart disease." (The claim is a structure or function claim because it states that the supplement can improve the structure and function of the heart.)

"This supplement improves the structure and function of the heart, thereby reducing the risk of heart disease." (The claim is a structure or function claim because it states that the supplement can improve the structure and function of the heart.)

"This supplement improves the structure and function of the heart, thereby reducing the risk of heart disease." (The claim is a structure or function claim because it states that the supplement can improve the structure and function of the heart.)

"This supplement improves the structure and function of the heart, thereby reducing the risk of heart disease." (The claim is a structure or function claim because it states that the supplement can improve the structure and function of the heart.)

*The web resource for Biologic Oncology*

**Click  
here**

## **Medscape**

Search for "(DISEASE MANAGEMENT)" in  
Medscape's free Full-Text Articles or the Medscape Bookstore

### **Title**

Economic evaluation of pharmacist involvement in *disease* management in a community pharmacy setting.

### **Author**

Munroe WP; Kunz K; Dalmady-Israel C; Potter L; Schonfeld WH

### **Address**

MedOutcomes, Inc., Richmond, Virginia, USA.

### **Source**

Clin Ther, 19(1):113-23 1997 Jan-Feb

### **Abstract**

This study evaluated the economic impact of patient-focused pharmacist intervention in the community retail setting in patients with hypertension, diabetes, asthma, and/or hypercholesterolemia. Specially trained pharmacists intervened by providing targeted patient education, performing systematic patient monitoring, offering feedback and behavior modification, and communicating regularly with patients' physicians to enable early intervention for drug-related problems. We evaluated prescription drug costs and total medical costs by comparing claims data from 188 patients enrolled in the program at three intervention pharmacies with data from 401 control patients at five nonparticipating pharmacies from the same retail chain. For all *disease* states, the average cost per prescription was significantly higher in the group receiving intervention than in the control group. Differences in total monthly prescription costs were significant only for patients with asthma, with higher monthly costs in the group receiving intervention. Substantial savings were demonstrated across all cost analyses for total monthly medical costs. Savings ranged from a conservative estimate of \$143.95 per patient per month to \$293.39 per patient per month when accounting for the possible influence of age, comorbid conditions, and *disease* severity. Our data indicate that pharmacist intervention in this community pharmacy-based *disease* management model substantially reduced monthly health care costs in patients with hypertension, hypercholesterolemia, diabetes, and asthma.

### **Language**

Eng

### **Unique Identifier**

97237235

### **MESH Headings**

Aged ; Community Pharmacy Services \*EC/\*OG ; Comparative Study ; Economics, Pharmaceutical \* ; Female ; Health Care Costs ; Human ; Male ; Middle Age ; Patient Education ; Prescription Fees \* ; Support, Non-U.S. Gov't