

BREAST AND CERVICAL CANCER PREVENTION AND
TREATMENT ACT OF 1999

NOVEMBER 22, 1999.—Ordered to be printed

Mr. BLILEY, from the Committee on Commerce,
submitted the following

R E P O R T

together with

ADDITIONAL VIEWS

[To accompany H.R. 1070]

[Including cost estimate of the Congressional Budget Office]

The Committee on Commerce, to whom was referred the bill (H.R. 1070) to amend title XIX of the Social Security Act to provide medical assistance for certain women screened and found to have breast or cervical cancer under a federally funded screening program, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

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AMENDMENT

The amendments are as follows:

Strike out all after the enacting clause and insert in lieu thereof the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the “Breast and Cervical Cancer Prevention and Treatment Act of 1999”.

SEC. 2. OPTIONAL MEDICAID COVERAGE OF CERTAIN BREAST OR CERVICAL CANCER PATIENTS.

(a) COVERAGE AS OPTIONAL CATEGORICALLY NEEDY GROUP.—

(1) IN GENERAL.—Section 1902(a)(10)(A)(ii) of the Social Security Act (42 U.S.C. 1396a(a)(10)(A)(ii)) is amended—

- (A) in subclause (XIII), by striking “or” at the end;
- (B) in subclause (XIV), by adding “or” at the end; and
- (C) by adding at the end the following:

“(XV) who are described in subsection (aa) (relating to certain breast or cervical cancer patients);”.

(2) GROUP DESCRIBED.—Section 1902 of the Social Security Act (42 U.S.C. 1396a) is amended by adding at the end the following:

“(aa) Individuals described in this paragraph are individuals who—

- “(1) are not described in subsection (a)(10)(A)(i);
- “(2) have not attained age 65;
- “(3) have been screened for breast and cervical cancer under the Centers for Disease Control and Prevention breast and cervical cancer early detection program established under title XV of the Public Health Service Act (42 U.S.C. 300k et seq.) in accordance with the requirements of section 1504 of that Act (42 U.S.C. 300n) and need treatment for breast or cervical cancer; and
- “(4) are not otherwise covered under creditable coverage, as defined in section 2701(c) of the Public Health Service Act (45 U.S.C. 300gg(c)).”.

(3) LIMITATION ON BENEFITS.—Section 1902(a)(10) of the Social Security Act (42 U.S.C. 1396a(a)(10)) is amended in the matter following subparagraph (F)—

- (A) by striking “and (XIII)” and inserting “(XIII)”; and
- (B) by inserting “, and (XIV) the medical assistance made available to an individual described in subsection (aa) who is eligible for medical assistance only because of subparagraph (A)(10)(ii)(XV) shall be limited to medical assistance provided during the period in which such an individual requires treatment for breast or cervical cancer” before the semicolon.

(4) CONFORMING AMENDMENTS.—Section 1905(a) of the Social Security Act (42 U.S.C. 1396d(a)) is amended in the matter preceding paragraph (1)—

- (A) in clause (x), by striking “or” at the end;
- (B) in clause (xi), by adding “or” at the end; and
- (C) by inserting after clause (xi) the following:

“(xii) individuals described in section 1902(aa).”.

(b) PRESUMPTIVE ELIGIBILITY.—

(1) IN GENERAL.—Title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) is amended by inserting after section 1920A the following:

“PRESUMPTIVE ELIGIBILITY FOR CERTAIN BREAST OR CERVICAL CANCER PATIENTS

“SEC. 1920B. (a) STATE OPTION.—A State plan approved under section 1902 may provide for making medical assistance available to an individual described in section 1902(aa) (relating to certain breast or cervical cancer patients) during a presumptive eligibility period.

“(b) DEFINITIONS.—For purposes of this section:

“(1) PRESUMPTIVE ELIGIBILITY PERIOD.—The term ‘presumptive eligibility period’ means, with respect to an individual described in subsection (a), the period that—

“(A) begins with the date on which a qualified entity determines, on the basis of preliminary information, that the individual is described in section 1902(aa); and

“(B) ends with (and includes) the earlier of—

“(i) the day on which a determination is made with respect to the eligibility of such individual for services under the State plan; or

“(ii) in the case of such an individual who does not file an application by the last day of the month following the month during which the entity makes the determination referred to in subparagraph (A), such last day.

“(2) QUALIFIED ENTITY.—

“(A) IN GENERAL.—Subject to subparagraph (B), the term ‘qualified entity’ means any entity that—

“(i) is eligible for payments under a State plan approved under this title; and

“(ii) is determined by the State agency to be capable of making determinations of the type described in paragraph (1)(A).

“(B) REGULATIONS.—The Secretary may issue regulations further limiting those entities that may become qualified entities in order to prevent fraud and abuse and for other reasons.

“(C) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be construed as preventing a State from limiting the classes of entities that may become qualified entities, consistent with any limitations imposed under subparagraph (B).

“(c) ADMINISTRATION.—

“(1) IN GENERAL.—The State agency shall provide qualified entities with—

“(A) such forms as are necessary for an application to be made by an individual described in subsection (a) for medical assistance under the State plan; and

“(B) information on how to assist such individuals in completing and filing such forms.

“(2) NOTIFICATION REQUIREMENTS.—A qualified entity that determines under subsection (b)(1)(A) that an individual described in subsection (a) is presumptively eligible for medical assistance under a State plan shall—

“(A) notify the State agency of the determination within 5 working days after the date on which determination is made; and

“(B) inform such individual at the time the determination is made that an application for medical assistance under the State plan is required to be made by not later than the last day of the month following the month during which the determination is made.

“(3) APPLICATION FOR MEDICAL ASSISTANCE.—In the case of an individual described in subsection (a) who is determined by a qualified entity to be presumptively eligible for medical assistance under a State plan, the individual shall apply for medical assistance under such plan by not later than the last day of the month following the month during which the determination is made.

“(d) PAYMENT.—Notwithstanding any other provision of this title, medical assistance that—

“(1) is furnished to an individual described in subsection (a)—

“(A) during a presumptive eligibility period;

“(B) by a entity that is eligible for payments under the State plan; and

“(2) is included in the care and services covered by the State plan;

shall be treated as medical assistance provided by such plan for purposes of section 1903.”.

(2) CONFORMING AMENDMENTS.—

(A) Section 1902(a)(47) of the Social Security Act (42 U.S.C. 1396a(a)(47)) is amended by inserting before the semicolon at the end the following: “and provide for making medical assistance available to individuals described in subsection (a) of section 1920B during a presumptive eligibility period in accordance with such section”.

(B) Section 1903(u)(1)(D)(v) of such Act (42 U.S.C. 1396b(u)(1)(D)(v)) is amended—

(i) by striking “or for” and inserting “, for”; and

(ii) by inserting before the period the following: “, or for medical assistance provided to an individual described in subsection (a) of section 1920B during a presumptive eligibility period under such section”.

(c) ENHANCED MATCH.—The first sentence of section 1905(b) of the Social Security Act (42 U.S.C. 1396d(b)) is amended—

(1) by striking “, (2)” and inserting “, (2)”; and

(2) by striking “and” before “(3)”; and

(3) by inserting before the period at the end the following: “, and (4) in the case of a State for which the Federal medical assistance percentage is otherwise less than 75 percent, it shall be equal to 75 percent with respect to medical assistance provided to individuals who are eligible for such assistance only on the basis of section 1902(a)(10)(A)(ii)(XV)”.

(d) **EFFECTIVE DATE.**—The amendments made by this section apply to medical assistance for items and services furnished on or after October 1, 2000, without regard to whether final regulations to carry out such amendments have been promulgated by such date.

SEC. 3. HUMAN PAPILLOMAVIRUS; ACTIVITIES OF CENTERS FOR DISEASE CONTROL AND PREVENTION.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by inserting after section 317G the following section:

“HUMAN PAPILLOMAVIRUS

“SEC. 317H. (a) **SURVEILLANCE.**—

“(1) **IN GENERAL.**—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall—

“(A) enter into cooperative agreements with States and other entities to conduct sentinel surveillance or other special studies that would determine the prevalence in various age groups and populations of specific types of human papillomavirus (referred to in this section as ‘HPV’) in different sites in various regions of the United States, through collection of special specimens for HPV using a variety of laboratory-based testing and diagnostic tools; and

“(B) develop and analyze data from the HPV sentinel surveillance system described in subparagraph (A).

“(2) **REPORT.**—The Secretary shall make a progress report to the Congress with respect to paragraph (1) not later than one year after the effective date of this section.

“(b) **PREVENTION ACTIVITIES; EDUCATION PROGRAM.**—

“(1) **IN GENERAL.**—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall conduct prevention research on HPV, including—

“(A) behavioral and other research on the impact of HPV-related diagnoses on individuals;

“(B) formative research to assist with the development of educational messages and information for the public, for patients, and for their partners about HPV;

“(C) surveys of physician and public knowledge, attitudes, and practices about genital HPV infection; and

“(D) upon the completion of and based on the findings under subparagraphs (A) through (C), develop and disseminate educational materials for the public and health care providers regarding HPV and its impact and prevention.

“(2) **REPORT; FINAL PROPOSAL.**—The Secretary shall make a progress report to the Congress with respect to paragraph (1) not later than one year after the effective date of this section, and shall develop a final proposal not later than two years after such effective date, including a detailed summary of the significant findings and problems. The report shall outline the further steps needed to make HPV a reportable disease and the best strategies to prevent future infections.

