State of Maine
Department of Health and Human Services

Partnership for a Tobacco Free Maine,
Maine Center for Disease Control and Prevention
and
Office of MaineCare Services

Preliminary Report
on
Resolve, Regarding Tobacco Cessation and Treatment

January 15, 2008

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Executive Summary

Resolve 2007, c. 34 ("Resolve, Regarding Tobacco Cessation and Treatment") directed the Department of Health and Human Services to "undertake a study of best practice ("best practice") treatment and clinical practice guidelines for tobacco cessation treatment" and to "use the most recent available clinical practice guidelines ("Guidelines") of the U.S. Department of Health and Human Services Public Health Service".

The study would include development of a model tobacco cessation treatment program for use in the public sector and private sector and was to be conducted by the Partnership For A Tobacco-Free Maine ("PTM"), Maine Center for Disease Control and Prevention ("ME CDC") and the Office of MaineCare Services ("OMS"). PTM and OMS were required to report back to the Joint Standing Committee on Health and Human services ("the Committee") by January 15, 2008.

A study workgroup was convened in the summer of 2007 by PTM and OMS; a great deal of research, information exchange and four meetings of policy level staff occurred over the course of the past five months.

There was consensus among members of the workgroup, given the broad and comprehensive charge of the Resolve, that there was sufficient time to address tobacco dependence treatment in the public sector only by January 15, 2008. Additional time is needed to

1) further explore and develop preliminary proposals (outlined below);
2) proactively engage interested parties within the private sector, including tobacco treatment payers, such as insurers and large employers with self funded plans, as well as provider representatives, in collaborative efforts and development of a model program.

The Department therefore provides this report on a preliminary basis and recommends that the Committee require a final report back by December 15, 2008.

The following is a summary of the study, model program and preliminary proposals:

1) **Costs**

Costs include direct health care 'smoking attributable' costs paid by OMS ($216 million/year); prevention costs to eliminate tobacco addiction paid by PTM ($3 million/year; $.236 million of which are federal funds) and by OMS ($1.4 million/year; $.844 million of which are federal matching funds). Private insurance claims paid for tobacco dependence treatment were ($14 million/year for counseling; $3 million for pharmacotherapy). Cost savings five years after 50% of current smokers who are MaineCare members quit: $47 million.

PTM has determined that it can implement the proposals outline below within existing budgetary resources. OMS has determined that proposals 5 and 6 below will have a fiscal impact on existing resources with the Department. The extent of the impact is not yet known but will be explored as additional information is compiled and an analysis is conducted.

2) **Guidelines**

Guidelines, including a draft update, were reviewed. System strategy interventions recommended:

1. Identification of tobacco users and intervention at every visit in every practice
2. Providers are given education, resources and feedback to help them intervene
3. Provider practice staff are dedicated to provide treatment and that treatment is assessed
4. Counseling and pharmacotherapy are paid services for all members of health plans and
5. Clinicians and specialists are reimbursed for effective treatment.

- PTM incorporates these strategies in its approach. PTM has a limited ability to require clinicians, other than Helpline clinicians, to adopt strategies and does not bear sole responsibility for financing all tobacco dependence treatment—counseling and pharmacotherapy- for uninsured or under-insured tobacco users who want to quit in Maine.

- OMS reimburses clinicians and MaineCare members for counseling and pharmacotherapy on a limited basis. PTM provides free counseling for smokers who are MaineCare members (and for the insured, under-insured and uninsured) who call the Helpline and provides free NRT vouchers through the Helpline for eligible callers (also distributed to eligible patients by rural health centers)

- OMS does not currently address Guideline recommendations (1) and (2) but has proposed doing so (see preliminary proposals 1 and 2, below). Implementation of these recommendations as outlined in the proposals will encourage primary care physicians to identify and assess tobacco use among their patients, to prescribe pharmacotherapy, where clinically indicated and to refer them on to the Helpline or other trained counselors. If more MaineCare smokers 'start' their quit process at a doctors' visit (not just their annual physical), there will be better access to medications as well as counseling. MaineCare callers who 'start' their quit process by calling the Helpline first encounter a 'delayed medication' obstacle because they are referred back to their provider for medication, per federal Medicaid rules. A nicotine patch or gum 'starter' pack distributed by the Helpline cannot be paid by PTM or by OMS for MaineCare members without sacrificing the federal matching share.

- OMS has met Guideline recommendations (4) or (5) at a moderate level since all pharmacotherapies costs are covered to some degree but coverage is subject to small co-pays, annual limits and the inhaler, spray and lozenges are subject to prior authorization requirements. On January 1, 2008, MaineCare moved varenicline

(Chantix) from a non-preferred to a preferred status so that prior authorization is no longer required for payment. OMS is considering the feasibility of removing some of the overall price and duration barriers. It should be noted that no state Medicaid program has yet met all the Guideline standards and MaineCare has retained its policy of covering some of the cost of these treatments despite ongoing considerable budgetary constraints. Having noted that, claims paid by OMS for pharmacotherapies and especially for counseling are only a very small fraction of the overall $1.6 billion MaineCare budget.

3) **Best Practice**

- "Best practice" for tobacco control programs, according to the US CDC, requires funding at the recommended level. It also requires that the above Guidelines system strategy changes be adopted, that quitline services be sustained and expanded, that treatment for face to face counseling be supported and that cost and other barriers to treatment for the uninsured and populations disproportionately affected by tobacco use be eliminated. PTM has attained or is demonstrably close to attaining this best practice standard.

- "Best practice" for Medicaid programs according to the U.S. CDC requires, among other things, that coverage be not less than two 90 day courses of treatment per enrollee per plan year and that counseling be limited to not less than four counseling sessions and at least 90 minutes total contact time over all sessions with two programs paid per enrollee per year. MaineCare's systematic approach to tobacco dependence treatment does not adopt this 'best practice'. It should be noted that the workgroup is not aware that any Medicaid program has attained this standard.

- MaineCare's reimbursement mechanisms for counseling are currently in the process of revision and Resolve workgroup discussions will likely affect the outcome. Further work remains to be done to understand counseling reimbursement differences among federally qualified health centers (FQHCs are paid on a cost reimbursement basis) and other rural health centers, private primary care providers and those affiliated with a hospital. As a starting proposition, MaineCare cannot pay more than the Medicare rate and current policy generally requires that MaineCare reimburse at 53% of the Medicare rate. The workgroup will determine in this context whether positive changes can be made to improve the counseling cost reimbursement system that drives, to some extent, counseling utilization by these health care providers.

4) **Model Program**

The workgroup finds that a model tobacco dependence treatment program would include:

1. Screening, identification and intervention for tobacco use by every practice with referral as necessary for further counseling
2. Evidence based pharmacotherapy is readily available to all
3. Pharmacotherapy and counseling are not linked in a payment scheme; one can be reimbursed without the other

4. Cost sharing and deductibles are minimal; the duration of treatment reimbursed reflects successful quit patterns
5. Benefits are targeted to those most in need such as pregnant smokers and those with behavioral health problems such as major depression
6. Providers are given adequate reimbursement for counseling
7. Education is conducted about benefits offered and evaluation of the treatment provided is conducted on a regular basis

5) **Preliminary proposals**

Proposals designed to move Maine closer to the model program, put forward for further consideration and action before the end of the current fiscal year, if feasible (implementation may extend into the next fiscal year) by the workgroup:

1. MaineCare's Physician Incentive Payment for clinicians would include tobacco use screening, tracking, intervention and counseling as a performance measure MC
2. A fax referral system to the Tobacco Helpline implemented statewide with feedback to providers on the patients referred MC/PTM
3. A demonstration project that emphasizes intensive counseling for youth, pregnant smokers and others who have co-morbidity or mental health issues would be offered through rural health centers PTM
4. A pilot project would be implemented using a 'stepped care' approach that combines Helpline counseling with face to face treatment for youth and pregnant smokers and others who have co-morbidity or mental health issues requiring additional professional support to quit. PTM
5. MC will explore increasing the reimbursement rate for more intensive counseling and certified tobacco treatment specialists and reimbursing others for this work MC
6. MC will explore waiving co-pays and other patient cost sharing and step therapies for tobacco dependence treatment MC

I. Introduction

The directive of Resolve 34 arose out of concern among legislators that smokers, especially low income smokers, encounter significant barriers to getting help to quit. Although much progress has been made in recent years, many of the state's residents still endure the negative health consequences of tobacco addiction; the entire State also incurs great associated health and other costs. This study report required by the Resolve is designed to respond to a perceived lack of access in the State to appropriate counseling and nicotine replacement therapy and other medications for Maine smokers who want to quit, especially low income smokers.

The study was conducted by the Partnership for a Tobacco-Free Maine (PTM), a program of the Department of Health and Human Services within the Maine Center for Disease Control and Prevention (ME CDC). A copy of the Resolve is attached as Appendix A.

A workgroup consisting of members from PTM and PTM partner organizations was convened to discuss the process for addressing the Resolve. Workgroup members are listed in Appendix B. Stakeholders who received a copy of the workgroup preliminary proposals are listed in Appendix C.

II. Study

The focus of this preliminary report, its study results, its model tobacco dependence[1] treatment program and preliminary proposals related to that program concern treatment in the **public sector**.

