DEPARTMENT OF HEALTH AND SOCIAL SERVICES
DIVISION OF PUBLIC HEALTH
Statutory Authority: 16 Delaware Code, Section 133(16 Del.C. §133)

ORDER

FINAL

Cancer Treatment Program Regulations

Nature Of The Proceedings

Delaware Health and Social Services ("DHSS") initiated proceedings to adopt State of Delaware Cancer Treatment Program Regulations. The DHSS proceedings to adopt regulations were initiated pursuant to 29 **Del.C.** Ch. 101 and authority as prescribed by 16 **Del.C.** 133.

On May 1, 2004 (Volume 7, Issue 11), DHSS published in the Delaware Register of Regulations its notice of proposed regulations, pursuant to 29 Delaware Code Section 10115. It requested that written materials and suggestions from the public concerning the proposed regulations be delivered to DHSS by May 31, 2004, or be presented at a public hearing on May 21, 2004, after which time DHSS would review information, factual evidence and public comment to the said proposed regulations.

Written and verbal comments were received during the public comment period and evaluated. The results of that evaluation are summarized in the accompanying "Summary of Evidence."

Findings Of Fact

The Department finds that the proposed regulations, as set forth in the attached copy should be adopted in the best interest of the general public of the State of Delaware. The proposed regulations include minor modifications from those published in the May 1, 2004, Register of Regulations, based on comments received during the public comment period. These modifications are deemed not to be substantive in nature.

THEREFORE, IT IS ORDERED, that the proposed State of Delaware Cancer Treatment Program Regulations are adopted and shall become effective July 10, 2004, after publication of the final regulation in the Delaware Register of Regulations.

Vincent P. Meconi,
Secretary, Department of Health
and Social Services
Date of Signature 6.15.04

Summary Of Evidence

A public hearing was held on May 21, 2004, at 9:30 a.m. in the Third Floor Conference Room of the Jesse Cooper Building located on Federal and Water Streets, Dover, Delaware before David P. Walton, Hearing Officer. The purpose of the hearing was to discuss the proposed Department of Health and Social Services (DHSS) Cancer Treatment Program Regulations. Announcements regarding the public hearing were published in the Delaware State News, the News Journal and the Delaware Register of Regulations in accordance with Delaware Law. Paul Silverman, Section Chief of the Center of Health Information Management and Disease Prevention of the Division of Public Health (DPH) made the agency's presentation. Four individuals made comments at the hearing and five letters were received commenting on the proposed Regulations. All comments were received during the public comment period (May 1 through May 31, 2004). Organizations that commented included:

- Delaware Developmental Disabilities Council
- State Council for Persons with Disabilities
- Governor's Advisory Council for Exceptional Citizens
- National Oncology Nursing Society
- American Cancer Society

- The Leukemia and Lymphoma Society (Delaware Chapter)

Public comments and the DHSS (Agency) responses are as follows:

- **Section 4.1.1 states, "Cancer treatment will not include routine monitoring for pre-cancerous conditions, or monitoring for recurrence during or after remission." There was concern expressed that cancer treatment will not include monitoring for cancer recurrence during or after remission for patients with indolent or chronic cancers such as Chronic Lymphocytic Leukemia or Indolent Non-Hodgkin Lymphoma.**

Agency Response: If in the opinion of the physician the patient is in remission an only requires monitoring and not cancer treatment, the cost of monitoring is not covered under the Cancer Treatment Program (CTP). While the Agency would like to cover such monitoring expenses, the CTP has a limited budget designed to provide benefits for active cancer treatment for as many eligible people as possible. The Agency will monitor the occurrence of this situation and evaluate the potential for program expansion to address this need.

- **Section 10.1.4, states, eligibility terminates 12 months after the date of cancer diagnosis. There was a concern expressed for certain kinds of cancer, treatment may not be necessary for a year or more. It was recommended that this section be changed to read, eligibility terminates 12 months after the date of first treatment.**

Agency Response: The Agency agrees with this comment and has revised the regulations accordingly.