“(c) **CONDOM EFFECTIVENESS; EDUCATION.**—The Secretary shall require that the Department of Health and Human Services and all contractors, grantees, and subgrantees of such Department specifically state the effectiveness or lack of effectiveness of condoms in preventing the transmission of HPV, herpes, and other sexually transmitted diseases in all informational materials related to condoms or sexually transmitted diseases that are made available to the public. The Secretary shall assure that such information is made available to relevant operating divisions and offices of the Department of Health and Human Services. This subsection shall be effective within 6 months of the date of its enactment.”

SEC. 4. LABELING OF CONDOMS WITH RESPECT TO HUMAN PAPILLOMAVIRUS.

(a) **IN GENERAL.**—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

“(u) If it is a condom, unless its label and labeling bear information providing that condoms do not effectively prevent the transmission of the human papillomavirus and that such virus can cause cervical cancer.”

(b) **APPLICABILITY.**—The amendment made by subsection (a) applies to condoms manufactured on or after the expiration of the 180-day period beginning on the date of the enactment of this Act.

SEC. 5. MENTAL HEALTH PARTIAL HOSPITALIZATION SERVICES.**(a) LIMITATION ON LOCATION OF PROVISION OF SERVICES.—**

(1) **IN GENERAL.**—Section 1861(ff)(2) of the Social Security Act (42 U.S.C. 1395x(ff)(2)) is amended in the matter following subparagraph (I)—

(A) by striking “and furnished” and inserting “furnished”; and

(B) by inserting before the period the following: “, and furnished other than in a skilled nursing facility, residential treatment facility or other residential setting (as determined by the Secretary)”.

(2) **EFFECTIVE DATE.**—The amendments made by paragraph (1) apply with respect to partial hospitalization services furnished on or after the first day of the third month beginning after the date of the enactment of this Act.

(b) QUALIFICATIONS FOR COMMUNITY MENTAL HEALTH CENTERS.—

(1) **IN GENERAL.**—Section 1861(ff)(3)(B) of such Act (42 U.S.C. 1395x(ff)(3)(B)) is amended by striking “entity” and all that follows and inserting the following: “entity that—

“(i)(I) provides the mental health services described in section 1913(c)(1) of the Public Health Service Act; or

“(II) in the case of an entity operating in a State that by law precludes the entity from providing a service described in such section itself, provides for such service by contract with an approved organization or entity (as determined by the Secretary);

“(ii) meets applicable licensing or certification requirements for community mental health centers in the State in which it is located; and

“(iii) meets such additional conditions as the Secretary shall specify to ensure (I) the health and safety of individuals being furnished such services, (II) the effective and efficient furnishing of such services, and (III) the compliance of such entity with the criteria described in such section.”

(2) **CLARIFICATION OF CRITERIA FOR COMMUNITY MENTAL HEALTH CENTERS.**—Section 1913(c)(1)(E) of the Public Health Service Act (42 U.S.C. 300x-3(c)(1)(E)) is amended to read as follows:

“(E) Determining the clinical appropriateness of admissions to inpatient psychiatric hospitals by engaging a full-time mental health professional who is licensed or certified to make such a determination by the State involved.”

(3) **EFFECTIVE DATE.**—The amendments made by this subsection apply with respect to community mental health centers furnishing services under the medicare program on or after the first day of the third month beginning after the date of the enactment of this Act.

(c) REFINEMENT OF PERIODICITY OF REVIEW OF PLAN FOR PARTIAL HOSPITALIZATION SERVICES.—

(1) **IN GENERAL.**—Section 1835(a)(2)(F)(ii) of the Social Security Act (42 U.S.C. 1395n(a)(2)(F)(ii)) is amended by inserting “at a reasonable rate (as determined by the Secretary)” after “is reviewed periodically”.

(2) **EFFECTIVE DATE.**—The amendment made by paragraph (1) applies with respect to plans of care for furnishing partial hospitalization services established on or after the first day of the third month beginning after the date of the enactment of this Act.

(d) RECERTIFICATION OF PROVIDERS OF PARTIAL HOSPITALIZATION SERVICES.—

(1) **IN GENERAL.**—With respect to each community mental health center that furnishes partial hospitalization services for which payment is made under title XVIII of the Social Security Act, the Secretary of Health and Human Services shall provide for periodic recertification to ensure that the provision of such services complies with applicable requirements of such title.

(2) **DEADLINE FOR FIRST RECERTIFICATION.**—The first recertification under subsection (a) shall be completed not later than one year after the date of the enactment of this Act.

(e) **GUIDELINES FOR ITEMS AND SERVICES COMPRISING PARTIAL HOSPITALIZATION SERVICES.**—Not later than one year after the date of the enactment of this Act, the Secretary shall promulgate regulations using a negotiated rulemaking process under subchapter III of chapter 5 of title 5, United States Code, for national coverage policies for partial hospitalization services furnished under title XVIII of the Social Security Act, including for periodicity of review under section 503 of this title.

SEC. 6. SENSE OF COMMITTEE ON COMMERCE TO FULLY PAY FOR ADDITIONAL EXPENDITURES BEFORE PASSAGE BY THE HOUSE OF REPRESENTATIVES.

It is the sense of the Committee on Commerce of the House of Representatives that the additional net expenditures resulting from the enactment of this bill, as

reported by the Committee, should be fully offset in an appropriate manner before the bill is passed by the House of Representatives.

Amend the title so as to read:

A bill to amend title XIX of the Social Security Act to provide medical assistance for certain women screened and found to have breast or cervical cancer under a federally funded screening program, to amend the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act with respect to surveillance and information concerning the relationship between cervical cancer and the human papillomavirus (HPV), and for other purposes.

PURPOSE AND SUMMARY

The purpose of H.R. 1070, the Breast and Cervical Cancer Prevention and Treatment Act of 1999, is to amend title XIX of the Social Security Act to provide health prevention and medical assistance for certain women screened and found to have breast or cervical cancer under a Federally funded screening program.

BACKGROUND AND NEED FOR LEGISLATION

H.R. 1070 is the latest in a series of efforts made by the Committee on Commerce to address breast and cervical cancer. On March 16, 1999, the Subcommittee on Health and Environment held a hearing on cervical cancer in order to bring this disease to a higher level of public awareness. In the last Congress, the Committee passed the Mammography Quality Standards Reauthorization Act of 1998 (Public Law 105-248), which now requires that written notification of test results be sent directly to the patient. The Committee has encouraged mammography facilities to urge their patients to follow up with their own physicians.

The Committee also successfully bolstered the Centers for Disease Control and Prevention (CDC) breast and cervical cancer screening program by enacting into law the Women's Health Research and Prevention Amendments of 1998 (Public Law 105-340; 42 U.S.C. 242k et seq.), which authorizes CDC to increase its assistance to State, territorial, and tribal governments for case management services. Since CDC requires that all the women screened with cancer be offered treatment in their own States, this new authority will help many uninsured women in this program more quickly find treatment in their communities.

In 1990, this Committee authorized the Breast and Cervical Cancer Mortality Prevention Act (Public Law 101-354; 42 U.S.C. 300k et seq.), which screens certain low-income women who do not qualify for Medicaid or Medicare for breast and cervical cancer. An estimated 2 million American women will be diagnosed with breast or cervical cancer in this decade, and half a million women will lose their lives to these diseases. Excluding skin cancer, breast cancer is the most common cancer among American women and is second only to lung cancer as a cause of cancer-related death in the United States. An estimated 175,000 new cases of breast cancer among women will be diagnosed in 1999, and 43,300 women will die of this disease. Each year, an estimated 15,000 cases of cervical cancer are diagnosed in the United States, and 5,000 American women die from the disease annually.

The incidence of invasive cervical cancer has decreased significantly over the last 40 years, in large part because of early detec-

tion efforts. Precancerous tissue, however, is detected at very high levels, primarily through Pap tests. Research indicates that over 99 percent of women with cervical cancer had "high-risk" human papillomavirus (HPV), which is recognized as the cause of cervical cancer. According to the National Cervical Cancer Public Education Campaign, HPV is one of the most common sexually transmitted diseases (STDs) in the United States. Experts indicate that as many as 24 million Americans are infected with HPV, and the frequency of infection and disease appears to be increasing.

Screening and early detection is very important for breast and cervical cancer. The earlier it is detected, the better the survival rate. When breast cancer is diagnosed at a local stage, the 5-year survival rate is 97 percent. When breast cancer is diagnosed after it has spread, the 5-year survival rate decreases to 21 percent. Cervical cancer screening also offers great benefits. For a woman found to have precancerous cervical lesions or to have cancer in its earliest stage, the likelihood of survival is almost 100 percent with timely and appropriate treatment and follow-up. In Africa and Asia, where women don't have regular screening tests, cervical cancer is the most common cause of cancer-related death.

Recognizing the value of screening and early detection, Congress passed the Breast and Cervical Cancer Mortality Prevention Act of 1990. This Act authorized CDC to provide critical breast and cervical cancer screening services to uninsured women who are relatively poor but not poor enough to qualify for Medicaid, and too young to qualify for Medicare.

With Fiscal Year 1999 appropriations of approximately \$158 million, CDC targets the population with the highest incidence of breast and cervical cancer: post-menopausal women. Through the National Breast and Cervical Cancer Early Detection Program (NBCCEDP), CDC now supports screening activities in all 50 States, in 5 U.S. territories, in the District of Columbia, and through 15 American Indian/Alaska Native organizations. By October 1997, more than 1.5 million screening tests had been provided by the NBCCEDP.