"Public sector" support in Maine includes:

1. Federal support through Medicare (briefly described below);
2. State reimbursement for pharmacotherapy and counseling through the Medicaid (MaineCare) program;
3. Payment for over the counter nicotine replacement therapy and counseling by the tobacco control program in Maine—PTM.

PTM, with funds from the tobacco settlement, also supports numerous training and education initiatives each year designed to promote tobacco use cessation and to end tobacco initiation. These include the training and education efforts among health care providers (for example, staff at Riverview Psychiatric Center) of the Center for Tobacco Independence (which also runs the Helpline) and the education efforts of the Healthy Maine Partnerships, located throughout Maine. PTM has undertaken a strategic planning process, scheduled to conclude in March, 2008, which focuses on addressing the disparate impact of tobacco addiction among some populations, such as persons with

1 A note on terms: the phrase "tobacco dependence" rather than 'tobacco cessation' treatment, the term referenced in the Resolve, is used in this study The terms are synonymous but the former is used more frequently in references cited in this report Both describe over the counter and prescribed nicotine replacement therapies ("NRT") and other non-nicotine medications, all of which are "pharmacotherapies" 'Treatment' also includes counseling to assist tobacco users who want to eliminate their addiction to tobacco

severe depression and other mental illness, American Indians and others, in Maine. These efforts will not be discussed further here. The focus and scope of this report is on financial and other systems level support for tobacco users who want to quit through face to face counseling and pharmacotherapy paid by private and public payers and provided by the health care community. This is the focus of the U.S. Public Health Service Guidelines and U.S. Centers for Disease Control and Prevention's (U.S. CDC) Best Practices for Tobacco Cessation.

Tobacco dependence treatment does not 'treat' a disease or illness in the traditional sense; it is primarily a prevention measure designed to eliminate an addiction sometimes described as a 'chronic disease' with its consequent associated serious health impact.

The report to be issued in December, 2008, will make final recommendations concerning the proposals herein and will expand discussion to include recommendations related to tobacco dependence treatment in the private sector and to opportunities for collaboration between both sectors.

A. Overview of Problem and Costs

Tobacco Use

Commercially produced tobacco[2] is most commonly smoked as cigarettes, cigars, little cigars, cigarillos, or pipes or rolled by the consumer into cigarette paper 'tubes'. It is also chewed as smokeless moist or hard snuff. About 95% of the tobacco sold in the U.S. (and in Maine) is in the form of cigarettes. Smoking is a known cause of multiple cancers, including lung cancer, heart disease, stroke, pregnancy complications and COPD. It is estimated that more than 80% of all lung cancers are directly related to cigarette smoking.[3] Cigarette smoking is the leading cause of preventable illness and mortality in the United States today.[4] It is also a well established fact that smokeless tobacco use and traditional pipe and cigar smoking, although not generally associated with respiratory illness, can cause oral –mouth and throat—cancer, and other detrimental health effects. [5]

Second hand tobacco smoke has an established connection to adverse health outcomes in adults and children such as asthma, SIDS, respiratory infection and lung cancer. The U.S. Surgeon General recently concluded that there is no level of exposure to second hand smoke without some associated risk.[6] Reducing smoking tobacco consumption therefore has an indirect benefit in reducing health risks for non-smokers**.**

Commercial tobacco is extremely addictive. Although three quarters of smokers say they want to quit, only about 5% at any given time are successful at quitting on their own. With the help of treatment—both counseling and pharmacotherapy—a smoker's chances

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2 Traditional use of tobacco leaf for spiritual, religious or other purposes by Native Americans or others is not the subject of this report

3 U S Surgeon General's Report, (SG) 2004, "The Health Consequences of Smoking"

4 U S CDC MMWR, 2002:51; 300-303

5 American Cancer Society Questions about Tobacco: accessed January 8, 2008 at http://www cancer org/docroot/PED/content/PED_10_2x_Questions_About_Smoking_Tobacco_and_Health asp

6 SG, 2006, "The Health Consequences of Involuntary Exposure to Tobacco Smoke"

of quitting increases as much as six fold. It still takes an average of six or seven attempts to successfully quit.

Nationally, about 21% or 45 million of all adults smoke.[7] Smoking prevalence has dropped significantly since 1965 when the adult smoking rate peaked at more than 42%.[8]Today**,** there are more former smokers than current smokers. [9]Adult smoking rates among all but one state (Utah) and two U.S. territories are still far from the target of 12% by 2010 cited in the U.S. CDC report 'Healthy People'.[10]

Smoking and other tobacco use is associated with low socioeconomic status. Generally, higher rates in Maine can be seen among adults without medical insurance (40%), those who receive medical assistance through MaineCare (43%), or who have low income (31%) and less than a high school education (35%). [11] It is also associated with high stress occupations such as military duty and with 'outdoor' work such as construction, farming and logging.[12] Pregnant women on MaineCare smoke at much higher rates (33%) than the average population (18%)[13].

Persons with major depression and other serious behavioral health problems, such as schizophrenia, appear to have very high smoking rates.[14] According to a recent survey, Maine's adults with behavioral health problems who are not institutionalized smoke at the rate of thirty percent.[15] A new demonstration project conducted by Dr. Jan Blalock at the University of Texas with 250 pregnant smokers, "Project Baby Steps", is testing whether non-drug intensive depression therapy will help pregnant smokers quit. Pharmacotherapy is contraindicated for most pregnant women due to concerns about the affect on the fetus. The participants have low income; many have a history as victims of abuse.[16] Dr. Renee Goodwin, a Columbia University epidemiologist, tracked more than 1,500 pregnant women in 2002 who took part in a larger study of Americans' health. A surprising 22 percent smoked at some point during pregnancy, and about 12 percent were classified as nicotine-dependent. Strikingly, 30 percent of the smokers had a mental health disorder, as did more than 50% who were nicotine-addicted — and the vast majority with a disorder suffered depression. [17] .

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7 National Center for Health Statistics: Health, United States, 2006

8 U S CDC MMWR 2005:54: 1121-1124

9 U S CDC: Cigarette smoking among adults –U S , 2004 MMWR 2005, 54:509-513

10 CDC, 2000

11 BRFSS, 2006

12 Health Care provider smoking cessation advice among U S worker groups, Lee, David J et al, Tobacco Control 2007;16:325-328, Accessed on January 8, 2008 at http://tobaccocontrol bmj com/cgi/content/abstract/16/5/325

Based upon a recent survey, certain low income outdoor occupations with high rates of smoking receive less advice to quit by their health care providers than smokers in white collar occupations CDCMMWR report, September, 2007

13 Pregnancy Risk Assessment Monitoring System (PRAMS) 2005

14 Superintendant David Profitt, of the state's inpatient psychiatric center, Riverview Psychiatric Center, stated in a 2006 message that its patients had a smoking rate of 68% See http://www maine gov/dhhs/riverview/message/2006/smoking html

15 Armour BS, Campbell VA, Crews Je, Malarcher A, Maurice E, Richard RA State Level Prevalence of Cigarette Smoking and Treatment Advice, by Disability status, U S , 2004 Prev Chronic Dis 2007, 4(4); http://www cdc gov/pcdissues/2007/oct/06_017 htm Accesed October 20, 2007

16 Medical Health, September 17, 2007; last accessed January 8, 2008 at http://google-sina com/2007/09/17/does-smoking-make-pregnant-women-depressed/

17 Id

Finally, smoking is associated with racial, ethnic and sexual preference based minorities, including lesbians, gays and transgender persons, Native Americans and certain segments of recent Asian and African immigrants.[18] In Maine, prevalence rates also vary dramatically by region, with the lowest adult prevalence rates in the relatively wealthy, more urban district of Cumberland (16%) and the highest (28.4%) in rural Aroostook.[19]

218,585 Maine adults currently smoke[20]. This is 20.9% of the adult population[21]. Maine's adult smoking rate is slightly higher than the median rate for the country (20.1%). The state rate, reflecting the national experience, has gradually declined, from a high of about 27% in 1990. Per capita cigarette pack consumption in Maine was at an all time low in 2006 (64.8 million) and more smokers now state that they are 'sometime' rather than 'every day smokers', suggesting that, even if the prevalence rate has not declined recently, smokers, although not quitting, may be smoking fewer cigarettes. [22] Maine had the highest smoking attributable deaths (304) per 100,000 persons among New England states (2001) according to CDC's SAMMEC software and more than 80% of all lung cancer deaths were related to smoking. [23]

Only 14% of high school students (7% of middle schoolers) now smoke in Maine, down from 39% in 1996. This is one of the lowest rates in the country and in New England. Maine has experienced a 64% drop in smoking rates in this age group in the past ten years—a major success story for Maines tobacco control program—especially for a state ranked 34th for median income[24].

However, these very positive results among teens are not mirrored among all other sub-populations. Maine's socio- demographics characteristics likely contribute to its relatively high young adult smoking rates. A striking difference in smoking rates has long existed between college-bound and non-college bound high school seniors. In 2003, smoking a half-pack or more per day was about 3 times as prevalent among the non college-bound seniors (17.2% vs. 5.5%) [25].

30% of young adults (18-44) smoke in Maine; this is the fourth highest state smoking rate in this age group in the country and the highest in New England. Smoking prevalence has gradually increased in the past decade for young adults in Maine in the lowest education and income groups. [26] By contrast, smoking rates for adults with a college education (10%) and income of $50,000+(13%) are low and continue to decline.