- **Section 10.2 states, "If eligibility is terminated, it may only be renewed for an individual who is diagnosed with another cancer for which coverage has not been previously provided." Once again, this would affect those with chronic or indolent cancers for which recurrence may happen (and often times worse than the initial diagnosis). Perhaps allowing coverage to extend up to 2 or 3 recurrences before termination may be a better alternative.**

Agency Response: Because eligibility for CTP benefits is limited to 12 months following the initiation of cancer treatment, this suggested modification to the regulation is not feasible at this time. The Agency will monitor the occurrence of this situation and evaluate the potential for program expansion to address this need.

- **Due to limited funding for this program, priority for treatment funds should be given to those patients with the best odds of attaining a meaningful remission.**

Agency Response: The CTP is designed to provide eligible individuals coverage for cancer treatment as prescribed by a physician, regardless of their prognosis.

- **Patients with metastasis disease at diagnosis with less than 30 percent chance of obtaining a remission should be excluded from treatment. However funding should be allotted for palliative care, i.e. radiation and medications for symptom management, as well as hospice care.**

Agency Response: The CTP is not designed to exclude patients based on their prognosis. The physician decides on appropriate treatment and the CTP provides benefits based on the physician's prescribed treatment regimen.

- **Appropriate interim monitoring for treatment response should be included.**

Agency Response: If monitoring for treatment response is part of the treatment plan established by the physician and all other program eligibility factors are met, then it will be covered by the CTP.

- **Terminating care at 12 months is not appropriate. Patients should continue to have appropriate follow-up with the oncologist/hematologist.**

Agency Response: While the Agency would like to cover follow-up expenses outside the 12-month eligibility period, the CTP has a limited budget designed to provide benefits for active cancer treatment for as many eligible people as possible. The Agency will monitor the occurrence of this situation and evaluate the potential for program expansion to address this need.

- **Patients who relapse within 12 months after completion of initial chemotherapy, should not be retreated, but receive palliative care.**

Agency Response: Cancer treatment decisions are made by the physician for each individual case and the CTP will provide benefits for cancer treatment based on the physician's professional judgment.

- **Select patients with indolent lymphoma, multiple myeloma, chronic lymphocyte leukemia, and insolent solid tumors, who do not require treatment at the time of diagnosis, should be included in the program to receive appropriate monitoring until such time as treatment is necessary.**

Agency Response: If the patient is diagnosed with cancer and monitoring is part of the physician's prescribed treatment plan in the 12-month eligibility period, the CTP will cover these expenses.

- **Patients with chronic myeloid leukemia should receive coverage for Glcevec.**

Agency Response: All treatments covered by Medicaid will be covered by the CTP. If Glcevec is covered by Medicaid, it will be covered by the CTP.

- **Section 3.1: The word "disability" should be substituted for "handicap".**

Agency Response: Section 3.1 was amended to reflect this update.

- **Section 3.3 and 15.0: Appeal rights are ostensibly limited to an internal review. In contrast, other DHSS discretionary programs generally incorporate the DSSM 5000 regulatory fair hearing process. It would be preferable to authorize access to the DSS fair hearing system or provide access to comparable appeal rights.**

Agency Response: The CTP is not a federally sponsored entitlement program, but is based on available state funding allotted on a yearly basis. As such, the Agency appeal process as stated in the regulations is sufficient and will be an appropriate and fair process.

- **References to "couples" in section 5.5 are problematic. It is unclear if sections 5.5.1-5.5.3.5 are disjunctive or conjunctive, i.e., requiring only 1 of 5 criteria to be met or all 5 criteria to be met. There is no "or" or "and" to clarify intention. If disjunctive, section 5.5.3.5 is overbroad since it would count as a "couple" anyone who holds joint resources (even if unrelated and not co-habiting) and even though resources are immaterial to eligibility.**

Agency Response: Based on this comment this section was amended to clarify intentions. Additionally, it was determined that section 5.5.3.5 was not appropriate and was deleted.

- **There was a concern that there was no standard for processing applications for the program. If DPH took 3 months to process an application, the applicant would have less than 9 months of services eligibility left.**

Agency Response: The Agency will process applications in an expeditious manner. Once applications are approved, treatment will be retroactively covered to the date of the initiation of cancer treatment ensuring the patient 12 months of benefits in the CTP.