The Breast and Cervical Cancer Mortality Prevention Act of 1990 does not authorize CDC to pay for treating breast and cervical cancer. However, under the cooperative agreements entered into by the CDC and State, territorial, and tribal programs, participating governments must certify that treatment will be offered to all women who have been diagnosed with cancer through the program. CDC's data set of some 2 million women screened indicate that a majority of women screened initiate treatment within 8 days of diagnosis. According to CDC,

participating state programs have been determined and creative in ensuring that treatment services are available for women diagnosed with breast cancer or cervical abnormalities. The availability of treatment sources reflects the extent of state and local government support, the generosity of medical providers, and the commitment of communities. (Dr. Nancy C. Lee, Director, Division of Cancer Prevention and Control, Centers for Disease Control and Prevention, Testimony before the Subcommittee on Health Environment hearing on Women's Health: Raising Aware-

ness of Cervical Cancer, March 16, 1999, Hearing Serial No. 106-4.)

Although the majority of women diagnosed with cancer through the program initiate treatment within eight days, a CDC report found that the system of treatment available to these women can be “tenuous and fragile at best.” (CDC Morbidity and Mortality Weekly Report, March 27, 1998, vol. 47, no. 11, p. 215.) At a hearing before the Subcommittee on Health and Environment on July 21, 1999, Ms. Carolyn Tapp, President of the Women of Color Breast Cancer Survivors Support Project in Los Angeles, spoke of the difficulties women in the project face in getting treatment:

For these breast cancer patients there is really no system of care—and the care they receive is often partial and very often inadequate. Treatment services are difficult to find; increasingly physicians have not been willing to provide their services for free or for little charge. The women we see often have to wait for care, or wait to see if they qualify for [Medicaid]. Most often they end up at public health facilities or end up with medical bills in the thousands of dollars that they will never be able to pay. (Ms. Carolyn Tapp, President, Women of Color Breast Cancer Survivors Support Project, Testimony before the Subcommittee on Health and Environment hearing on H.R. 1070, July 21, 1999, Hearing Serial No. 106-42.)

Although most women initiate treatment within eight days of diagnosis through this program, the lag in State data reporting has given many Members of this Committee concern that the Clinton Administration has failed to aggressively pursue State collection of program data to assure Congress that these governments are not failing to meet their obligations under the CDC compacts to treat women through this program. One solution to the problem Ms. Tapp described in her testimony is embodied in H.R. 1070, which would, at a State’s option, automatically qualify for Medicaid these women who have been screened and diagnosed through the CDC program with breast or cervical cancer. The good news is that CDC-initiated audits of the treatment programs through the CDC/State cooperative agreements have found no evidence that women are failing to receive treatment, and that the Department of Health and Human Services (HHS) Office of Inspector General has never received any complaints about women eligible for treatment through this program but failing to receive it.

A bipartisan amendment approved by the Full Committee expands the bill into the area of cancer prevention by requiring, among other things, that the Centers for Disease Control and Prevention study the prevalence of human papillomavirus (HPV) infection and carry on educational activities about HPV among health care providers and the public. This amendment also directs the Food and Drug Administration to develop a warning label for condom packages to advise consumers that condoms are ineffective in preventing the transmission of HPV.

The Council on State and Territorial Epidemiologists in conjunction with CDC has designated 58 infectious diseases as notifiable on a national level. This list does not include HPV, which an article

in the Journal of Pathology this year found is the cause of 99.7 percent of cervical cancers (Journal of Pathology, September 1999, 189(1): 12–19). Although most women with HPV will not develop cervical cancer, according to the National Cervical Cancer Public Education Campaign, HPV is one of the most common sexually transmitted diseases in the United States, and the frequency of infection and disease appears to be increasing. Under current law, HPV is not a disease on which the CDC compiles data as a notifiable disease, yet cervical cancer caused by HPV kills more American women than complications caused by all the other sexually transmitted diseases combined, including HIV. Among the sexually transmitted diseases for which CDC compiles surveillance data (gonorrhea, syphilis, and chancroid from all 50 States; chlamydia is reported in 49 States), there were 2,665 female deaths attributable to HIV; 99 to syphilis; and 3 to gonorrhea in 1992, the latest year for which comparable data are available. (Ebrahim et al., “Mortality Related to STD in US Women, 1973 through 1992”, American Journal of Public Health, 1997, 87: 938–44; CDC Responses to Questions on HPV and Cervical Cancer from the Subcommittee on Health and Environment, April 2, 1999). Five thousand American women will die from HPV-caused cervical cancer this year.

Since HPV is not a reportable disease, there is no reliable data to determine its true magnitude. By confidentially reporting cases of HPV to state health departments, those responsible for disease control can more accurately determine the current extent of the epidemic, future trends, rates of progression to cancer, populations at risk, possible changes in transmissibility, and other critical factors of disease control. Such information allows for the development of long-term prevention strategies based on reliable data.

Due to the lack of reliable data on HPV, the estimated number of Americans with HPV has been cited to be anywhere from 24 million (by the National Cancer Institute) to 100 million (by the CDC, based on serologic studies done in 1997). CDC stated the reason for such disparity stems from the fact that “HPV infection is not diagnosed in most people who are infected and because there are no systems in place for reporting of HPV infection, assessment of prevalence can only be based on very general estimates.” (CDC Responses to Questions on HPV and Cervical Cancer from the Subcommittee on Health and Environment, reprinted in hearing on Women’s Health: Raising Awareness of Cervical Cancer, March 16, 1999, Hearing Serial No. 106–4.)

The Lazio-Eshoo-Coburn amendment to H.R. 1070 will help to address this lack of knowledge about the prevalence of HPV. H.R. 1070 permits the Secretary of Health and Human Services (the Secretary) to enter into cooperative agreements with States and other entities to conduct sentinel surveillance or other special studies that would determine the prevalence of specific types of HPV, and requires the Secretary to develop and analyze the data from the surveillance system and make a progress report to Congress.

Scientific studies have proven conclusively that condoms do not provide complete protection against HPV, the cause of cervical cancer. According to the National Cancer Institute, “Condoms are ineffective against HPV because the virus is prevalent not only in

mucosal tissue (genitalia) but also on dry skin of the surrounding abdomen and groin and it can migrate from those areas into the vagina and the cervix.” (February 19, 1999, Letter from National Cancer Institute to Committee on Commerce Chairman Tom Bliley). The National Cancer Institute conclusion that condoms are ineffective against HPV infection “is based on the results of several long term studies which have failed to show that barrier contraceptives prevent cervical HPV infection, dysplasia or cancer” (National Cancer Institute response letter dated April 8, 1999, to Subcommittee on Health and the Environment Chairman Michael Bilirakis). The CDC noted that “The most reliable means of preventing sexual transmission of genital HPV infection is likely to be abstinence, although, as noted above, non-sexual routes of transmission are possible” (April 2, 1999, CDC Responses to Questions on HPV and Cervical Cancer from the Subcommittee on Health and Environment).

Even though the National Cancer Institute has concluded that condoms cannot prevent the transmission of HPV, the dangers of this virus are unknown to most Americans. According to a recent poll, 70 percent of women do not know the cause of cervical cancer. Of those who say they know the cause of cervical cancer, only 5 percent cited HPV or sex with an HPV-infected partner while 76 percent of the respondents have not heard of HPV (Wirthlin Worldwide, May 6, 1999). The fact that HPV is often asymptomatic complicates educational efforts about this disease. Women may not be aware that they may be infected until they have an abnormal Pap test. Men are even less likely to know that they have HPV, because they do not receive the benefit of a corresponding screening test that can indicate the presence of the virus. H.R. 1070 authorizes the Secretary to conduct prevention research on HPV through the Director of the Centers for Disease Control and Prevention, and requires the Secretary to make a progress report to Congress and develop a final proposal. To broaden educational outreach, H.R. 1070 mandates that the Secretary require the Department of Health and Human Services (HHS) and all contractors, grantees, and subgrantees of HHS to specifically state the effectiveness or lack of effectiveness of condoms in preventing the transmission of HPV, herpes, and other sexually transmitted diseases in all informational materials related to condoms or sexually transmitted diseases that are made available to the public.

The Committee believes that warning labels on condom packages will increase the awareness of HPV and cervical cancer, and inform the purchaser that condom use does not protect against HPV infection. H.R. 1070 provides that a condom shall be deemed to be misbranded for purposes of the Federal Food, Drug, and Cosmetic Act unless its label and labeling bear information providing that condoms do not effectively prevent the transmission of HPV.

HEARINGS

The Subcommittee on Health and Environment held a hearing on H.R. 1070 on July 21, 1999. The Subcommittee received testimony from: Dr. Nancy C. Lee, Director, Division of Cancer Prevention and Control, Centers for Disease Control and Prevention; Ms. Fran Visco, President, National Breast Cancer Coalition; Ms. Susan

Braun, President and CEO, The Susan G. Komen Breast Cancer Foundation, Dallas, Texas; Ms. Carolyn Tapp, President, Women of Color Breast Cancer Survivors Support Project, Los Angeles, California; and Dr. Stanley Klausner, Sayville, New York.