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18 It h as been estimated that, nationally, Native American prevalence rates are about 34% National data is not reflective of regional or tribal differences which may vary widely, however and cannot be used to estimate the incidence of smoking among Maine's Native American population or tribes CDC, Cigarette Smoking Among Adults-United States, 2004 MMWR, 2005, 54(44): 1121-1124

19, BRFSS,2006

20 BRFSS, 2007; U S Census 2007

21 BRFSS, 2006

22Orchiewiz and Walker, The Tobacco Tax Burden—2006 (March, 2007) BRFSS 2006 survey results support this : more adults report that they are 'sometime' rather than every day smokers

23 Maine Cancer Report, 2007

24 YRBS 2007

25 YRBS, 2007

26 CDC MMWR 2007 9/28/07

There is some indication that low income adult smokers are more price insensitive to cigarette price (and tax) increases than other smokers. This 'effect', noted in the early days of tobacco control program implementation, may have ended, however, as lower priced cigarettes have become increasingly scarce. In any case, it is undisputed that smoking and other tobacco use in Maine and around the country has become increasingly associated with low socio-economic status. This has heightened the need for all publicly funded tobacco control programs to increase their efforts to lessen barriers to access to tobacco dependence treatment for low income smokers who want to quit. [27]

Costs

Tobacco is not only hazardous to health, it also produces tremendous costs to society. In Maine, it is estimated that seventeen percent of smokers have MaineCare benefits and fifteen percent are uninsured.[28] The adverse health effects of smoking, as estimated using the U.S. CDC's SAMMEC (Smoking Attributable Mortality, Morbidity and Economic Costs) software, result in about 13% of all of MaineCare's health care costs, annually.

Smoking causes $602 million in direct health care costs in the state. Smoking attributable medical costs to MaineCare have been estimated [29] to be as follows:

- $216 million in direct smoking attributable medical costs (more than one-third of the total attributable costs for the state)
- $208.67 in costs per capita (adult) ($129.90 average nationally)
- $6.37 in medical costs per pack of cigarettes ($5.31 average nationally)
- $5.23 in productivity costs per pack of cigarettes ($5.16 average nationally)
- $2.29 in medical costs per pack of cigarettes ($1.63 average nationally)

The MaineCare program covers 20% of all Maine residents and pays for approximately 28.4% of all smoking-caused healthcare costs in the State. [30]. Because of the high prevalence of smoking among MaineCare adult members who have children, it has been estimated that Maine covers about 30% of all children but pays for 60% of the smoking attributable health care costs for children in the state. [31]

A recent economic analysis, "Saving Lives, saving Money, II, Tobacco Free States Spend Less on Medicaid" prepared by RTI International, and published November, 29, 2007, for the American Legacy Foundation, reported that the annual net Medicaid cost per 24 year old female smoker was $1,242.[32] The same study, in a cross sectional analysis, estimates that the MaineCare program, would save $47 million five years after 50% of all

27 Cigarette Prices, Smoking and the Poor: Implications of Recent Trends, Franks, Jerant, Leigh, Lee, Chlem, Lewis and Lee, American Journal of Public Health, Vol 97, No 10, Oct 2007

28 MATS 2007

29 Direct medical costs for adults CDC, Tobacco Control State Highlights, 2002

30 Miller, L, et al , "State Estimates of Total Medical Expenditures Attributable to Smoking, 1993" Public Health Reports, September/October 1998

31 U S CDC 2007; Maine State Tobacco Control Highlights accessed on October 21, 2007

32 The lifetime Medicaid cost per 24 year old smoker was $41 (in 2005 dollars), due to their shorter than average life span and income taxes paid to the state despite their higher smoking related health costs American Legacy Foundation report, 2007

MaineCare smokers quit ($93 million if all smokers on MaineCare quit). [33] The estimate does not include other medical costs to other payers such as Medicare and private insurers or out of pocket payments, productivity losses and the effects of second hand smoke and smoking during pregnancy. One study in 1999 found that although individual consequential health care costs due to smoking while pregnant (low birth weight, etc) may be extremely high and vary widely, for each low income pregnant smokers who quits, Medicaid saved $1,274.[34]

The Maine Advisory Council on Health Systems Development Data Book, issued October 29, 2007, quotes from the McKinsey Global Institute's report, "Accounting for the Cost of Health Care in the United States": [although only a small portion of additional U.S. spending is explained by a higher disease burden] "the high prevalence of some conditions…(heart conditions diabetes, and select types of cancer) indicates that ***prevention programs*** targeted at reducing the prevalence of disease, particularly disease with high treatment costs, would offer very substantial opportunities for better health and lower costs (emphasis added)".

B. Tobacco Dependence Treatment; Its Benefits and Efficacy

Pharmacotherapy

Nicotine Replacement Therapies (NRT) have been on the market for at least ten or fifteen years. The nicotine patch (a transdermal patch which releases nicotine into the skin and delivers milligrams of nicotine correlating to the degree of the user's addiction to cigarettes or other tobacco) and nicotine gum, which is chewed to release small doses of nicotine, are now available over the counter. A nicotine spray and an inhaler are available by prescription for smokers, and are useful for those who don't tolerate the patch due to skin rash or can't chew the gum, due to dentures. Lozenges (available over the counter as brand name, " Commit" or in generic version) may also be useful for the above reasons. Buproprion, an anti-depressant, is also an effective prescribed treatment and is marketed under the brand name, " Zyban" as a smoking dependence treatment.

Varenicline (brand name, Chantix), a non-nicotine pharmacotherapy available by prescription is a partial agonist that both reduces cravings for and decreases the pleasurable effects of cigarettes and other tobacco products. It was U.S. Food and Drug Administration (FDA) - approved in May, 2006 for use in the U.S. and has been widely accepted as generally more effective than NRT, based upon clinical trials. In November, 2007, the FDA announced it had received reports that patients using Chantix for smoking cessation had experienced suicidal ideation and occasional suicidal behavior. The FDA is currently reviewing reports.[35]

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33 Based on total MaineCare expenditures in 2005 of $1,635,000,000

34 Lightwood JM, Phibbs CS, Glantz SA: short term health and economic benefits of smoking cessation: low birth weight, Pediatrics 1999, 104:1312-1320

35 It is unknown whether the psychiatric symptoms are related to the drug or to nicotine withdrawal symptoms, although not all patients had stopped smoking In a widely publicized case in 2007 involving the singer, Carter Albrecht, he was shot to death by his neighbor after, in an apparent state of delirium, he hit his girlfriend and tried to force entry in a neighbor's apartment The case of delirium appeared to be caused, however, by taking varenicline with a high dose of alcohol

The cost of the nicotine patch and gum is comparable, out –of- pocket (about $60-$120 per month), to the cost of a pack of cigarettes for a pack a day smoker but may be much more expensive, relatively speaking, for lighter smokers, for smokers who roll their own cigarettes or who smoke pipes or machine made cigars. (See Appendix D for cost estimates of pharmacotherapies to MaineCare). Lozenges, spray, inhalers and varenicline are usually more expensive out of pocket even to a pack a day smoker, especially the spray and inhaler ($100-$250). For any smoker who does not have insurance or for insured smokers who may have little to no pharmacy coverage, these products may be more and very costly, especially if used long term.

Counseling

Counseling, including face to face individual and group counseling and phone based counseling has been widely cited as effective in assisting smokers to quit. Maine has a program for certifying tobacco treatment specialists. All of the Maine Tobacco Helpline counselors who offer free assistance to callers are certified. Thirty health care professionals around the state have become certified through an intensive program (see Appendix E for description of Certification) offered through the Tobacco Treatment Specialist Certification Commission, a voluntary organization coordinated through the American Lung Association of Maine.

The Center for Tobacco Independence also provides training in tobacco treatment for health care professionals. Counseling may be brief, intermediate or intensive. Counselors, other than in limited circumstances, are not reimbursed by the state for tobacco related counseling unless they fall within certain disciplines, pursuant to MaineCare rules or are affiliated with certain facilities. MaineCare has reimbursed certain medical providers $20 for 'brief' counseling by private providers. Counseling reimbursement conducted through outpatient clinics, and at rural health centers, including federally qualified health centers (FQHC's), is subject to different cost related rates. OMS cannot pay counseling rates that are higher than Medicare rates. Tobacco dependence counseling reimbursement is currently under review within OMS; additional 'codes' for reimbursement may be opened in the near future. The workgroup will be discussing counseling in greater detail in the coming year.

There is general consensus among the workgroup that there is currently little financial incentive for private provider practices to identify and provide brief intervention with patients who use tobacco or for certified tobacco treatment specialists to obtain certification which is why relatively few health care providers obtain certification that will allow them to do more intensive counseling. There is also little or no financial incentive for clinical practices to allow their trained specialist staff to leave their other duties to counsel tobacco users.

This may change for some providers if the MaineCare Primary Care Physician Incentive Program (for private providers only) includes tobacco identification and intervention within its quality indicators, as recommended in this report. MaineCare currently pays an incentive payment to primary care physicians ranked above the 20th percentile on specified performance measures, not including tobacco cessation related activities, but do

include lead screening and mammogram rates. This will be addressed in more detail in the final report. Appendix F provides an overview of current coverage for tobacco dependence pharmacotherapy and counseling in Maine.