- **Is there a mechanism for patients who have no insurance and qualify for this program to be moved into other programs?**

Agency Response: The patient's ability to become eligible for Medicaid is not waived as a result of their participation in this program. If they are eligible for Medicaid, which has programs with many more benefits,

patients can take advantage of Medicaid benefits.

- **There was a general concern that the program income qualification level may exclude some needing cancer treatment who are uninsured.**

Agency Response: After careful review of the income level qualification requirements, the regulation was adjusted to allow higher income levels to qualify for the CTP.

In addition to comments made above, there were many positive comments about Delaware enacting such a program to cover cancer treatment for the uninsured.

In addition to amendments noted above, minor grammatical corrections were made to the regulation for purposes of clarity.

The public comment period was open from May 1, 2004 to May 31, 2004.

Verifying documents are attached to the Hearing Officer's record. The regulation has been approved by the Delaware Attorney General's office and the Cabinet Secretary of DHSS.

203 Cancer Treatment Program

1.0 Purpose

The Cancer Treatment Program (CTP) is a program of Delaware Health and Social Services (DHSS), Division of Public Health (DPH) intended to provide medical insurance coverage to Delawareans for the treatment of cancer. The program serves Delawareans who have no health insurance.

2.0 Availability Of Funds

2.1 Benefits will be available to enrollees provided that funds for this program are made available to DHSS.

2.2 In the event that funds are not available, DHSS will notify enrollees and providers.

3.0 General Application Information

3.1 The application must be made in writing on the prescribed CTP form. An individual, agency, institution, guardian or other individual acting can make this request for assistance for the applicant with his knowledge and consent. The CTP will consider an application without regard to race, color, age, sex, **[~~handicap,~~ disability,]** religion, national origin or political belief as per State and Federal law.

3.2 Each individual applying for the CTP is requested, but not required, to furnish his or her Social Security Number.

3.3 Filing an application gives the applicant the right to receive a written determination of eligibility and the right to appeal the written determination.

4.0 Technical Eligibility

4.1 The following are required to receive benefits under this program. The applicant must:

4.1.1 Need treatment for cancer in the opinion of the applicant's licensed physician of record. Cancer treatment will not include routine monitoring for pre-cancerous conditions, or monitoring for recurrence during or after remission.

4.1.2 Be a Delaware resident.

4.1.3 Have been a Delaware resident at the time cancer was diagnosed.

4.1.4 Have no health insurance.

4.1.4.1 Examples of health insurance include comprehensive, major medical and catastrophic plans, Medicare, and Medicaid.

4.1.4.2 Excepted are the following types of insurance plans, which do not exclude eligibility for the CTP: dental, vision, dismemberment, drug, mental health, nursing home, blood bank, workman's compensation, accident, family planning, the Delaware Prescription Assistance Program, the Delaware Chronic Renal Disease program, and non-citizen medical coverage.

4.1.4.3 The CTP is the payer of last resort and will only provide benefits to the extent that they are not covered by the plans listed in 4.1.4.2.

4.1.5 Be over the age of 18 years.

4.1.6 Be diagnosed with any cancer on or after July 1, 2004, or be receiving benefits for the treatment of

colorectal cancer through the Division of Public Health's Screening for Life program on June 30, 2004.

4.2 An inmate of a public institution shall be eligible for the CTP, provided that the benefits of the CTP are not otherwise provided in full or in part.

4.2.1 For the purposes of the CTP, the definitions of public institution and inmate shall be the same as used by the Delaware Medicaid program.

4.3 The Medical Assistance Card is the instrument used to verify an individual's eligibility for benefits. Prior to rendering services, medical providers are required to verify client eligibility using the client's identification number by accessing one of the Electronic Verification Systems (EVS) options. Instructions for accessing EVS are described in the EVS section of the billing manual.

5.0 Financial Eligibility

5.1 To be eligible for the CTP the applicant must have countable household income that is less than **[~~500%~~ 650%]** of the Federal Poverty Level (FPL).

5.2 Income is any type of money payment that is of gain or benefit to an individual. Income is either counted or excluded for the eligibility determination.