COMMITTEE CONSIDERATION

On September 30, 1999, the Subcommittee on Health and Environment met in open markup session and approved H.R. 1070 for Full Committee consideration, without amendment, by a voice vote. On October 28, 1999, the Full Committee met in open markup session and ordered H.R. 1070 reported to the House, amended, by a voice vote, a quorum being present.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House requires the Committee to list the record votes on the motion to report legislation and amendments thereto. There were no record votes taken in connection with ordering H.R. 1070 reported. An Amendment in the Nature of a Substitute by Mr. Lazio, #1, to make the following changes to the bill: (1) provide that the short title of the bill shall be the "Breast and Cervical Cancer Prevention and Treatment Act of 1999"; (2) add a provision to clarify that the 75/25 enhanced Federal match is only for individuals being added to Medicaid through the effect of this bill, not for women already on Medicaid, and clarify that women qualifying for Medicaid would be eligible for treatment for all health concerns, not just those that are cancer-related; (3) require the Centers for Disease Control and Prevention to study the prevalence of human papillomavirus (HPV) infection and to carry on educational activities about HPV among health care providers and the public; and (4) direct the Food and Drug Administration to develop a warning label for condom packages to advise consumers that condoms are ineffective in preventing the transmission of HPV, was agreed to, amended, by a voice vote. An Amendment to the Lazio Amendment in the Nature of a Substitute by Mr. Lazio, offered by unanimous consent, #1A, to provide an offset for the legislation by reforming the partial hospitalization program for Community Mental Health Centers by elevating the quality of the provision of mental health services, was agreed to by a voice vote. A motion by Mr. Bliley to order H.R. 1070 reported to the House, amended, was agreed to by a voice vote, a quorum being present.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee held a legislative hearing and made findings that are reflected in this report.

COMMITTEE ON GOVERNMENT REFORM OVERSIGHT FINDINGS

Pursuant to clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, no oversight findings have been submitted to the Committee by the Committee on Government Reform.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX
EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 1070, the Breast and Cervical Cancer Prevention and Treatment Act of 1999, would result in increased direct spending in the amounts described in the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, November 10, 1999.

Hon. TOM BLILEY,
*Chairman, Committee on Commerce,
House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 1070, the Breast and Cervical Cancer Prevention and Treatment Act of 1999.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Dorothy Rosenbaum.

Sincerely,

DAN L. CRIPPEN, *Director.*

Enclosure.

*H.R. 1070—Breast and Cervical Cancer Prevention and Treatment
Act of 1999*

Summary

H.R. 1070 would allow states to receive federal Medicaid funds for providing medical care to low-income women who have been screened under a Centers for Disease Control and Prevention (CDC) screening program and found to have breast or cervical cancer. The bill also would reduce Medicare expenditures on partial hospitalization services for mental health conditions; would require the CDC to undertake surveillance, prevention, and education activities with respect to the human papillomavirus (HPV); and would require manufacturers of condoms to change their labels to state that the product does not effectively prevent transmission of HPV.

CBO estimates that the bill would increase direct spending by \$205 million over the 2000–2004 period. Assuming appropriation of

authorized amounts for CDC's new responsibilities, CBO estimates increased discretionary spending of \$43 million over the same five-year period.

H.R. 1070 would impose a private-sector mandate as defined in the Unfunded Mandates Reform Act (UMRA) but CBO estimates that the costs associated with the mandate would fall well below the \$100 million threshold established in UMRA. H.R. 1070 contains no intergovernmental mandates as defined in UMRA. CBO estimates that states would spend an additional \$93 million on their Medicaid programs over the 2000–2004 period to implement the provision that would allow them to increase such spending for the treatment of breast and cervical cancer.

Estimated cost to the Federal Government

The estimated budgetary impact of H.R. 1070 is shown in the following table. The costs of this legislation fall within budget functions 550 (health) and 570 (Medicare).

| | By fiscal year, in millions of dollars— | | | | |
|--|---|------------------|------------------|------------------|------------------|
| | 2000 | 2001 | 2002 | 2003 | 2004 |
| CHANGES IN DIRECT SPENDING | | | | | |
| Breast and cervical cancer treatment: | | | | | |
| Medicaid: | | | | | |
| Estimated budget authority | 0 | 25 | 60 | 85 | 110 |
| Estimated outlays | 0 | 25 | 60 | 85 | 110 |
| Mental health partial hospitalization: | | | | | |
| Medicare: | | | | | |
| Estimated budget authority | -7 | -16 | -17 | -17 | -18 |
| Estimated outlays | -7 | -16 | -17 | -17 | -18 |
| Medicaid: | | | | | |
| Estimated budget authority | (¹) | (¹) | (¹) | (¹) | (¹) |
| Estimated outlays | (¹) | (¹) | (¹) | (¹) | (¹) |
| Total direct spending: | | | | | |
| Estimated budget authority | -7 | 9 | 43 | 68 | 92 |
| Estimated outlays | -7 | 9 | 43 | 68 | 92 |
| CHANGES IN SPENDING SUBJECT TO APPROPRIATION | | | | | |
| Centers for Disease Control and Prevention: | | | | | |
| Estimated authorization level | 12 | 10 | 10 | 10 | 11 |
| Estimated outlays | 4 | 9 | 10 | 10 | 10 |

¹ Savings of less than \$500,000.

Basis of estimate

For the purpose of this estimate CBO assumes that H.R. 1070 will be enacted in November 1999 and that the authorized funds will be appropriated for each fiscal year.

Optional Medicaid Coverage of Certain Breast or Cervical Cancer Patients

H.R. 1070 would give states the option of providing Medicaid coverage to women who have been screened under the CDC's National Breast and Cervical Cancer Early Detection Program and found to have breast or cervical cancer. States with a federal Medicaid match rate below 75 percent would receive a 75 percent match rate for services to women newly eligible for Medicaid under the provision. States with a higher match rate would receive their regular match rate. Federal Medicaid funds would be available beginning in fiscal year 2001. CBO estimates that the provision would in-

crease federal Medicaid spending by \$280 million over the 2000–2004 period.

Under current law, women with breast or cervical cancer are eligible for Medicaid only if they fall into an existing eligibility category. The principal eligibility categories for low-income women are pregnancy, and welfare-related or disability-related coverage (which is largely based on receipt of either Temporary Assistance for Needy Families or Supplemental Security Income). If a woman is found to have breast or cervical cancer, does not have health insurance, and does not qualify for Medicaid, she either pays for treatment with her own funds, receives treatment through a state, local, or privately funded program, receives charity care, or goes without treatment.

Congress created the National Breast and Cervical Cancer Early Detection Program in 1990 and appropriated \$158 million for the program for fiscal year 1999. The funds support screening activities in all 50 states, in the District of Columbia and U.S. Territories, and for several American Indian/Alaska Native organizations. States set their own income eligibility levels, at or below 250 percent of the federal poverty line. Most states have set eligibility criteria at about 200 percent of poverty. The CDC estimates that the program currently screens 12 to 15 percent of the eligible population. Program funds are not available for treating breast and cervical cancer.

The provision's effect on federal Medicaid spending depends on the number of women who would receive Medicaid-funded treatment as a result of the bill, the cost of the treatment, and the number of states that would choose the option. The following discussion focuses on the estimate for breast cancer treatment, which accounts for over 90 percent of the estimated costs of the bill. A brief discussion of the cost of cervical cancer treatment can be found at the end of the section.

Number of beneficiaries.—The states provided 208,000 mammograms with funds available under the CDC screening program in 1997. Some states currently supplement the CDC screening funds with their own funds for screening, diagnosis, and treatment. Under the bill, CBO expects that the number of mammograms under the CDC program would rise to 500,000 by 2003, as states that fund diagnosis and treatment services redirect their funds to supplement the screening funds in the CDC program. Because participation in that program would provide access to federal Medicaid funds for diagnosis and treatment of breast cancer, states would have an incentive to redirect their own funds into the CDC screening program.

Of women screened for breast cancer by the CDC program since its inception, about 0.5 percent, or 5 per 1,000, have been found to have breast cancer. Another 7 percent has had abnormal screens that required additional diagnosis and perhaps minor treatment. CBO assumes that the same incidence of cancer and other abnormal results would continue under the bill, resulting in the identification of about 2,500 new cancers and 35,000 abnormal mammograms each year by 2003.

In addition to those new cases, CDC reports that it has already diagnosed over 3,600 breast cancers. CBO anticipates that about

1,500 of these women would receive coverage under the bill if their states adopt the option.

Cost of Treatment.—Based on data from a large health maintenance organization, CBO has estimated the average cost of breast cancer treatment by age and year since diagnosis. In the first year after diagnosis, CBO estimates that cancer treatment would cost about \$17,000. In subsequent years, CBO estimates about \$6,000 a year in ongoing care costs, until the last year of a patient's life, when costs total about \$30,000. CBO used information from the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) Program to estimate age-specific mortality rates from the time of diagnosis.

For women who have an abnormal mammogram, but who are not ultimately diagnosed with cancer, CBO estimates average treatment cost of about \$2,000 in the year after the mammogram for follow-up diagnostic and treatment services.

The costs discussed above are for cancer treatment only and are expressed in fiscal year 2000 dollars. Because the bill would extend full Medicaid coverage during the time the woman needs cancer treatment, CBO added \$1,000 a year to the costs of cancer treatment (one-third of the average per capita Medicaid cost for adults) to determine total Medicaid costs for women newly eligible because of the bill. CBO expects that the average annual cost of treatment would rise at the same rate as the Consumer Price Index for medical care.

State participation.—In 2001, CBO anticipates that, states with 30 percent of potential Medicaid costs would choose to cover breast cancer patients screened through the CDC program in their Medicaid programs. By 2005, CBO projects that proportion would rise to two-thirds.

Cervical Cancer.—The costs of cervical cancer treatment under the bill stem principally from treatment of pre-cancerous conditions since screening often results in an abnormal finding at an early stage of the disease. CBO anticipates about 100 new cases of cervical cancer would be diagnosed each year under the screening program, with average annual treatment costs similar to the treatment costs for breast cancer. CBO expects about 10,000 abnormal pap smears each year, with treatment costs averaging \$1,000 to \$2,000. In total, CBO estimates that treatment of cervical cancer under the bill would cost about \$10 million a year by 2004.