Benefits

Smoking cessation has major immediate health benefits for people of all ages: cardio-vascular disease deaths are halved within 1-2 years after cessation and lung cancer mortality is reduced by 50-70% within five years of cessation. Ten-fifteen years after quitting, former smokers can expect a life expectancy comparable to non-smokers.[36]

Efficacy

Only 5% of all smokers who attempt to quit on their own are eventually successful. As many as one third (33%) of smokers who have the benefit of repeated interventions including counseling and medication successfully quit. [37] For example, quit rates on Maine's Tobacco Helpline when counseling and NRT is provided to a caller, after six months, were about 35% in 2006.

C. **U.S. Public Health Service Clinical Practice Guidelines (" Guidelines") and Best Practice Treatment**

The Guidelines are published under the auspices of the U.S. Public Health Service and the U.S. Centers for Disease Control and Prevention. The first Guideline was published in 1996, the second in 2000. The draft update (" Update") is scheduled to be published in final form in March, 2008 and is available now in hard copy. As it is not a final report, Update comments noted here are subject to change.

The Guidelines focus on advising clinicians on tobacco dependence treatment at the individual practice level and address prescribing standards and other physician practice issues. Methods for identifying tobacco use and intervention and counseling are recommended in the first four chapters. For example, the seven pharmacotherapies, patch, gum, pray, inhaler, Buproprion, including the newer, lozenges and varenicline (Chantix) are recommended as first line treatments to be suggested by physicians where clinically appropriate for all smokers wishing to quit.

The fifth Chapter of all editions of the Guidelines addresses system change and benefit design as well as system level implementation of benefit design, which are applicable to state 'purchasers' and hence, to devising a model state program. Chapter 6 of the Update on 'evidence', provides new meta-analyses of studies supporting the system intervention recommendations of chapter 5. This is helpful as it provides a comparative analysis of success for the different methods of treatment.

The Update notes that there is a need for innovative and more effective counseling strategies to help adolescents, American Indians and those with low educational

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36 U S DHHS The health benefits of smoking cessation: A report of the SG U S DHHS, PHS, CDC, Office on Smoking and Health Rockville, MD 1990

37 U.S. Public Health Service Clinical Practice Guidelines, 2000.

attainment, real world research rather than clinical trials and strategies to create consumer demand for proven treatments. It also addresses in much greater detail than prior editions the effectiveness of proactive quitlines, cessation interventions for individuals with low socio economic status, adolescent smokers, pregnant smokers and those with psychiatric illness.

The Guidelines seven chapters:

1. Overview and Methods
2. Assessment of Tobacco Use
3. Brief Clinical Interventions
4. Intensive Clinical Interventions
5. Systems Interventions
6. Evidence
7. Special Populations

The System Interventions (Strategies) for system administrators and purchasers (briefly) are :

1. Implement a tobacco user identification system in every clinic
2. Provide education, resources and feedback to promote provider intervention
3. Dedicate staff to provide tobacco dependence treatment and assess the delivery of this treatment in evaluations
4. [Hospital based care intervention omitted as non-applicable.]
5. Include tobacco dependence treatments (counseling and pharmacotherapy) identified as effective in the guideline as paid or covered services for all subscribers or members of health insurance packages
6. Reimburse clinicians and specialists for delivery of effective tobacco dependence treatments and include these interventions among the defined duties of clinicians

The Update notes progress in that 90% (25% in 1997) of private insurance plans-- by 2003-- covered one tobacco treatment and that 72% (up from 42% in 2000) of Medicaid programs --by 2005- offered at least one form of Guideline recommended treatment.

The Update also notes that studies have demonstrated the superior effectiveness of particular combinations of counseling and medications (33%) vs. just counseling (22%) or just medication alone (12%).

Optimal counseling time, according to Update meta-analysis review, is more than 31 minutes and less than 300 minutes (26% to 28%). Varenicline or Chantix (at 2 mg/day) (33%) and the patch, used for more than 14 weeks plus use of the gum or spray, as needed (36%), seem to have the highest success rate among pharmacotherapies, relative to a placebo.

In addition, physicians have increased their identification of smoking status and, to a much lesser extent, among certain populations of smokers, advising smokers to quit and providing brief counseling. However, there is still very little prescription by primary care physicians of nicotine replacement therapies and non-nicotine tobacco dependence medications.

One just published study found that physicians prescribe in only about 1% of all smoker visits and that physician tobacco use counseling has actually decreased since the late 90's.[38] Since 70% of smokers see a physician every year, this represents a significant missed opportunity to counsel, to refer smokers to a helpline or to motivate those not ready to quit to consider doing so.

The lack of progress in the medical community in counseling may also be indirectly related to growing dependence upon tobacco dependence quitlines staffed by trained, certified tobacco counselors; they are now in all 50 states including Maine. The Update also notes that there is still little coordination of tobacco treatment between physicians, insurers and quitlines**.**

It is important to note that the best quitlines annually assist only about 4-6% (about 10,000 callers in Maine) of the smoker population. Also, counseling exclusively via a telephone quitline may not be appropriate for all smokers, such as those with serious mental illness. The advantage of face to face counseling by a trained counselor for those smokers who have serious tobacco addiction and behavioral problems or co-dependence is apparent.

The Update notes that, while many private insurance plans and some Medicaid plans offer some reimbursement for medications or counseling, many still provide low annual or lifetime caps or other limits (high co-pays, deductibles) on medication use and little or no financial incentive for counseling. Trained tobacco cessation specialists, unless they fall within the professional disciplines eligible for reimbursement, generally are not reimbursed for counseling by the MaineCare program and are only reimbursed, in most instances, $20 regardless of the intensity level of the counseling. (The final report will provide more information concerning counseling reimbursement in the public and private sectors.)

The Update provides information about recent successful treatment efforts with special populations such as pregnant women (quit rates double with psycho social interventions); adolescents (quit rates double with counseling); persons with low socioeconomic status (quit rates increase with counseling by about 50%); psychiatric patients (buproprion is effective in smokers with depression and may be with schizophrenics); those suffering from chemical dependency; with co-morbid conditions and with minorities including African Americans and Hispanics and Native Americans.

The Guidelines conclude that it may be in the best interest of insurance companies, managed care organizations and governmental bodies within a specific geographic area to

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[38] In the past decade, despite evidence that physician's advice to quit increases patients' smoking cessation rates, and the promotion of cessation by PHS Guidelines and other publications, physicians' rates of identifying patient's smoking status have increased only slightly and counseling smokers has generally decreased (from 22%in 1996 to 20% in 2003). This lack of progress may reflect barriers in the U.S. health care environment, including limited physician time to provide counseling, lack of insurance coverage for smoking cessation pharmacotherapies and physician pessimism about whether smokers can quit. The authors state that embedding physicians in a broader system that integrates treatment into practice is needed. *The Treatment of Smoking by U.S. Physicians Suring Ambulatory Visits: 1994-2003*, Thorndike, Regan, Rigotti, AJPH, Vol. 97, No. 10, Oct. 2007 The study also notes that certain HMO's have documented reductions in smoking prevalence after the adoption of aggressive system level strategies to identify and document status and to refer smokers to cessation resources.

work collectively to ensure that tobacco dependence interventions are a covered benefit and enrollees are aware of these benefits.

Best Practice Cessation Treatment

In October, 2007, the U.S. CDC updated its report, last issued in 1999,on best practices for comprehensive tobacco control. That report revised its funding range estimates by states and provided additional guidance on program elements necessary for a comprehensive tobacco program, including cessation treatment.

Based upon the updated report, state action on tobaco dependence treatment should include the following elements:

1. Sustaining, expanding and promoting the services available through population based counseling and treatment programs, such as cessation quitlines
2. Covering treatment for tobacco use under both public and private insurance, including individual group and telephone counseling and all FDA approved medications
3. Eliminating cost and other barriers to treatment for underserved populations, particularly the uninsured and populations disproportioately affected by tobacco use
4. Making the health care system changes recommended by the U.S. Public Health Service clinical practice guidelines

The revised U.S. CDC budget recommendations are based on the 1999 funding formula adjusted for changes in state population and inflation, attainable rates of quitline usage and provision of NRT to callers. Maine's recommended level of funding for cessation intervention in FY07 was $5.1 million with a range of $2.9 to $7.7 million. Actual spending on cessation treatment by Maine's Tobacco program was $2.8 million in FY07 and will be more than $3 million in FY08.

An earlier document outlines 'best practice' recommendations for state Medicaid programs. This is contained in the Medicaid Contract Sample Purchasing Specifications Related to Tobacco Use Prevention and Cessation Services, A Technical Assistance Document (October, 2002) published by the GWU Center for Health Services Research and Policy with the U.S. CDC. The document recommends that Medicaid programs limit pharmacotherapy treatment reimbursement to no less than two 90 day courses of treatment per enrollee per plan year and tobacco use counseling programs to four counseling seessions (two programs) and at least 90 minutes total contact time over all sessions per enrollee per year.

Maine's tobacco program, through PTM guidance and funding, sustains, expands and promotes the Maine Tobacco Helpline. The Helpline provides free counseling by trained counselors and free NRT through a medication voucher system to the uninsured. PTM generally follows the 'best practice' standards, although funding for cessation treatment did not reach the minimum recommended by the October, 2007 document for FY07 until FY08. The preliminary proposals outlined in this report are responsive to the system changes addressed in the Guidelines and the Update to the Guidelines.

