U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF THE GENERAL COUNSEL

PHONE: (202) 690-6318
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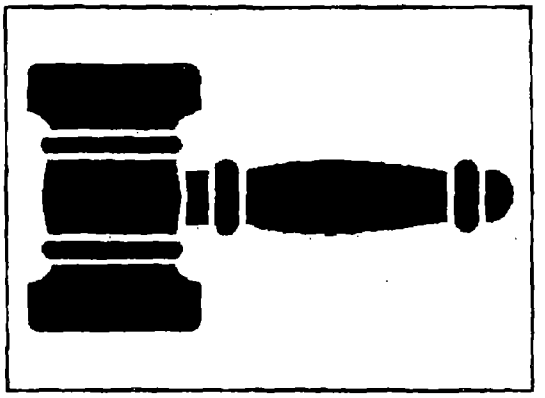
DATE: January 2, 1997



TO: **ELIZABETH DRYE**
fax: 456-7028

FROM: ANDREW D. HYMAN
Special Assistant to the General Counsel
U.S. Department of Health and Human Services
Office of the General Counsel, Room 707F
200 Independence Ave., SW
Washington, D.C. 20201

COMMENTS: Call me about the attachment when you get this.

No. of Pages (including cover): 2

Date **DRAFT**

Dear :

Your State Project Officer wrote to you on December 9, 1996 regarding your State's compliance with the requirements of section 1926 of the Public Health Service Act. In that letter you were asked to submit the information needed to determine compliance under this provision by December 20. As you know, section 1926 of the Public Health Service Act requires States to enact and enforce laws making it illegal to sell and distribute tobacco products to minors. It also requires that States conduct random, unannounced inspections of outlets in order to develop a baseline rate of compliance with the law, thereby measuring the effectiveness of State enforcement efforts. If a State fails to meet these requirements, section 1926 requires the Department of Health and Human Services to penalize the State by reducing the FY 1997 Substance Abuse Prevention and Treatment Block Grant award by 30 percent.

Since that letter, you have assured us that your State will finish the design of your methodology and conduct an appropriate number of random, unannounced inspections using that methodology by the middle of January 1997.

Based on your assurances, the date by which you must complete the inspections and submit the information to the Substance Abuse and Mental Health Services Administration can be extended to February 1, 1997. If you fail to submit the information by that date, your State will be considered not in compliance with section 1926 for fiscal year 1996 as specified in regulations issued January 19, 1996. At that time, SAMHSA will inform you of its intention to penalize the State in accordance with section 1926 (a) and offer you an opportunity for a hearing as required by section 1945 (e) of the Public Health Service Act.

The information that must be received by February 1, 1997 is as follows:

- o A detailed explanation of the State's sampling methodology,
- o A detailed explanation of the State's methodology for inspections;
- o A report on the completion of the State's inspections, consistent with the methodology, through February 1, 1997; and
- o A plan describing how the State will reduce its violation rate to 20 percent.

If you have any questions or need additional information, please contact Mr. Lee Wilson at (301) 443-6085.

Sincerely,

Steffie O'Neill
Acting Director
Center for Substance Abuse Prevention

HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

CDC Media Advisory
EMBARGOED FOR RELEASE
UNTIL January 25, 1996

CONTACT:
Tim Hensley or Llelwyn Grant
770-488-5493
CDC Office of Public Affairs
404-639-3286

The Centers for Disease Control and Prevention (CDC) today released a new report that summarizes the data on tobacco use in all 50 states and the District of Columbia. *State Tobacco Control Highlights, 1996* is the first compilation of state-based data on the prevalence of tobacco use, the health impact and costs associated with tobacco use, tobacco control laws, tobacco agriculture and manufacturing, and tobacco use prevention and control programs.

According to the CDC report, tobacco use remains the leading preventable cause of death in the United States, causing more than 400,000 deaths each year at an annual cost of more than $50 billion. Nationally, smoking results in more than 5 million years of potential life lost each year.