Mental health partial hospitalization

CBO estimates that the bill's provisions that deal with partial hospitalization for mental health conditions would lower federal expenditures by \$7 million in 2000 and by \$75 million over the 2000–2004 period. Under current law, Medicare provides qualified beneficiaries with certain partial hospitalization services. The bill would reduce Medicare fee-for-service expenditures by prohibiting the provision of those services in residential settings, authorizing the Secretary of Health and Human Services (HHS) to specify new conditions of participation for community mental health centers (CMHCs), requiring inpatient psychiatric hospital admissions by CMHCs to be certified by a state-licensed mental health professional, and requiring periodic recertification of CMHCs by the Sec-

Estimated impact on state, local, and tribal governments

H.R. 1070 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA). A new coverage option in the bill would allow states to increase spending in their Medicaid programs for the treatment of breast and cervical cancer. CBO estimates that the state portion of Medicaid expenditures for this optional coverage would total \$93 million over the 2000–2004 period.

State spending for the treatment of breast and cervical cancer among women who would otherwise be ineligible for Medicaid would qualify for at least a \$3 federal match for every \$4 in state spending. Some states may already be covering this type of treatment in state-funded public health programs. In those cases, the federal matching funds would allow states to increase their overall level of spending for existing programs or to redirect a portion of their current spending to screening or other state programs.

Estimated impact on the private sector

H.R. 1070 would impose a mandate upon condom manufacturers and distributors that operate in the U.S. market. The bill would require such companies to meet new labeling requirements that would state that condoms do not effectively prevent the transmission of HPV and that such a virus can cause cervical cancer. The mandate would require companies to incur a largely one-time cost for modifying their labels. CBO estimates that the costs associated with the mandate would fall well below the \$100 million threshold established in UMRA.

Estimate prepared by: Federal costs: Dorothy Rosenbaum (Medicaid), Michael Birnbaum (Medicare and CDC), Julia Christensen (Food and Drug Administration); impact on State, local, and tribal governments: Leo Lex; impact on the Private Sector: Rekha Ramesh.

Estimate approved by: Robert A. Sunshine, Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the Constitutional authority for this legislation is provided in Article I, section 8, clause 3, which grants Congress the power to regulate commerce with foreign nations, among the several States, and with the Indian tribes.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 establishes the short title of the bill as the “Breast and Cervical Cancer Prevention and Treatment Act of 1999.”

Section 2. Optional Medicaid coverage of certain breast or cervical cancer patients

Section 2 provides for an optional Medicaid benefit for women under the age of 65 who have been screened for breast and cervical cancer under the Centers for Disease Control and Prevention Breast and Cervical Cancer Early Detection Program, and who need treatment for breast or cervical cancer. Such women must not be otherwise covered under creditable coverage for purposes of the Medicaid program. Benefits for medical assistance are limited to medical assistance provided during the period in which a woman requires treatment for breast or cervical cancer.

Section 2 also adds a new section 1920B to the Social Security Act defining presumptive eligibility for medical assistance under a State Medicaid plan for certain women diagnosed with breast or cervical cancer. The term of presumptive eligibility begins with the date on which a Medicaid eligible entity determines that a woman qualifies for the medical assistance benefit for women with breast or cervical cancer as described in Section 1902(aa) of the Social Security Act. The term of presumptive eligibility ends with the earlier of either the day of a woman’s determination of eligibility for Medicaid services, or, in the case where a woman does not file an application for Medicaid, the last day of the month following the month during which the woman was found to be qualified for medical services under this section.

If a qualified entity determines that a woman is presumptively eligible for medical assistance under a State Medicaid plan the entity shall notify the State Medicaid agency of such determination within 5 working days, and inform the individual that an application for medical assistance must be made before the last day of the month following the month of the initial determination. The Secretary may issue regulations defining “qualified entities” for purposes of determining the eligibility of women who have been screened for breast and cervical cancer and who need treatment for breast or cervical cancer. In addition, States are free to limit the classes of entities that may become qualified entities, subject to the Secretary’s regulations.

The bill requires that the State Medicaid agency shall provide application forms and information on assistance for eligible women to complete and file application forms. This section also provides for an enhanced match by the Federal government for medical assistance payments to States under the Medicaid program for individuals who are eligible for such assistance on the basis of eligi-

bility under this section for treatment of breast or cervical cancer. The amendments made by this section shall apply to medical assistance furnished on or after October 1, 2000, without regard to whether final regulations to carry out such amendments have been promulgated by such date.

Section 3. Human papillomavirus; activities of Centers for Disease Control and Prevention

Section 3 amends part B of title III of the Public Health Service Act (PHSA) (42 U.S.C. 243 et seq.) to establish a new section for the surveillance and research of human papillomavirus.

Section 317H(a) permits the Secretary to enter into cooperative agreements with States and other entities to conduct sentinel surveillance or other special studies that would determine the prevalence of specific types of HPV. The Secretary is required to develop and analyze the data from the surveillance system and make a progress report to Congress.

Section 317H(b) allows the Secretary to conduct prevention research on HPV through the Director of the Centers for Disease Control and Prevention. The Secretary is required to make a progress report to Congress and develop a final proposal. The report must outline the further steps needed to make HPV a reportable disease and the best strategies to prevent future infections.

Section 317H(c) mandates that the Secretary require the Department of Health and Human Services (HHS) and all contractors, grantees, and sub-grantees of HHS to specifically state the effectiveness or lack of effectiveness of condoms in preventing the transmission of HPV, herpes, and other sexually transmitted diseases in all informational materials related to condoms or sexually transmitted diseases that are made available to the public.

Section 4. Labeling of condoms with respect to human papillomavirus

Section 4 amends section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) by adding a new section for the labeling of condoms. A condom shall be deemed to be misbranded unless its label and labeling bear information providing that condoms do not effectively prevent the transmission of the human papillomavirus and that such virus can cause cervical cancer.

Section 5. Mental health partial hospitalization services

Section 5 establishes new definitions and requirements for partial hospitalization services and community mental health centers.

Section 5(a) amends section 1861(ff)(2) of the Social Security Act (42 U.S.C. 1395x(ff)(2)) to exclude from the definition of "partial hospitalization services" items and services that are provided in a skilled nursing facility, residential treatment facility, or other residential setting.

Section 5(b) establishes new definitions and requirements for community mental health centers furnishing services under the Medicare program.

Section 5(b)(1) amends section 1861(ff)(3)(B) of the Social Security Act (42 U.S.C. 1395x(ff)(3)(B)) to define the term "community mental health center" to include an entity that provides the mental health services described in section 1913(c)(1) of the Public Health

Service Act (42 U.S.C. 300x-2(c)(1)) or in the case of an entity operating in a State that by law precludes the entity from providing a service described in such section, provides the service by contract with an approved organization or entity.

Section 5(b)(2) amends section 1913(c)(1)(E) of the Public Health Service Act (42 U.S.C. 300x-2(c)(1)(E)) to require community mental health centers to determine the clinical appropriateness of admissions to inpatient psychiatric hospitals by engaging a full-time mental health professional who is licensed or certified to make such a determination by the State involved.

Section 5(c) amends section 1835(a)(2)(F)(ii) of the Social Security Act (42 U.S.C. 1395n(a)(2)(F)(ii)) to permit the periodic review of individualized, written plans for furnishing partial hospitalization services to occur at a reasonable rate.

Section 5(d) requires that the Secretary provide for the periodic recertification of each community mental health center that furnishes partial hospitalization services for which payment is made under title XVIII of the Social Security Act.

Section 5(e) requires that the Secretary promulgate regulations for national coverage policies for partial hospitalization services furnished under title XVIII of the Social Security Act using a negotiated rulemaking process within one year after the enactment of the bill.

Section 6. Sense of Committee on Commerce to fully pay for additional expenditures before passage by the House of Representatives

Section 6 expresses the sense of the Committee on Commerce that the additional net expenditures resulting from the enactment of the Act should be fully offset in an appropriate manner before the bill is passed by the House of Representatives.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

SOCIAL SECURITY ACT

* * * * *

TITLE XVIII—HEALTH INSURANCE FOR THE AGED AND DISABLED

* * * * *

PART B—SUPPLEMENTARY MEDICAL INSURANCE BENEFITS FOR THE AGED AND DISABLED

* * * * *

PROCEDURE FOR PAYMENT OF CLAIMS OF PROVIDERS OF SERVICES

SEC. 1835. (a) Except as provided in subsections (b), (c), and (e), payment for services described in section 1832(a)(2) furnished an individual may be made only to providers of services which are eligible therefor under section 1866(a), and only if—

(1) * * *

(2) a physician certifies (and recertifies, where such services are furnished over a period of time, in such cases, with such frequency, and accompanied by such supporting material, appropriate to the case involved, as may be provided by regulations) that—

(A) * * *

* * * * *

(F) in the case of partial hospitalization services, (i) the individual would require inpatient psychiatric care in the absence of such services, (ii) an individualized, written plan for furnishing such services has been established by a physician and is reviewed periodically *at a reasonable rate (as determined by the Secretary)* by a physician, and (iii) such services are or were furnished while the individual is or was under the care of a physician.

* * * * *

PART D—MISCELLANEOUS PROVISIONS

DEFINITIONS OF SERVICES, INSTITUTIONS, ETC.