MaineCare provides coverage for brief individual counseling up to three times per year and all preferred medications are covered up to 3 months (Varenicline (Chantix) is now covered for up to 6 months) although there are modest co-pays, some prior authorization requirements for non-preferred medications and annual and lifetime limits. Coverage is better than many other Medicaid programs but does not strictly comply with 'best practice' recommended in the Guidelines and in the CDC/GW 2002 Contract Specifications.

Private insurance standard contract coverage of tobacco dependence treatment, when it is covered, is generally subject to co-pays, deductibles and annual and lifetime limits in Maine; detailed discussion in the final report will follow.

D. Model Tobacco Dependence Treatment Program

Based upon the recommendation of the above Guidelines and Best Practices and the results of its preliminary study, the workgroup has determined that an optimal tobacco dependence treatment benefit for employees, the beneficiaries served, or the lives covered through a benefit plan offered by state or privately funded health plans includes:

1. Screening and counseling for tobacco use treatment

• All benefit elements are consistent with the recommendations and conclusions of major evidence based Guidelines*, including the U.S. Public Health Services' *Treating Tobacco Use and Dependence: A Clinical Practice Guideline, 2000 (as updated).*

• Tobacco use by the patient must be identified, documented, assessed and addressed by all clinicians in every clinical setting and at every visit (i.e., not just the annual physical).

• There is ready access to evidence-based counseling services, including individual (at brief and more intensive levels), group and telephone based counseling services, ensuring multiple opportunities for treatment.

2. Evidence based pharmacotherapy is readily available

• There is ready access to all U.S. Food and Drug Administration (FDA) approved tobacco use treatment medications, including prescription and over-the-counter products. The first line medications currently include the nicotine replacement therapy patch, gum, lozenges, spray and inhaler and the anti-depressant buproprion and varenicline (Chantix). Coverage is provided for multiple simultaneous use of pharmacotherapies, when clinically indicated.

3. Unlinked benefits

• While strongly recommended, there is no requirement of participation in a formal counseling program as a precondition for gaining access to a medication benefit. Medication and counseling are most effective when combined but medication or counseling, alone, are more effective than self-help only.

4. Cost sharing and deductibles minimal; duration of treatment reflects successful quit patterns

• Patient out-of-pocket treatment costs are minimal; there are no significant co-payments, deductibles, step, prior authorization or lifetime or annual limits on coverage provided.

•Tobacco treatment services and benefits are made available for multiple episodes of treatment per year for four or more sessions, with coverage of a minimum of two 90 day courses of treatment per year per beneficiary; sessions should last more than 10 minutes each; in recognition of the common pattern of relapse in tobacco use dependence and efficacy of intensity of sessions

5. Targeting benefits to those most in need

• There is a targeted benefit for special populations such as pregnant smokers tailored to the unique needs of that population (e.g., with pregnant smoker, more intensive, proactive and frequent counseling is offered; Nicotine Replacement Therapy use is contraindicated). Other special populations that would benefit from standard supplemented by targeted treatment include smokers with behavioral health and substance abuse problems, low income persons, teens, gay, lesbian, transgender persons, and persons in racial or ethnic minorities such as Hispanic/Latinos, Asians and Native Americans.

6. Adequate reimbursement to appropriate providers

•A variety of trained clinicians, including certified tobacco treatment specialists, not just physicians, are eligible for reimbursement for providing tobacco cessation treatment.

• Reimbursement to providers for tobacco use treatment services is adequate to cover reasonable costs of delivering the service.

7. Education offered and Evaluation conducted

• A sustained education/promotional campaign is offered to raise awareness of the benefits and to encourage utilization (among health systems, providers and consumers).

• The program provides a mechanism for collection of key data elements to monitor treatment and benefit use consistent with the existing Health Plan Employer Data and Information Set (HEDIS) and the National Committee for Quality Assurance (NCQA) requirements specific to tobacco use and for the purposes of evaluating the population and individual-level impacts of the benefit.

This preliminary model program is an 'overview' and will be refined and revised in the final report based on additional study and collaboration with representatives from the private sector including providers, large employers, and private insurers.

E. State Support

Medicaid (MaineCare)

Smoking cessation benefits such as counseling and drug therapy are optional benefits under federal Medicaid rules (except for children covered under the Early, Periodic, Screening, Diagnosis and Treatment –EPSDT-- program). Preferred medications paid by MaineCare currently include Buproprion (also used for depression) nicotine replacement

therapy (patch, gum) and, as of January 1, 2008, non-nicotine based varenicline (Chantix). MaineCare will pay for other methods of nicotine delivery such as the spray, inhaler, lozenges, with prior authorization, under certain conditions. All pharmacotherapy is subject to the $3.00 co-pay and three month annual limit, with the exception of Chantix which may be covered for six months, once in a lifetime. Brief counseling at the rate of $20 per episode in most clinical settings, 3 times per year, is also reimbursed for a physician or physician supervised staff member. See Appendix F for comparative chart summarizing these MaineCare benefits.

Maine Tobacco Helpline (PTM)

Since August, 2001, the Partnership for a Tobacco - Free Maine, has administered and paid for operation of the Maine Tobacco Helpline through funding derived from the Master Settlement Agreement with tobacco manufacturers.

The Helpline provides evidenced-based treatment for tobacco dependence based on the U.S. Public Health Service Clinical Practice Guidelines. Components include: (1) the Maine Tobacco HelpLine, (2) nicotine replacement provided through the Tobacco Medication Voucher program, and (3) Tobacco Treatment Training to educate health professionals about tobacco dependence and train Tobacco Specialists.

The program operates a telephony based counseling and, since August, 2002, a medication voucher program that distributes free medication –the patch and nicotine gum. The program also provides trained tobacco treatment specialists who offer fee counseling to Maine resident smokers who call and are interested in quitting.

It serves on an annual basis an average of 4-6% (about 8-13,000 callers) of the current smokers in Maine. This is a high utilization rate, compared to other quitlines around the country.

Callers are assisted by a trained certified tobacco cessation treatment counselor within 24 hours, are evaluated, with medical supervision, and, if clinically appropriate, are offered a voucher for free medication (the patch, gum or lozenges), with certain exceptions. Vouchers are not provided to callers who indicate that they have alternative coverage for cessation treatment. These include those who are privately insured and believe that they have insurance coverage or who are covered by publicly financed programs such as MaineCare or Medicare. Actual coverage status is not verified by the counselor. Callers who have private insurance, MaineCare or Medicare are referred back to their provider for a script for medication. Medication is provided to many callers with insurance who indicate their policy has no coverage or that the limits have been exhausted. Obtaining an appointment with a primary care doctor can take a month or more so access to medication may be delayed, in this instance. About 25% of all callers are uninsured, 21% are on MaineCare; 54% of callers indicate that they have private insurance.

The Helpline accepts fax referrals from providers and has provided forms for that purpose to federally qualified health centers, other rural health centers and hospitals. The Helpline's callers are generally representative of the entire adult smoking population in Maine, although proportionally more uninsured adults and fewer young adults call in. It

assists a small number of callers with behavioral health issues and teen smokers. Teen and pregnant smokers receive only counseling.

While the Helpline is not a suitable venue to most effectively assist all smokers and only offers free over the counter medication—the patch, lozenges and gum-to certain callers, nevertheless, the Helpline (with the possible exception of some large employer sponsored programs) may provide the most *barrier free* access for adult smokers to medication and counseling in the state.

State Master Settlement Agreement Funding for tobacco dependence treatment

Maine is one of the few states in the country that allocates more than the minimum amount of tobacco company settlement dollars for tobacco control and health programs. About $17 million was allocated in FY08 to tobacco programs administered by PTM [39], including over $3 million which will be used for new initiatives and for counseling and medication vouchers distributed through the Tobacco Helpline and certain community based providers. This funding is nevertheless modest, by U.S. CDC 'best practices' standards. See discussion on best practice. It has been estimated by the Helpline that, for the past several years, about half of the medication voucher budget represents vouchers distributed to Helpline callers who have private insurance coverage which either has been exhausted or which does not pay for tobacco dependence medication.

MaineCare

MaineCare paid $1.3-$1.5 million in FY 05-07 for pharmacotherapy and counseling for smokers who receive MaineCare pharmacy and other benefits who are attempting to quit. Counseling payments represent only 3% of all costs paid. These sums are the total paid; the state's share was only 36.73% (or $515,300) in FY07. See Appendix H for a chart summarizing all MaineCare claims paid.

A survey report issued in April, 2007 assessing state Medicaid program adoption of the Guidelines' system strategies found that, of the four strategies reviewed (identification system, education and feedback, coverage of treatment and reimbursement of clinicians) MaineCare reported that it had adopted some portion of three of the four strategies. The first strategy –related to a systematic tobacco user identification system--was not addressed. See *Adoption of System Strategies for Tobacco Cessation by State Medicaid Programs*, Bellows, Nicole M. et al, Medical Care, Vol. 45, Number 4, April, 2007 and Appendix G. Three states---Oregon, Pennsylvania and West Virginia—had adopted some part of all four system strategies for cessation.