5.3 Countable income includes but is not limited to:

5.3.1 Social Security benefits – as paid after deduction for Medicare premium

5.3.2 Pension – as paid

5.3.3 Veterans Administration Pension – as paid

5.3.4 U.S. Railroad Retirement Benefits – as paid

5.3.5 Wages – net amount after deductions for taxes and FICA Senior Community Service Employment – net amount after deductions for taxes and FICA

5.3.6 Interest/Dividends – gross amount

5.3.7 Capital Gains – gross amount from capital gains on stocks, mutual funds, bonds.

5.3.8 Credit Life or Credit Disability Insurance Payments – as paid

5.3.9 Alimony – as paid

5.3.10 Rental Income from entire dwelling – gross rent paid minus standard deduction of 20% for expenses

5.3.11 Roomer/Boarder Income – gross room/board paid minus standard deduction of 10% for expenses

5.3.12 Self Employment – countable income as reported to Internal Revenue Service (IRS)

5.3.13 Unemployment Compensation - as paid

5.4 Excluded income includes but is not limited to:

5.4.1 Annuity payments

5.4.2 Individual Retirement Account (IRA) distributions

5.4.3 Payments from reverse mortgages

5.4.4 Capital gains from the sale of principal place of residence

5.4.5 Conversion or sale of a resource (i.e. cashing a certificate of deposit)

5.4.6 Income tax refunds

5.4.7 Earned Income Tax Credit (EITC)

5.4.8 Vendor payments (bills paid directly to a third party on behalf of the individual)

5.4.9 Government rent/housing subsidy paid directly to individual (i.e. HUD utility allowance)

5.4.10 Loan payments received by individual

5.4.11 Proceeds of a loan

5.4.12 Foster care payments made on behalf of foster children living in the home

5.4.13 Retired Senior Volunteer Program (RSVP)

5.4.14 Veterans Administration Aid and Attendance payments

5.4.15 Victim Compensation payments

5.4.16 German reparation payments

5.4.17 Agent Orange settlement payments

5.4.18 Radiation Exposure Compensation Trust Fund payments

5.4.19 Japanese-American, Japanese-Canadian, and Aleutian restitution payments

5.4.20 Payments from long term care insurance or for inpatient care paid directly to the individual

5.5 Determination of the household income will be based on the family budget group, which is the total number of persons whose income is budgeted together. This will always include the following:

5.5.1 Married couples if they live together**[; and,]**

5.5.2 Unmarried couples who live together as husband and wife.

5.5.3 Couples will be considered as living together as husband and wife if:

5.5.3.1 They say they are married, even if the marriage cannot be verified**[; or,]**
5.5.3.2 They are recognized as husband and wife in the community**[; or,]**
5.5.3.3 One partner uses the other's last name**[; or,]**
5.5.3.4 They state they intend to marry.
[~~5.5.3.5 They jointly hold resources.~~]

5.6 In households that include a caretaker, the caretaker's children and other children that are the caretaker's responsibility, the caretaker's income and those of his/her children are always budgeted together. The income of any other children in the home will be considered separately. In these situations, the separate budget groups can be combined to form a single family budget group only when the following conditions are met:

5.6.1 CTP benefits would be denied to any of the recipients by maintaining separate budget groups.

5.6.2 The caretaker chooses to have his/her income and those of his/her children considered with the income of any other people in the home.

6.0 Residency

6.1 A Delaware resident is an individual who lives in Delaware with the intention to remain permanently or for an indefinite period, or where the individual is living and has entered into a job commitment, or seeking employment whether or not currently employed.

6.2 Factors that may be taken into account when determining residency are variables such as the applicant's age, location of dwellings and addresses, location of work, institutional status, and ability to express intent.

6.3 Eligibility:

6.3.1 Will not be denied to an otherwise qualified resident of the State because the individual's residence is not maintained permanently or at a fixed address.

6.3.2 Will not be denied because of a durational residence requirement.

6.3.3 Will not be denied to an institutionalized individual because the individual did not establish residence in the community prior to admission to an institution.

6.3.4 Will not be terminated due to temporary absence from the State, if the person intends to return when the purpose of the absence has been accomplished.

6.4 When a State or agency of the State, including an entity recognized under State law as being under contract with the State, arranges for an individual to be placed in an institution in another State, the State arranging that placement is the individual's State of residence.