SEC. 1861. For purposes of this title—

Spell of Illness

(a) * * *

* * * * *

Partial Hospitalization Services

(ff)(1) * * *

(2) The items and services described in this paragraph are—

(A) * * *

* * * * *

(I) such other items and services as the Secretary may provide (but in no event to include meals and transportation); that are reasonable and necessary for the diagnosis or active treatment of the individual's condition, reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization, [and] furnished pursuant to such guidelines relating to frequency and duration of services as the Secretary shall by regulation establish (taking into account accepted norms of medical practice and the reasonable expectation of patient improvement), *and furnished other than in a skilled nursing facility, residential treatment facility or other residential setting (as determined by the Secretary).*

* * * * *

(3)(A) * * *

(B) For purposes of subparagraph (A), the term “community mental health center” means an [entity—

[(i) providing the services described in section 1916(c)(4) of the Public Health Service Act; and

[(ii) meeting applicable licensing or certification requirements for community mental health centers in the State in which it is located.]

entity that—

(i)(I) provides the mental health services described in section 1913(c)(1) of the Public Health Service Act; or

(II) in the case of an entity operating in a State that by law precludes the entity from providing a service described in such section itself, provides for such service by contract with an approved organization or entity (as determined by the Secretary);

(ii) meets applicable licensing or certification requirements for community mental health centers in the State in which it is located; and

(iii) meets such additional conditions as the Secretary shall specify to ensure (I) the health and safety of individuals being furnished such services, (II) the effective and efficient furnishing of such services, and (III) the compliance of such entity with the criteria described in such section.

* * * * *

TITLE XIX—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

* * * * *

STATE PLANS FOR MEDICAL ASSISTANCE

SEC. 1902. (a) A State plan for medical assistance must—

(1) * * *

* * * * *

(10) provide—

(A) for making medical assistance available, including at least the care and services listed in paragraphs (1) through (5), (17) and (21) of section 1905(a), to—

(i) * * *

(ii) at the option of the State, to any group or groups of individuals described in section 1905(a) (or, in the case of individuals described in section 1905(a)(i), to any reasonable categories of such individuals) who are not individuals described in clause (i) of this subparagraph but—

(I) * * *

* * * * *

(XIII) who are in families whose income is less than 250 percent of the income official poverty line (as defined by the Office of Management and Budget, and revised annually in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981) applicable to a family of the size

involved, and who but for earnings in excess of the limit established under section 1905(q)(2)(B), would be considered to be receiving supplemental security income (subject, notwithstanding section 1916, to payment of premiums or other cost-sharing charges (set on a sliding scale based on income) that the State may determine); **[or]**

(XIV) who are optional targeted low-income children described in section 1905(u)(2)(C); or

(XV) who are described in subsection (aa) (relating to certain breast or cervical cancer patients);

* * * * *

(F) at the option of a State, for making medical assistance available for COBRA premiums (as defined in subsection (u)(2)) for qualified COBRA continuation beneficiaries described in section 1902(u)(1);

except that (I) the making available of the services described in paragraph (4), (14), or (16) of section 1905(a) to individuals meeting the age requirements prescribed therein shall not, by reason of this paragraph (10), require the making available of any such services, or the making available of such services of the same amount, duration, and scope, to individuals of any other ages, (II) the making available of supplementary medical insurance benefits under part B of title XVIII to individuals eligible therefor (either pursuant to an agreement entered into under section 1843 or by reason of the payment of premiums under such title by the State agency on behalf of such individuals), or provision for meeting part or all of the cost of deductibles, cost sharing, or similar charges under part B of title XVIII for individuals eligible for benefits under such part, shall not, by reason of this paragraph (10), require the making available of any such benefits, or the making available of services of the same amount, duration, and scope, to any other individuals, (III) the making available of medical assistance equal in amount, duration, and scope to the medical assistance made available to individuals described in clause (A) to any classification of individuals approved by the Secretary with respect to whom there is being paid, or who are eligible, or would be eligible if they were not in a medical institution, to have paid with respect to them, a State supplementary payment shall not, by reason of this paragraph (10), require the making available of any such assistance, or the making available of such assistance of the same amount, duration, and scope, to any other individuals not described in clause (A), (IV) the imposition of a deductible, cost sharing, or similar charge for any item or service furnished to an individual not eligible for the exemption under section 1916(a)(2) or (b)(2) shall not require the imposition of a deductible, cost sharing, or similar charge for the same item or service furnished to an individual who is eligible for such exemption, (V) the making available to pregnant women covered under the plan of services relating to pregnancy (including prenatal, delivery, and postpartum services) or to any other condition which may complicate pregnancy shall not, by reason of this paragraph (10), require the making

available of such services, or the making available of such services of the same amount, duration, and scope, to any other individuals, provided such services are made available (in the same amount, duration, and scope) to all pregnant women covered under the State plan, (VI) with respect to the making available of medical assistance for hospice care to terminally ill individuals who have made a voluntary election described in section 1905(o) to receive hospice care instead of medical assistance for certain other services, such assistance may not be made available in an amount, duration, or scope less than that provided under title XVIII, and the making available of such assistance shall not, by reason of this paragraph (10), require the making available of medical assistance for hospice care to other individuals or the making available of medical assistance for services waived by such terminally ill individuals, (VII) the medical assistance made available to an individual described in subsection (l)(1)(A) who is eligible for medical assistance only because of subparagraph (A)(i)(IV) or (A)(ii)(IX) shall be limited to medical assistance for services related to pregnancy (including prenatal, delivery, postpartum, and family planning services) and to other conditions which may complicate pregnancy, (VIII) the medical assistance made available to a qualified medicare beneficiary described in section 1905(p)(1) who is only entitled to medical assistance because the individual is such a beneficiary shall be limited to medical assistance for medicare cost-sharing (described in section 1905(p)(3)), subject to the provisions of subsection (n) and section 1916(b), (IX) the making available of respiratory care services in accordance with subsection (e)(9) shall not, by reason of this paragraph (10), require the making available of such services, or the making available of such services of the same amount, duration, and scope, to any individuals not included under subsection (e)(9)(A), provided such services are made available (in the same amount, duration, and scope) to all individuals described in such subsection, (X) if the plan provides for any fixed durational limit on medical assistance for inpatient hospital services (whether or not such a limit varies by medical condition or diagnosis), the plan must establish exceptions to such a limit for medically necessary inpatient hospital services furnished with respect to individuals under one year of age in a hospital defined under the State plan, pursuant to section 1923(a)(1)(A), as a disproportionate share hospital and subparagraph (B) (relating to comparability) shall not be construed as requiring such an exception for other individuals, services, or hospitals, (XI) the making available of medical assistance to cover the costs of premiums, deductibles, coinsurance, and other cost-sharing obligations for certain individuals for private health coverage as described in section 1906 shall not, by reason of paragraph (10), require the making available of any such benefits or the making available of services of the same amount, duration, and scope of such private coverage to any other individuals, (XII) the medical assistance made available to an individual described in subsection (u)(1) who is eligible for medical assistance only because of subparagraph (F)

shall be limited to medical assistance for COBRA continuation premiums (as defined in subsection (u)(2)), [and] (XIII) the medical assistance made available to an individual described in subsection (z)(1) who is eligible for medical assistance only because of subparagraph (A)(ii)(XII) shall be limited to medical assistance for TB-related services (described in subsection (z)(2)), and (XIV) the medical assistance made available to an individual described in subsection (aa) who is eligible for medical assistance only because of subparagraph (A)(10)(ii)(XV) shall be limited to medical assistance provided during the period in which such an individual requires treatment for breast or cervical cancer;

* * * * *

(47) at the option of the State, provide for making ambulatory prenatal care available to pregnant women during a presumptive eligibility period in accordance with section 1920 and provide for making medical assistance for items and services described in subsection (a) of section 1920A available to children during a presumptive eligibility period in accordance with such section and provide for making medical assistance available to individuals described in subsection (a) of section 1920B during a presumptive eligibility period in accordance with such section;

* * * * *

(aa) Individuals described in this paragraph are individuals who—

- (1) are not described in subsection (a)(10)(A)(i);
- (2) have not attained age 65;
- (3) have been screened for breast and cervical cancer under the Centers for Disease Control and Prevention breast and cervical cancer early detection program established under title XV of the Public Health Service Act (42 U.S.C. 300k et seq.) in accordance with the requirements of section 1504 of that Act (42 U.S.C. 300n) and need treatment for breast or cervical cancer; and
- (4) are not otherwise covered under creditable coverage, as defined in section 2701(c) of the Public Health Service Act (45 U.S.C. 300gg(c)).

PAYMENT TO STATES

SEC. 1903. (a) * * *

* * * * *

(u)(1)(A) * * *

* * * * *

(D)(i) * * *

* * * * *

(v) In determining the amount of erroneous excess payments, there shall not be included any erroneous payments made for ambulatory prenatal care provided during a presumptive eligibility period (as defined in section 1920(b)(1)) [or for], for items and services described in subsection (a) of section 1920A provided to a child

during a presumptive eligibility period under such section, or for medical assistance provided to an individual described in subsection (a) of section 1920B during a presumptive eligibility period under such section.