F. Federal Support

Medicare

Medicare's coverage of tobacco dependence treatment for its members has improved but is still limited. Medicare generally pays for two types of counseling: intermediate (3-10 minutes per session) and intensive (greater than 10 minutes) per session. Medicare will cover two quit attempts per year. Each quit attempt may include a maximum of four

[39] PL 2007, c 240

intermediate or intensive counseling session with a total benefit coverage of up to 8 sessions in a 12 month period. To be eligible, a Medicare beneficiary must have a condition that is adversely affected by tobacco use or a metabolism or dosing of a medication used to treat a condition that is being adversely affected by his or her tobacco use. Medications may be covered under a Medicare "Part D" prescription payment plan depending upon the plan (each plan may vary), however, over the counter treatments such as the nicotine patch or gum are not covered by the Medicare plan.

Other

Thirty four percent of persons in the U.S. military currently smoke. Prevalence rates have remained the same since 2002 and there is evidence that younger members of the military are smoking more.[40] Maine has a large veteran and active duty military population. The Army, Navy, Marine Corps, Air Force and Coast Guard offer to active duty, national guard, reserve and retired service members and their families, group tobacco cessation classes. [41] Tricare, the health program for veterans and their families, does not generally cover pharmacotherapy or counseling for tobacco dependence treatment. In May, 2006, Tricare instituted a pilot tobacco cessation program, "Healthy Choices for Life" in four states (not including Maine) to provide free one on one counseling via a special quitline and free NRT through a pharmacy mail order program to members wanting to quit.[42]

Privately Funded Tobacco Dependence Treatment -- Insurers and Employers

Maine's private health insurance market will be discussed in greater detail in the final report. It generally consists of:

- the small group and individual insurance market (regulated by the Maine Bureau of Insurance) with insurers Anthem, Cigna, Aetna and Harvard Pilgrim comprising most of those markets;
- the large group market (unregulated by the state of Maine) which includes « ASO » or plans where the employer assumes the financial risk and negotiates its own plan such as the Maine State Employees Health Plan, Municipal Employees Health Trust, and Hannaford Brothers and Bowdoin College ;
- "Dirigo Choice", the state sponsored health program with subsidized premiums for low income persons, with coverage through Harvard Pilgrim Health , effective January 1, 2008.

About 60% of Maine residents are covered by some form of private insurance. About half of the private insurance market are self insured plans with large employers; the other half is dominated by four companies: Anthem (about 49% of individuals covered), Aetna (21%), Cigna (16%) and Harvard Pilgrim, which includes Dirigo Choice coverage (11%).

Anthem provides a standard insurance benefit for tobacco dependence treatment but it contains fairly restrictive lifetime and annual limits for pharmacotherapy and limited

40 Information accessed on January 9, 2008 at: http://www usmedicine com/article cfm?articleID=1055&issueID=73

41 Information accessed on January 9, 2008 at: http://www tricare mil/pressroom/press_article aspx?fid=436

42 Information accessed on January 9, 2008 at: http://www tricare mil/healthychoices/init cfm

counseling coverage. Other insurers such as Aetna offer no or less coverage through their standard plans. Enhanced benefits may be offered by these insurers through 'ASO' plans.

For example, some of Maine's large employers, such as the Maine State Employees Association, have negotiated health plans which include more comprehensive tobacco treatment. On July 1, 2007, MSEA eliminated yearly and lifetime caps on benefits for NRT coverage. Co-pays and deductibles are also eliminated for these services if one sees a preferred provider (about half participating providers are preferred). "Preferred providers' are awarded two or three blue ribbons by the Maine Health Management Coalition's "Pathways to Excellence" program. Some employers such as Hannaford's and Bowdoin College are not only offering excellent benefit coverage but also on- site smoking cessation classes for their employees. See Appendix I for commercial insurance claims data.

Preliminary research indicates that large employers have a greater financial incentive than insurers to offer smoking cessation as a wellness plan incentive or tobacco dependence treatment as a negotiated covered benefit. More information will be provided in the final report.

H. Innovative Treatment Partnerships

Here is a sample of some innovative collaboration and cost sharing on treatment between the public and private sector around the country:

Massachusetts Quitworks,

Referrals of smokers willing to quit are faxed by primary care physicians or dentists to quitlines; largest insurers in state subsidize quitline (by paying a lump sum annually) and provide incentive to physicians to make more referrals; insurers and physicians receive quarterly reports from quitline on outcomes of referrals

Utah Quitline and state health plan

The state currently has a partnership with the Public Employee's Health Program (PEHP). PEHP members are those who are employees or retired from the State of Utah, public or higher education, a city, town, county, or special service district. PEHP contracts with the tobacco program to provide Utah Tobacco Quit Line services (counseling, and NRT as appropriate) for their members. The contract budget is $35,000, though they have yet to reach this upper limit in the history of this partnership. This represents a very small but still significant portion of the overall Quit Line budget. Another of Utah's major insurers, IHC/Select Health contracts directly with the Quit Line service provider to provide services to their members.

Michigan Quitline partnership with Medicaid.

The state has five Medicaid Managed Care Plans that cost-share with the Quitline. The Medicaid Managed Care Plan Partners contribute $25 towards the cost of counseling for each of their members who enroll. This is paid directly to the vendor through a separate

contract. The plans also contribute in-kind with advertising to their members through newsletters and mailings. The amount contributed varies depending on the number of members enrolled each year.

Ohio Quitline's private sector partnership

The state's quitline has over 80 corporate, business, medical centers, schools, and pension plan partners as well as 8 health plans throughout Ohio. These partners contribute up to $46 of the $92 dollars of actual costs of nicotine replacement patches for each member who participates in the Ohio Tobacco Quit Line counseling program. The tobacco using member receives 4 weeks at $23 dollars from the partners and $23 from OTPF and if they remain in the Ohio Tobacco Quit Line Counseling program, they will receive another four week supply at the same cost to the partner. Over the past fiscal year from July 1, 2006 to June 30, 2007, partners have contributed $633, 132.00.

III. Proposals

Proposals are grouped according to Guidelines' system strategy addressed and state agency primarily responsible (or jointly responsible) for proposal is noted by acronyms PTM or MC.

(1) Implement systematic tobacco use identification and intervention in every clinical practice

- Add physician systematic tobacco use identification, recording/tracking and intervention (with training provided by PTM contractor, Center for Tobacco Independence) for patients as one of the performance measures for which participating physicians may be paid an incentive payment by MaineCare **MC/PTM**

(2) Provide education, resources and feedback to promote provider intervention

- Implement patient fax referral system statewide through primary care providers to Maine Tobacco Helpline and provide robust feedback to providers on patient outcomes; evaluate fax referral system's cost benefit **MC/PTM**
- Provide feedback to primary care providers on utilization of tobacco counseling services by MaineCare members within their practice by developing a quarterly report of counseling code utilization **MC**
- Educate identified MaineCare members who smoke about pharmacotherapies and about tobacco cessation options through tracking of their claims and through partnership with manufacturers' pharmacy representatives **MC**

(3) Dedicate staff to provide tobacco dependence treatment and assess that treatment

- Develop a demonstration project that implements and evaluates the impact of community-based, face-to-face tobacco treatment counseling that emphasizes intensive treatment for pregnant women and youth and those who have co-

morbidity/mental health issues, delivered through Rural Health Centers in underserved areas of Maine. **PTM**

- Implement a pilot project that provides, and evaluates the impact of, a stepped care approach that combines HelpLine counseling with tailored face-to-face treatment for young tobacco users, for tobacco users who are pregnant or who have co-morbidity/mental health issues and who require additional professional support to quit. **PTM**

(4) Include tobacco dependence treatments (counseling and pharmacotherapy) as paid services for all subscribers/members of health plans

- MC will explore increasing rate of reimbursement for more intensive tobacco counseling and for professionals including certified tobacco cessation specialists who provide this service (fiscal impact) **MC/PTM**
- MC will explore waiving co-pays for pharmacotherapies and eliminating current requirements of step therapy (fiscal impact) **MC**

(5) Reimburse clinicians and specialists for effective tobacco dependence treatment

- MC will explore reimbursable counseling reimbursement to additional provider disciplines, including certified tobacco cessation specialists (fiscal impact) **MC**

IV. Conclusions

The workgroup hopes that this report, the model tobacco dependence treatment program and related preliminary proposals will provide a foundation for an informed and constructive discussion on public and private sector support for treatment and on collaboration between the two sectors, among policymakers, among stakeholders and among others interested in improving the tobacco dependence treatment system in Maine.

The workgroup finds that the body of research and evidence supports the conclusion that tobacco dependence treatment can be highly effective in achieving abstinence, is the number one preventive health care measure that is highly cost effective but is generally insufficiently addressed by the majority of insurers—both public and private, by many employers in designing their health benefits and by many primary care physicians and is also underutilized by tobacco users.

The Guidelines and other reports also suggest that around the country and in Maine there has been improvement but there remain numerous barriers to smokers accessing affordable treatment; these include the low rate of provider systematic identification of smoker status and referral for more intensive treatment, the high out of pocket cost of NRT and other medications, the often spotty public and private insurance coverage, particularly of counseling, and the wait to see a primary care doctor for a prescription. [43]

43 National Commission on Prevention Priorities Preventive Care: A National Profile on Use, Disparities, and Health Benefits Partnership for Prevention, August 2007

With additional time, the workgroup believes it can develop an action plan for implementation of the preliminary proposals outlined, if they are found to be fiscally feasible (before the end of fiscal year, 2008). It also can enter into a deeper discussion during the remainder of the year with physicians, tobacco treatment specialists and other service providers, insurers and employers to develop a set of final recommendations which will involve collaborative efforts to improve access to tobacco dependence treatment for Maine's residents**.**

Appendix A

PLEASE NOTE: The Office of the Revisor of Statutes *cannot* perform research, provide legal advice, or interpret Maine law. For legal assistance, please contact a qualified attorney.