These data show wide variations among states in the use of tobacco and in policies to reduce tobacco use. For example:

- Past-month smoking among young people (grades 9-12) ranges from 16.7 percent in D.C. to 38.9 percent in West Virginia, more than a two-fold difference. [Note: Data recently released by the National Institute on Drug Abuse in its 1995 Monitoring the Future Study showed a continued increase in monthly and daily tobacco use among 8th, 10th and 12th graders. The increase in daily smoking among 12th graders (up to 21.6 percent from 19.4 percent in 1994) is the highest reported since 1979.]

- Daily smoking among adults ranges from 15.1 percent in Utah to 30.3 percent in Nevada, also more than a two-fold difference. Similarly, the smoking-related death rate is more than twice as high in Nevada (478 deaths per 100,000 population) as in Utah (218).

- Smokeless tobacco use varies even more. Among young people, prevalence of use ranges from 1.6 percent in D.C. to 24 percent in Montana. Among adults, prevalence ranges from 0.1 percent in Connecticut to 7.7 percent in West Virginia.

- Although 21 states have laws that restrict smoking in private worksites, only one (California) meets the nation's Healthy People 2000 objective to eliminate nonsmokers' exposure to environmental tobacco smoke.

- More -

- State-specific data highlight not only the wide range of smoking rates and policies in the United States, but also the wide range of smoking-related death rates -- and how less smoking translates to fewer deaths. This report shows there is much room for progress in reducing tobacco use and improving tobacco control measures, but that such progress can be -- and is being -- achieved.

Copies of the report are available to the press from CDC's Office on Smoking and Health.

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HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOR IMMEDIATE RELEASE
Thursday, Jan. 18, 1996

Contact: Victor Zonana
(202) 690-6343

HHS AND SAMHSA ISSUE FINAL RULE ON YOUTH ACCESS TO TOBACCO

The Department of Health and Human Services (HHS) and the Substance Abuse and Mental Health Services Administration (SAMHSA) today issued a final rule designed to ensure that states and territories adopt and enforce laws prohibiting the sale or distribution of tobacco products to children.

The rule provides guidance to the states on how to comply with the Synar Amendment, named for its author, the late Mike Synar, former Congressman from Oklahoma. Synar died of brain cancer Jan. 9. The amendment was enacted in 1992 as part of the Public Health Service Act and requires states to have and to enforce laws banning the sale and distribution of tobacco products to people under 18.

While all states currently have such laws, enforcement has been inconsistent; in 1991, an estimated 255 million cigarette packs were sold illegally to minors, according to the American Journal of Public Health. And in the 1995 Monitoring the Future Survey released last month, more than 90 percent of high school tenth graders surveyed said it was "fairly easy" or "very easy" to obtain cigarettes.

"The Synar regulation is an important part of the Clinton Administration's overall effort to help parents protect their children from the dangers of tobacco," said HHS Secretary Donna E. Shalala.

- More -

On August 10, President Clinton announced proposals by the Food and Drug Administration (FDA), another HHS agency, designed to reduce the access and appeal of tobacco products to young people. The FDA is currently reviewing public comments it received on its proposed regulations.

"These two initiatives would complement one another, and are intended to limit the access and appeal of tobacco products to young people," Shalala said.

Together, Shalala said, the Synar regulation and the proposed FDA regulations would provide a means to achieve President Clinton's goal of reducing the use of tobacco products by young people 50 percent within seven years.

The Synar regulation -- formally titled "Substance Abuse Prevention and Treatment Block Grants: Sale or Distribution of Tobacco Products to Individuals Under 18 Years of Age" -- requires states and territories to enforce their youth access laws through such methods as random spot checks of retail establishments. It would also require states to designate an office or agency for coordinating compliance activities.

States would be required to file annual progress reports and could suffer financial penalties through reductions in substance-abuse block grants for failing to achieve agreed-upon goals.

"States should have broad flexibility in achieving our common goal of preventing youth addiction to tobacco products, but we have to have effective enforcement," Nelba Chavez, SAMHSA's administrator, said.

"Despite the existence of laws barring the sale of tobacco to minors in all 50 states, enforcement has been uneven," Chavez continued.