* * * * *

DEFINITIONS

SEC. 1905. For purposes of this title—

(a) The term “medical assistance” means payment of part or all of the cost of the following care and services (if provided in or after the third month before the month in which the recipient makes application for assistance or, in the case of medicare cost-sharing with respect to a qualified medicare beneficiary described in subsection (p)(1), if provided after the month in which the individual becomes such a beneficiary) for individuals, and, with respect to physicians’ or dentists’ services, at the option of the State, to individuals (other than individuals with respect to whom there is being paid, or who are eligible, or would be eligible if they were not in a medical institution, to have paid with respect to them a State supplementary payment and are eligible for medical assistance equal in amount, duration, and scope to the medical assistance made available to individuals described in section 1902(a)(10)(A)) not receiving aid or assistance under any plan of the State approved under title I, X, XIV, or XVI, or part A of title IV, and with respect to whom supplemental security income benefits are not being paid under title XVI, who are—

(i) * * *

* * * * *

(x) individuals described in section 1902(u)(1), **[or]**

(xi) individuals described in section 1902(z)(1), *or*

(xii) *individuals described in section 1902(aa),*

but whose income and resources are insufficient to meet all of such cost—

(1) inpatient hospital services (other than services in an institution for mental diseases);

* * * * *

(b) Subject to section 1933(d), the term “Federal medical assistance percentage” for any State shall be 100 per centum less the State percentage; and the State percentage shall be that percentage which bears the same ratio to 45 per centum as the square of the per capita income of such State bears to the square of the per capita income of the continental United States (including Alaska) and Hawaii; except that (1) the Federal medical assistance percentage shall in no case be less than 50 per centum or more than 83 per centum, **[,]** (2) the Federal medical assistance percentage for Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa shall be 50 per centum, **[and]** (3) for purposes of this title and title XXI, the Federal medical assistance percentage for the District of Columbia shall be 70 percent, *and* (4) *in the case of a State for which the Federal medical assistance percentage is otherwise less than 75 percent, it shall be equal to 75 percent with respect to medical assistance provided to individuals who*

are eligible for such assistance only on the basis of section 1902(a)(10)(A)(ii)(XV). The Federal medical assistance percentage for any State shall be determined and promulgated in accordance with the provisions of section 1101(a)(8)(B). Notwithstanding the first sentence of this section, the Federal medical assistance percentage shall be 100 per centum with respect to amounts expended as medical assistance for services which are received through an Indian Health Service facility whether operated by the Indian Health Service or by an Indian tribe or tribal organization (as defined in section 4 of the Indian Health Care Improvement Act). Notwithstanding the first sentence of this subsection, in the case of a State plan that meets the condition described in subsection (u)(1), with respect to expenditures described in subsection (u)(2)(A) or subsection (u)(3) for the State for a fiscal year, and that do not exceed the amount of the State's allotment under section 2104 (not taking into account reductions under section 2104(d)(2)) for the fiscal year reduced by the amount of any payments made under section 2105 to the State from such allotment for such fiscal year, the Federal medical assistance percentage is equal to the enhanced FMAP described in section 2105(b).

* * * * *

PRESUMPTIVE ELIGIBILITY FOR CERTAIN BREAST OR CERVICAL CANCER PATIENTS

SEC. 1920B. (a) STATE OPTION.—A State plan approved under section 1902 may provide for making medical assistance available to an individual described in section 1902(aa) (relating to certain breast or cervical cancer patients) during a presumptive eligibility period.

(b) DEFINITIONS.—For purposes of this section:

(1) PRESUMPTIVE ELIGIBILITY PERIOD.—The term “presumptive eligibility period” means, with respect to an individual described in subsection (a), the period that—

(A) begins with the date on which a qualified entity determines, on the basis of preliminary information, that the individual is described in section 1902(aa); and

(B) ends with (and includes) the earlier of—

(i) the day on which a determination is made with respect to the eligibility of such individual for services under the State plan; or

(ii) in the case of such an individual who does not file an application by the last day of the month following the month during which the entity makes the determination referred to in subparagraph (A), such last day.

(2) QUALIFIED ENTITY.—

(A) IN GENERAL.—Subject to subparagraph (B), the term ‘qualified entity’ means any entity that—

(i) is eligible for payments under a State plan approved under this title; and

(ii) is determined by the State agency to be capable of making determinations of the type described in paragraph (1)(A).

(B) REGULATIONS.—*The Secretary may issue regulations further limiting those entities that may become qualified entities in order to prevent fraud and abuse and for other reasons.*

(C) RULE OF CONSTRUCTION.—*Nothing in this paragraph shall be construed as preventing a State from limiting the classes of entities that may become qualified entities, consistent with any limitations imposed under subparagraph (B).*

(c) ADMINISTRATION.—

(1) IN GENERAL.—*The State agency shall provide qualified entities with—*

(A) *such forms as are necessary for an application to be made by an individual described in subsection (a) for medical assistance under the State plan; and*

(B) *information on how to assist such individuals in completing and filing such forms.*

(2) NOTIFICATION REQUIREMENTS.—*A qualified entity that determines under subsection (b)(1)(A) that an individual described in subsection (a) is presumptively eligible for medical assistance under a State plan shall—*

(A) *notify the State agency of the determination within 5 working days after the date on which determination is made; and*

(B) *inform such individual at the time the determination is made that an application for medical assistance under the State plan is required to be made by not later than the last day of the month following the month during which the determination is made.*

(3) APPLICATION FOR MEDICAL ASSISTANCE.—*In the case of an individual described in subsection (a) who is determined by a qualified entity to be presumptively eligible for medical assistance under a State plan, the individual shall apply for medical assistance under such plan by not later than the last day of the month following the month during which the determination is made.*

(d) PAYMENT.—*Notwithstanding any other provision of this title, medical assistance that—*

(1) *is furnished to an individual described in subsection (a)—*

(A) *during a presumptive eligibility period;*

(B) *by a entity that is eligible for payments under the State plan; and*

(2) *is included in the care and services covered by the State plan;*

shall be treated as medical assistance provided by such plan for purposes of section 1903.

* * * * *

PUBLIC HEALTH SERVICE ACT

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**TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC
HEALTH SERVICE**

* * * * *

PART B—FEDERAL-STATE COOPERATION

* * * * *

HUMAN PAPILLOMAVIRUS

SEC. 317H. (a) SURVEILLANCE.—

(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall—

(A) enter into cooperative agreements with States and other entities to conduct sentinel surveillance or other special studies that would determine the prevalence in various age groups and populations of specific types of human papillomavirus (referred to in this section as “HPV”) in different sites in various regions of the United States, through collection of special specimens for HPV using a variety of laboratory-based testing and diagnostic tools; and

(B) develop and analyze data from the HPV sentinel surveillance system described in subparagraph (A).

(2) REPORT.—The Secretary shall make a progress report to the Congress with respect to paragraph (1) not later than one year after the effective date of this section.

(b) PREVENTION ACTIVITIES; EDUCATION PROGRAM.—

(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall conduct prevention research on HPV, including—

(A) behavioral and other research on the impact of HPV-related diagnoses on individuals;

(B) formative research to assist with the development of educational messages and information for the public, for patients, and for their partners about HPV;

(C) surveys of physician and public knowledge, attitudes, and practices about genital HPV infection; and

(D) upon the completion of and based on the findings under subparagraphs (A) through (C), develop and disseminate educational materials for the public and health care providers regarding HPV and its impact and prevention.

(2) REPORT; FINAL PROPOSAL.—The Secretary shall make a progress report to the Congress with respect to paragraph (1) not later than one year after the effective date of this section, and shall develop a final proposal not later than two years after such effective date, including a detailed summary of the significant findings and problems. The report shall outline the further steps needed to make HPV a reportable disease and the best strategies to prevent future infections.

(c) CONDOM EFFECTIVENESS; EDUCATION.—*The Secretary shall require that the Department of Health and Human Services and all contractors, grantees, and subgrantees of such Department specifi-*

cally state the effectiveness or lack of effectiveness of condoms in preventing the transmission of HPV, herpes, and other sexually transmitted diseases in all informational materials related to condoms or sexually transmitted diseases that are made available to the public. The Secretary shall assure that such information is made available to relevant operating divisions and offices of the Department of Health and Human Services. This subsection shall be effective within 6 months of the date of its enactment.

* * * * *

TITLE XIX—BLOCK GRANTS

* * * * *

PART B—BLOCK GRANTS REGARDING MENTAL HEALTH AND SUBSTANCE ABUSE

Subpart I—Block Grants for Community Mental Health Services

* * * * *

SEC. 1913. CERTAIN AGREEMENTS.

(a) * * *

* * * * *

(c) **CRITERIA FOR MENTAL HEALTH CENTERS.**—The criteria referred to in subsection (b)(2) regarding community mental health centers are as follows:

(1) With respect to mental health services, the centers provide services as follows:

(A) * * *

* * * * *

[(E) Screening for patients being considered for admission to State mental health facilities to determine the appropriateness of such admission.]

(E) Determining the clinical appropriateness of admissions to inpatient psychiatric hospitals by engaging a full-time mental health professional who is licensed or certified to make such a determination by the State involved.

* * * * *

SECTION 502 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

MISBRANDED DRUGS AND DEVICES

SEC. 502. A drug or device shall be deemed to be misbranded—

(a) * * *

* * * * *

(u) If it is a condom, unless its label and labeling bear information providing that condoms do not effectively prevent the trans-

mission of the human papillomavirus and that such virus can cause cervical cancer.

ADDITIONAL VIEWS

I strongly support H.R. 1070 because it provides essential treatment and follow-up services under Medicaid for women screened under the Breast and Cervical Cancer Screening program who are found to have cancer.

This bill is long overdue. It makes no sense to screen women and discover their cancer, and then leave them with the uncertainty of whether treatment will be available. It makes no sense to inhibit maximum State efforts to find and screen women because they fear they can not place them for treatment.

But it is sensible and humane to allow States to provide Medicaid coverage for the women with a positive cancer screen. And that is why a majority of this Committee has cosponsored this bill, and why it deserves to be enacted.

The provisions which strengthen preventive efforts regarding the human papilloma virus (HPV) deserve additional comment. The Committee shares an interest in better informing the public about HPV and about the fact that condom use does not assure that the virus will not be transmitted. But in informing people of these facts, we must be sure that we do not make them the victims of unintended consequences.

First, while no one disputes the seriousness and widespread prevalence of HPV, it is also true that only a very small proportion of those infected by the virus will develop cervical cancer. At any point in time, at least half of sexually active adults are likely to be infected with HPV, but for the vast majority of them, the virus will occur and disappear without symptoms or lasting effect.