Resolve

123rd Legislature

First Regular Session

Chapter 34
S.P. 499 - L.D. 1421

Resolve, Regarding Tobacco Cessation and Treatment

Sec. 1 Best practice and model treatment programs. Resolved: That the Department of Health and Human Services, through the Partnership for a Tobacco-Free Maine, Maine Center for Disease Control and Prevention and the Office of MaineCare Services, shall undertake a study of best practice treatment and clinical practice guidelines for tobacco cessation treatment. The study must use the most recent available clinical practice guidelines available from the United States Department of Health and Human Services Public Health Service and must include development of a model tobacco cessation treatment program for use in the public sector and private sector. The department shall report back to the Joint Standing Committee on Health and Human Services by January 15, 2008. The committee may submit legislation to the Second Regular Session of the 123rd Legislature related to best practice treatment and clinical practice guidelines for tobacco cessation treatment.

Effective September 20, 2007

Appendix B

Resolve 34: Workgroup Members

Department of Health and Human Services
Office of MaineCare Services (MaineCare)

Brenda McCormick	Director, Division of Health Care Management
Roderick Prior, MD	Medical Director, MaineCare
Steve Davis	Director, Division of Policy and Performance
Nicole Rooney	Comprehensive Health Planner II
Bruce McClenahan	Manager, Pharmacy Unit, Division of Health Care Management
Melody Martin	Manager, Quality Management Unit, Div. of Health Care Management

Partnership for a Tobacco Free Maine, Maine Center for Disease Control and Prevention

MaryBeth Welton	Tobacco Control Program Manager, Partnership for a Tobacco-Free Maine

Coalition on Smoking or Health/Health Policy Partners of Maine

Pamela MB Studwell	Senior Policy Analyst

Appendix C

Stakeholders

Maine Tobacco Helpline

Allesandra Kazura MD	Co-Director (medical), Maine Tobacco Helpline
Kenneth Lewis	Co-Director, Maine Tobacco Helpline

Tobacco Treatment Specialist Certification Commission

Alfred Wolff	Center for Tobacco Independence, Prog. Manager, Education and Training
Rebecca Hitchcock RN	CTI, Counselor

Health Insurance

Katherine Pelletreau	Director, Maine Association of Health Plans
Katie Fullam-Harris	Anthem, Director of Government Relations
Maxwell Barus, MD	Co-Medical Director, Anthem
Michael Fleming	HEDIS Coordinator, Anthem

Large Employers

Maureen Kenney	Employee Benefits, Hannaford Brothers
Ellie Udeh	Wellness Program Director, Hannaford Brothers

Health Policy Partners/Maine Coalition on Smoking or Health

Becky Smith	Executive Director
Pam Studwell	Senior Policy Analyst
Jo Linder MD	Chair
John LaCasse MD	Medical Care Development, (also, Maine Practice Improvement Network)
Ed Miller	Executive Director, American Lung Association of Maine

Other

Lani Graham MD	Maine Health Access Foundation
Daniel Meyer PhD	PTM Advisory Council (Dir. of Research, ME-Dartmouth Family Practice)
Rep. Lisa Miller	Maine House of Representatives
Joanne Joy	Healthy Communities, Capitol Area, Director, Behavioral Health Task Force
Phyllis Wolf	PTM Advisory Council

Appendix D

MaineCare Smoking Deterrents	Ave.$/mo/user State & Federal	Ave.$/mo/user State Share	Covered	PDL Status
Bupropion	$51.95	$19.08	YES	Preferred
Nicotine patches	$61.25	$22.50	YES	Preferred
Nicotine gum	$68.15	$25.03	YES	Preferred
Nicotine lozenges	$141.70	$52.05	YES	Non-Preferred
Nicotine nasal spray	$190.55	$69.99	YES	Non-Preferred
Nicotine inhaler	$259.35	$95.26	YES	Non-Preferred
Chantix	$105.35	$38.70	YES	Preferred*

Prepared by OMS on 4/07; state/federal share (FY07): 36.73% / 63.27%

Appendix E

TOBACCO TREATMENT SPECIALIST CERTIFICATION

The certification of trained Tobacco Treatment Specialists is
American Lung Association of Maine (ALAME).

Tobacco treatment is based on the Clinical Practice Guideline: *Treating Tobacco Use and Dependence* (U.S. Public Health Service, June 2000). The Guideline contains strategies and recommendations to assist tobacco treatment specialists and clinicians to deliver effective, evidence-based treatment for tobacco use and dependence.

The Certified Tobacco Treatment Specialist (**TTS-C)** is a trained health professional who specializes in the treatment of tobacco dependence as part of his or her professional role. The TTS-C demonstrates the knowledge and skills to provide current and effective treatment for tobacco dependence. The TTS-C also serves as a resource and consultant to other healthcare professionals. The TTS-C can also provide the most effective and appropriate treatment to special populations, e.g. patients with a variety of co-morbidities, chemical dependency, or pregnancy.

ALAME has organized a commission of professionals with expertise and experience in addiction and substance abuse; counseling and intensive tobacco treatment to oversee the certification of qualified individuals as certified tobacco treatment specialists.

Purpose of Certification

- Provide quality assurance to clients, third party payers, employers, and referring health care providers
- Ensure best practice performance standards

Eligibility Criteria

- Graduate of the 2-day Intensive Tobacco Training provided by the Partnership for a Tobacco Free Maine (PTM)

- Minimum of a 2-year degree in a health-related field such as but not limited to health education,mental health or nursing. A complete listing is on the application form.

- Documented 240 hours experience in intensive tobacco treatment* in the last three years.
    - You may include hours from the past 3 years up to and including hours completed until your case study is submitted for review by the TTS-C Commission.

*Refer to Practice Components of an Intensive Tobacco Treatment Intervention

- Certification Process – Each step must be successfully completed before moving on

Step 1: Complete and submit application Tobacco Treatment Certification Commission for review and acceptance

** The application requires the documentation of 240 hours of intensive tobacco treatment in the last three years, hours may continue to be accrued up until your case study is submitted for review

Step 2: Pass the TTS-C written certification examination

Step 3: Prepare and submit a case study of an intensive tobacco treatment intervention to the Commission for review and acceptance

Step 4: Demonstrate application of the Core Competencies of a Tobacco Treatment Specialist by successfully presenting your case study before the Commission once the case study has been accepted

Examination Fee $150

Certification Examination

The exam consists of multiple choice and essay questions. It is based on the Clinical Practice Guideline, and on core competencies: Biology of Nicotine Dependence, Patient/Client Intake and Assessment, Counseling, Pharmacology of Tobacco Treatment, Treatment of Special Populations, Relapse Prevention, Organizational Needs.

Program History

The American Lung Association of Maine (ALAME) worked in partnership with the Center for Tobacco Independence (CTI) and the Partnership for a Tobacco-Free Maine (PTM) to develop the Maine Tobacco Treatment Specialist Certification Program. A key program element is the separation that exists between the training program and the certification process. CTI is responsible for the training and ALAME is responsible for the certification process. This was done to model other best practice professional certification programs and to avoid any conflicts that could result from a single entity being responsible for training and certification.

For More Information

Contact: The American Lung Association of Maine at 1-800-499-5864
or
Email Lee Scott at lscott@lungme.org

Appendix F

CURRENT TOBACCO TREATMENT COVERAGE OVERVIEW - MAINE

Insurance Coverage for Nicotine Replacement Therapy, Bupropion & Counseling

Updated: January 8, 2008

Source of coverage	Nicotine Patch	Nicotine Gum	Spray	Lozenge	Inhaler	Zyban	Chantix (varenicline)	Smoking Cessation Programs	Counseling
Medicaid* (MaineCare)	Up to 3 months supply / year; CO PAY (3.00); requires provider script although over the counter medication	Up to 3 months supply / year; CO PAY (3.00); requires provider script although over the counter medication	LIMIT: w/prior authorization, if gum and patch tried and failed or if presence of a condition that prevents usage of preferred drug or interaction with another drug and preferred drugs exists COPAY, provider apptmt	LIMIT: Available to patients not able to tolerate patch or gum COPAY; provider apptmt	LIMIT: w/prior authorization, if gum and patch tried and failed or if presence of a condition that prevents usage of preferred drug or interaction with another drug and preferred drugs exists COPAY, provider apptmt	Bupropion SR 100 and 150mg instead, which is the generic form of Zyban. COPAY, provder apptmt	Up to 6 mos. w/COPAY; effective 1/1/08, available w/o prior authorization; Note: patch and gum prescribed with Chantix, may be paid, with prior authorization	not covered	99402 - used alone or in addition to appropriate code (3/patient/calendar year/doctor); effective 1/1/08 new codes 99406 3-10 minutes; and 99407 10+ mins
Dirigo	Harvard Pilgrim plan-- available 1/1/08; coverage unknown	Harvard Pilgrim plan-- available 1/1/08; coverage unknown	Harvard Pilgrim plan-- available 1/1/08; coverage unknown	Harvard Pilgrim plan-- available 1/1/08; coverage unknown	Harvard Pilgrim plan-- available 1/1/08; coverage unknown	Harvard Pilgrim plan-- available 1/1/08; coverage unknown	Harvard Pilgrim plan-- available 1/1/08; coverage unknown	Harvard Pilgrim plan-- available 1/1/08; coverage unknown	Harvard Pilgrim plan-- available 1/1/08; coverage unknown