"Moreover," added Shalala, "the problem of teen smoking is getting worse."

Last month, the 1995 Monitoring the Future Survey reported continued large increases in smoking among 8th, 10th and 12th graders.

Among 10th graders, 27.9 percent had smoked within 30 days of the survey, up from 25.4 percent a year earlier, and 16.3 percent smoked every day, compared to 14.6 percent a year earlier.

Among 12th graders, fully 33.5 percent had smoked within 30 days of the survey, up from 31.2 percent in 1994. Daily smoking among 12th graders increased to 21.6 percent from 19.4 percent.

And among the youngest members of the survey -- eighth graders who may be as young as 13 -- daily cigarette use jumped to 9.3 percent in 1995 from 7.2 percent in 1991, while past-month smoking among eighth graders soared to 19.1 percent from 14.3 percent in 1991.

"This four-year trend of increased smoking among American youth, if not reversed, will cost this country thousands of precious lives and billions of dollars in health costs," Shalala warned.

Shalala pointed to another worrisome finding in the Monitoring the Future survey. "Over 90 percent of tenth graders and 76 percent of eighth graders said it was fairly or very easy to get cigarettes," she said.

About 3,000 young people under the age of 18 become regular smokers every day and nearly 1,000 of them will eventually die of tobacco-related illnesses.

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HHS Briefing on Synar Amendments 1/17/96

Head of
Scott Balin — Coalition — Am. Heart Assn.

1992 102nd Congress Amended the Public Health Service Act.

- where is it already in force
- actions taken

1/17/96
TO: ELIZABETH

Rep Forbes

Points — ↑ in teen smoking
- Findings of AG's
Biennial report

Joseph Faha
Commerce CMM — Howard Cohen —
Asked for brfg. tomorrow at 1:00

Elain Johnson —
Dir — Substance Abuse Prev
c/in SAMSA
- Icaregn. - CBC / office of smoking and Health

- Regs publically released tomorrow
- published Friday
- Will take effect this year

Elaine Johnson

commenters (sent)
Wyden ✓
Meehan ✓
Hansen ✓
Durbin

Admin – Youth access to tobacco products
~~prevention~~ requires comprehensive approach

FDA – looking at the environment
Access, availability, appeal

Senate 1926 – features

– will work w/CDC to provide technical assistance and training

States
- Have had to come up w/sampling design – set a baseline – and then negotiate state-by-state a time frame for meeting the 20% failure rates
- HHS/SAM/HSA have NOT withheld any funds to date.
- States can use CDC's prevention health services block grant, and SAMHSA's (limited to random inspection) to enforce the law.

?

$1.2 annual block grant.

Data on non-compliance rates – local govts w/aggressive enforcement have achieved 20% or less.

205.402

20% goal is part of Healthy People 2000.

Changes from proposed rule
(proposed rule had 4 yr. term from for Mfg. 20% — based on state-by-state basis)

NPRM — Could only use 5% of Funds from blk grant ~~for Admin. Aspect to implement~~
— Opened up block grant for design, Inspections.

TOM — political concerns
SAMHSA — will direct community partnership
e.g. CA
$130 million — in 3rd applicable year — would lose 30%
10, 20, 30, 40% — This is the third applicable year.

Sept 30 — have to have run a random probability sample. Get used as base # for negotiations
- authority established
- State-wide strategy
- measures of compliance.
- ~~o~~

Negotiations will be completed as part of the application for 1997 funds (5-7 years). Interim targets —

Senate Appropriations bill
CONF Report See 104-93 — supportive of this provision — but penalties.

- legislation
~~Rule~~ came out before

Complement to FDA reg

Synar reg specifically focused on state-designed enforcement of prohibition on sales to minors.

- No penalties for retailers
- No ~~auth~~ requirement that states penalize retailers

FDA rule will help states meet this
(they're asked for the help)

20% failure rate is not a 20% access rate...

Lautenberg / Sander
Durbin / Tom Faletti 2463
Meehan / Bill McCann
Hansen / Brian Williams

Karen Deasy - CDC