It would be counterproductive to needlessly frighten every woman with HPV into believing that she will develop cervical cancer. There is no recommended treatment for asymptomatic HPV, nor are current HPV tests appropriate for widespread screening. Learning these facts would be cold comfort to a woman with HPV under the misapprehension that it will lead for certain to cervical cancer. Instead, the most desirable and appropriate outcome of educating American women about HPV should be to increase their understanding of the vital importance of Pap smear screening. Public health messages about HPV should emphasize all of the important risk factors for cervical cancer, including smoking, immunosuppression and the failure to obtain Pap smears.

Second, there is also a risk of unintentionally confusing the public about when condoms do or do not work. Condoms are unquestionably an important means of preventing the transmission of human immunodeficiency virus (HIV) and other sexually-transmitted diseases (STDs). But there is a danger that stressing a message about when condoms do not prevent the transmission of an STD may reduce their use in situations where they do, thereby increasing the transmission of STDs other than HPV.

I also am concerned that mandating HPV information on condom labels, labeling and advertising can result in so much information on such a small package that it ultimately reduces the effectiveness of any warnings or other information. Similarly, I fear that a blanket requirement on all contractors, grantees, and subcontractors of the Department that all information materials relating to STDs or condom effectiveness must contain information on the effectiveness or lack of effectiveness in preventing the transmission of HPV, herpes and other STDs, could ultimately hinder effective education or targeting of information that could be more effective if keyed to a single message.

Finally, I question the lack of authorized funding for the CDC to undertake all of these efforts. It would be counterproductive indeed to effectively reduce the already inadequate funding for the agency's STD program by adding new responsibilities without corresponding resources.

HENRY A. WAXMAN

ADDITIONAL VIEWS

In 1990, the Congress authorized the Breast and Cervical Cancer Mortality Prevention Act. (P.L. 101-354; 42 U.S.C. 300k et seq.). This Act, which originated in the Committee on Energy and Commerce, directed the Centers for Disease Control and Prevention (CDC) to establish a program that screens low-income, uninsured women for breast and cervical cancer. Currently, the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) operates in all 50 states, 5 U.S. territories, and through 15 Native American organizations. As a condition of receiving federal funding from CDC to conduct the screening program, the states must agree to provide treatment to women who are diagnosed with cancer.

Since this program was enacted, the problems of providing federal funds for screening but not for treatment have become more evident. The treatment that these women receive is often uncoordinated and incomplete. States are experiencing difficulties in identifying resources to provide treatment. H.R. 1070 is a response to the need for a secure, comprehensive system of care for women who are screened and diagnosed through this program. This bill would give states the option to enroll these women in Medicaid. They would then be eligible for all the items and services that the state Medicaid program provides during the duration of their cancer treatment.

H.R. 1070 unquestionably enjoys broad bipartisan support. The bill has 272 cosponsors, and it was reported unanimously out of the Commerce Committee by a voice vote on October 28, 1999.

THE NEED FOR H.R. 1070

Witnesses at the July 21, 1999 Subcommittee on Health and Environment hearing on H.R. 1070 illustrated the need for this legislation. The picture that emerged was one of women making dozens of unsuccessful contacts with the health care system and waiting months for free care that may or may not come through, all the while dealing with the fear and anguish that accompanies a cancer diagnosis. The fact that states agree to provide these women with treatment is no guarantee that the care will be affordable. Many women with low-paying jobs and few resources end up with medical bills in excess of \$20,000. Carolyn Tapp from the Women of Color Breast Cancer Survivors Support Project in Los Angeles summarized the current system of care for women who are diagnosed through the CDC's program:

For these breast cancer patients there is really no system of care—and the care they do receive is partial and very often inadequate. Treatment services are difficult to find; increasingly physicians have not been willing to provide their services for free or for little charge. The women

we see often have to wait for care, or wait to see if they qualify for [Medicaid]. Most often they end up at public health facilities or end up with medical bills in the thousands of dollars that they will never be able to pay. (Testimony of Ms. Carolyn Tapp, President, Women of Color Breast Cancer Survivors Support Project, Subcommittee on Health and Environment Hearing on H.R. 1070, July 21, 1999.)

One statistic that has often been misinterpreted is the CDC's report that 92% of the women diagnosed through the program initiate treatment within eight days. This statistic has been cited as an indication that H.R. 1070 is not necessary. However, Dr. Nancy Lee of the CDC clarified at a hearing that the information this statistic provides is limited. "Initiating treatment" may only mean that a woman has had one appointment with a physician. CDC has no information on whether these women complete treatment for breast cancer, or even finish the first round of services. This statistic does not provide any indication as to the coordination of services these women receive, or the quality of that care. (Dr. Nancy Lee, Centers for Disease Control and Prevention, Subcommittee on Health and Environment Hearing on H.R. 1070, July 21, 1999, hearing record.)

Several witnesses also mentioned that when these women do receive care, they may select a course of treatment against the recommendation of their physicians because they fear the extra costs of the recommended procedure. Ms. Fran Visco, President of the National Breast Cancer Coalition, spoke on National Public Radio about the horrible choices that uninsured women are forced to make: "We are told that many women who are diagnosed through this program choose to have a mastectomy when they could, in fact, have a lumpectomy. But with the lumpectomy, you must have radiation, the treatment is more expensive, it takes longer so that women will choose to lose their breast because they can't afford anything beyond surgery." (Fran Visco, National Public Radio's Morning Edition, November 10, 1999.)

Although surgical procedures are difficult enough for uninsured women to obtain, items such as drugs and durable medical equipment can be nearly impossible to find at low cost. Consequently, many women go without the necessary services that accompany breast cancer surgery. Ms. Carolyn Tapp stated that the women in her group often borrow Tamoxifen from each other, as the price of this medication makes it unaffordable. Many uninsured women cannot afford breast prostheses, either, and some in Ms. Tapp's group use water balloons instead. (Ms. Carolyn Tapp, President, Women of Color Breast Cancer Survivors Support Project, Subcommittee on Health and Environment Hearing on H.R. 1070, July 21, 1999, written record.) Reconstructive surgery is almost never an option. Dr. Stanley Klausner, a surgeon who has worked with the CDC program in Long Island since 1995, testified that he has never been able to obtain surgical reconstruction for one of his patients. (Testimony of Dr. Stanley Klausner, Subcommittee on Health and Environment Hearing on H.R. 1070, July 21, 1999.)

In his work with the CDC screening program in Long Island, one of Dr. Klausner's tasks is to identify local physicians and other pro-

viders who can offer low-cost or free services to women diagnosed with cancer. Dr. Klausner stated that over the years, this task has become more difficult as the changing health care system has forced providers to become more cost-conscious:

Over the years that my breast program has been in effect, a disturbing trend has been emerging. With the advent and penetration of managed care, physicians are faced with new challenges. They must see higher volumes [of patients] in order to maintain an acceptable bottom line. The "free services" they render to the working poor are straining their ability to adapt and is making the breast program more difficult to implement. (Testimony of Dr. Stanley Klausner, Subcommittee on Health and Environment Hearing on H.R. 1070, July 21, 1999.)

As more women have been screened through the CDC program, more women have been diagnosed with cancer. The increased number of patients, combined with the strains of the health care system, makes the states' obligation to offer treatment to these women problematic. Dr. Robert Brooks, the Secretary of the Department of Health from the Florida Department of Health and Human Services, writes:

We are starting to see the strain our providers are experiencing through their support of the program * * * One county program had had three women diagnosed with breast cancer during their first two years in operation; each one cared for by a different provider. Since October 1998, five additional women have been diagnosed and approximately 10 to 15 more have abnormal clinical breast exam mammogram results and could be diagnosed with cancer. Needless to say, the providers are concerned with these increasing numbers. Some of the providers have asked the local program coordinator not to refer additional patients to them for the remainder of this program year. * * * [In] another county program * * * we have been told that these current providers may not be willing to support the program when this county renews their program agreement this October * * * (Testimony of Fran Visco, President, National Breast Cancer Coalition, Subcommittee on Health and Environment Hearing on H.R. 1070, July 21, 1999.)

H.R. 1070 IS AN APPROPRIATE SOLUTION

Since its inception in 1990, the CDC's screening program has been a success. As of September 1998, more than 2 million screening tests had been provided to over 1.5 million women. Among all women 50 years and older, who are the program's target population, there has been a 20% increase in screening mammography rates since 1991. The disparate rates between the number of white women and the number of minority women who receive screening services have either been eliminated or reduced.

However, the National Breast Cancer Early Detection Program also exists to identify women with cancer and link them to appropriate treatment. Mammogram and Pap test rates give no indica-

tion of how this part of the program is functioning. From the evidence presented at the July 21 hearing, the link to treatment is uncertain and incomplete. Furthermore, as increasing numbers of women are screened and diagnosed, providing adequate treatment has become a strain on the resources of states and local providers.

H.R. 1070 would enable the states to make this program a complete success for women with breast and cervical cancer. States would have the option of enrolling women who are diagnosed with cancer in the Medicaid program. An enhanced federal match provides an incentive for states to take up this option. As a Medicaid beneficiary, these women would not have to wait for free care to become available, but could begin the first round of treatment immediately. They would have a secure source of coverage, so they would be able to complete the often lengthy course of treatment that may be required. Finally, these women would have access to a comprehensive health benefits package, so that they would no longer be forced to share medication or use homemade prostheses.

The ultimate goal of the Breast and Cervical Cancer Early Detection Program is to reduce the number of low-income, uninsured women who needlessly die of breast or cervical cancer because they are diagnosed too late. H.R. 1070 will help to meet this goal—and keep the promise of quality treatment to the women who participate in this program.

ANNA ESHOO.