Anthem**	LIMIT: Standard Coverage includes: Covered with prescription $200 / year (after deductible is met), $400 / lifetime (for all NRT and Zyban) $10 PCP co pay	LIMIT: Standard Coverage includes: Covered with prescription $200 / year (after deductible is met), $400 / lifetime (for all NRT and Zyban) $10 PCP co pay	LIMIT: Base Coverage includes: Covered with prescription $200 / year (after deductible is met), $400 / lifetime (for all NRT and Zyban) $10 PCP co pay	LIMIT: Base Coverage includes: Covered with prescription $200 / year (after deductible is met), $400 / lifetime (for all NRT and Zyban) $10 PCP co pay	LIMIT Base Coverage includes: Covered with prescription $200 / year (after deductible is met), $400 / lifetime (for all NRT and Zyban) $10 PCP co pay	LIMIT Base Coverage includes: Covered with prescription $200 / year (after deductible is met), $400 / lifetime (for all NRT and Zyban) $10 PCP co pay	LIMIT Base Coverage includes: Covered with prescription $200 / year (after deductible is met), $400 / lifetime (for all NRT and Zyban) $10 PCP co pay	Smoking cessation classes provided through a hospital or physician's office $35/class, $70 lifetime	Base coverage could include: 2 physician follow-up visits anually
Self-insured Plan * **	covered w/no co pay , annual or lifetime limits or deductibles	covered w/no co pay , annual or lifetime limits or deductibles	covered w/no co pay , annual or lifetime limits or deductibles	covered w/no co pay , annual or lifetime limits or deductibles	covered w/no co pay , annual or lifetime limits or deductibles	covered w/no co pay , annual or lifetime limits or deductibles	covered w/no co pay , annual or lifetime limits or deductibles	100% of cost; no lifetime limits on classes	unlimited MD visits
Maine Tobacco Helpline	free up to 8 weeks, 2 refills/year for uninsured	free up to 8 weeks, 2 refills/year for uninsured	not covered	free up to 8 weeks, 2 refills/year for uninsured; 2d course of treatment 6 mos after last call	not covered	not covered	not covered	N/A	free for any caller; initial assessment plus 4 proactive follow up calls; unlimited add'l support calls (if caller calls in)
Medicare (updated 1/08)	Not covered b/c OTC	Not covered b/c OTC	May be covered - depends on Part D drug plan	May be covered -d epends on Part D drug plan	May be covered - depends on Part D drug plan	May be covered - depends on Part D drug plan	May be covered - depends on Part D drug plan	not covrerd	2 cessation attempts covered per year - each attempt may include a maximum of four

									intermediate or intensive sessions (cover up to 8 sessions in 12 mo period).****

*pharmacotherapy coverage based on Prescription
Drug List (PDL) revised 10/07
**current as of 11/07; largest small group insurer; may represent most comprehensive tobacco cessation coverage among non-self-insured plans

***Self insured plan of Maine Health through Anthem
Note: Buproprion hydrochloride is sold in generic form under brands Wellbutrin (for depression) and Zyban (for smoking cessation).
Although Wellbutrin and Zyban contain same active ingredient only generic bupropion and Zyban are approved by the FDA for smoking cessation Rx.
****Counseling covered if has illness caused/ complicated by smoking or other tobacco use, such as heart disease; or is taking medications that tobacco use interferes with (including drugs to treat diabetes, high blood pressure)

Appendix G

N/A

Appendix H

Tobacco Cessation Prescriptions
Data Source: old
MMDSS
Run Date: 8/28/07 (updated 01/04/2008)
Time Period: SFY 2005, 2006 and 2007
by cycle date
Paid Claims (reversal date is null)
GPI = 621000 Smoking Deterrents

Note: Since Bupropion can be used for both smoking cessation and depression this is reported separately.

Smoking Deterrents excluding Bupropion

Time Period	Count of Claims	Count of Distinct Members	Total Paid Amount
SFY 05	21,754	11,009	$1,333,219.97
SFY 06	26,124	13,165	$1,593,536.50
SFY 07	24,473	12,850	$1,334,301.83
Total	72,351	28,195	$4,261,058.30

Bupropion Only

Time Period	Count of Claims	Count of Distinct Members	Total Paid Amount
SFY 05	327	220	$29,565.86
SFY 06	475	285	$29,085.56
SFY 07	407	265	$22,051.15
Total	1,209	712	$80,702.57

All Smoking Deterrents

Time Period	Count of Claims	Count of Distinct Members	Total Paid Amount
SFY 05	22,081	11,154	$1,362,785.83
SFY 06	26,599	13,333	$1,622,622.06
SFY 07	24,880	13,010	$1,356,352.98
Total	73,560	28,509	$4,341,760.87

Tobacco Cessation Counseling
Data Source: new
MMDSS
Run Date: 9/4/07
Time Period: SFY 2005, 2006 and 2007
by payment date
Paid Claims (claim line status 71)

Diagnosis Code	Diagnosis Short Description	Procedure Code	Procedure Short Description
3051	TOBACCO USE DISORDER	99401	Preventive counseling, indiv
30510	UNSPECIFIED	99402	Preventive counseling, indiv
30511	CONTINUOUS	99403	Preventive counseling, indiv
30512	EPISODIC		
30513	IN REMISSION		

Time Period	Count of Claim Lines	Count of Distinct Members	Total Payment Amount
SFY 05	3,319	2,479	$64,381.30
SFY 06	3,464	2,558	$64,849.57
SFY 07	2,403	1,835	$43,919.45
Total	9,186	5,701	$173,150.32

Appendix I

Tobacco Cessation Prescriptions For Selected Smoking Deterrents

Data Source: Maine All-claims database - Commercially Insured Maine Residents
Time Period: SFY 2005, 2006
Drug Codes: see list of drug names on detail tabs.

Smoking Deterrant Category	State FY	Number of Distinct Members	Number of Scripts (30day eqiv)	Total Paid (Plan+Member)
All Smoking Deterrants	SFY05	21,182	96,707	$8,924,483
All Smoking Deterrants	SFY06	23,041	107,545	$10,430,461
All Smoking Deterrants	Total	34,003	204,252	$19,354,944
Buproprion (excluding Wellbutrin)*	SFY05	10,560	43,105	$3,051,833
Buproprion (excluding Wellbutrin)*	SFY06	10,083	42,578	$2,569,237
Buproprion (excluding Wellbutrin)*	Total	16,183	85,683	$5,621,070
Nicotine Preparations	SFY05	2,690	3,920	$382,419
Nicotine Preparations	SFY06	3,175	4,700	$447,051
Nicotine Preparations	Total	5,404	8,620	$829,470
Wellbutrin*	SFY05	10,833	49,682	$5,490,231
Wellbutrin*	SFY06	12,208	60,267	$7,414,173
Wellbutrin*	Total	18,026	109,949	$12,904,404

*Pharmacy claims data do not identify the intended use and do not include diagnosis coding. Scripts identified under the REDBOOK therapeutic class of buproprion may be for persons treated for depression or other conditions but not smoking cessation.

Tobacco Cessation Counseling Visits

Data Source: Maine All-claims database - Commercially Insured Maine Residents
Time Period: SFY 2005, 2006
Counseling claim defination: claims with DX 3051, 30510, 30511, 30512, 30513 and CPT 99401, 99402, 99403*

State FY	Number of Distinct Members	Number of Visit Encounters	Number of Claim Lines	Total Paid (Plan+Member)
SFY05	14,623	20,368	53,858	$13,481,768
SFY06	15,154	21,851	61,300	$14,779,016
Total	27,021	42,219	115,158	$28,260,784

* Diagnosis codes (ICD9):

305.1	Tobacco use disorder	
305.10	Tobacco use disorder	- unspecified
305.11	Tobacco use disorder	- continuous
305.12	Tobacco use disorder	- episodic
305.13	Tobacco use disorder	- in remission

Common Procedure Terminology codes (CPT):

99401	Preventive medicine visit - individual counseling-15 minutes
99402	Preventive medicine visit - individual counseling-30 minutes
99403	Preventive medicine visit - individual counseling-45 minutes

Appendix J

References

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(4) *Ending the Tobacco Problem: A Blueprint for the Nation*, Institute of Medicine Report, May 24, 2007 http://www.iom.edu/CMS/3793/20076/43179.aspx

(5) *Low Use of Preventive Care including Tobacco Cessation Treatment*, August, 2007 Partnership for Prevention Report: http://www.prevent.org/content/view/129/72/

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(9) Updated Miscellaneous Reviews of the Cochrane Collaboration on Tobacco Cessation Treatment: *http://www.cochrane.org/reviews/en/topics/94.html*,

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(11) *A National Action Plan for Tobacco Cessation* (2003) Interagency Committee on Smoking or Health: *http://www.ctri.wisc.edu/Researchers/NatActionPlan%2002-04.pdf*

(12) *Medicaid Sample Contract Purchasing Specifications Related to Tobacco Use Prevention and Cessation Services (2002):* U.S. CDC/GWU School of Public Health *http://www.gwumc.edu/sphhs/healthpolicy/chsrp/newsps/tobacco/*