7.0 Verification of eligibility information

7.1 The CTP may verify information related to eligibility. Verification may be verbal or written and may be obtained from an independent or collateral source.

7.2 Documentation shall be date stamped and become part of the CTP case record.

7.3 Verifications received and/or provided may reveal a new eligibility issue not previously realized. Additional verifications may be required.

7.4 Failure to provide requested documentation may result in denial or termination of eligibility.

8.0 Disposition of applications

8.1 The CTP will dispose of each application by a finding of eligibility or ineligibility, unless:

8.1.1 There is an entry in the case record that the applicant voluntarily withdrew the application, and that the CTP sent a notice confirming the applicant's decision;

8.1.2 There is a supporting entry in the case record that the applicant is deceased; or

8.1.3 There is a supporting entry in the case record that the applicant cannot be located.

9.0 Changes in circumstances and personal information

9.1 Enrollees are responsible for notifying the CTP of all changes in his circumstances that could potentially affect eligibility for the CTP. Failure to do so may result in overpayments being processed and legal action taken to recover funds expended on his/her behalf during periods of ineligibility.

9.2 Enrollees are responsible for notifying the CTP of changes in the enrollee's name, address and telephone number.

10.0 Termination of eligibility

10.1 Eligibility terminates:

10.1.1 When the enrollee attains other medical insurance, including Medicare, Medicaid, and the Medicaid Breast and Cervical Cancer treatment program.

10.1.2 When the enrollee is no longer receiving treatment for cancer as defined in 4.1.1.

10.1.3 When the enrollee no longer meets the technical or financial eligibility requirements.

10.1.4 12 months after the date **[~~of~~ of that]** cancer **[~~diagnosis~~ treatment is initiated.]**

10.2 If eligibility is terminated, it may only be renewed for an individual who is diagnosed with another cancer for which coverage has not been previously provided.

11.0 Coverage and benefits

11.1 Coverage is limited to the treatment of cancer as defined by DHSS.

11.2 There is no managed care enrollment.

11.3 Benefits will be paid at rates equivalent to Medicaid under a fee for service basis. If a Medicaid rate does not exist for the service provided, the CTP will determine a fair rate.

11.4 Benefits will only be paid when the provider of the cancer treatment services is a Delaware Medicaid Assistance Provider.

11.5 Benefits for patients enrolled prior to September 1, 2004 (or whatever date is established by DHSS as having an operational benefits management information system), may not be paid until after that date.

11.6 The CTP is the payer of last resort and will only provide benefits to the extent that they are not otherwise covered by another insurance plan.

11.7 Eligibility may be retroactive to the day **[~~of diagnosis~~ that cancer treatment was initiated]** provided that the application is filed within one year of that day. In such circumstances, covered services will only be provided for the time period that the applicant is determined to have been eligible for the CTP.

11.8 In no case will eligibility be retroactive to a time period prior to July 1, 2004, except if the enrollee was receiving benefits for the treatment of colorectal cancer through the Division of Public Health's Screening for Life program on June 30, 2004. If this exception occurs, eligibility will be retroactive only to the date the enrollee was receiving benefits for colorectal cancer treatment through the Screening for Life program.

12.0 Cancer treatment services which are not covered

12.1 The cost of nursing home or long-term care institutionalization is not covered. (The cost of cancer treatment services within a nursing home or long term care institution is a covered benefit.)

12.2 Services not related to the treatment of cancer as determined by DHSS are not covered.

12.3 Cancer treatment services for which the enrollee is eligible to receive by other health plans as listed in 4.1.4.2 are not covered.

13.0 Changes in program services

13.1 When changes in program services require adjustments of CTP benefits, the CTP will notify enrollees who have provided an accurate and current name, and address or telephone number.

14.0 Confidentiality

14.1 The CTP will maintain the confidentiality of application, claim, and related records as required by law.

15.0 Review of CTP decisions

15.1 Any individual who is dissatisfied with a CTP decision may request a review of that decision.

15.2 Such request must be received by the CTP in writing within 30 days of the date of the decision in question.

15.3 The CTP will issue the results of its review in writing. The review will be final and not subject to further appeal.