IN THE DISTRICT COURT OF THE FIRST JUDICIAL DISTRICT OF THE STATE OF IDAHO, IN AND FOR THE COUNTY OF KOOTENAI

BURNICE HAUSER, Petitioner/Plaintiff, vs. IDAHO DEPARTMENT OF HEALTH AND WELFARE, Respondent/Defendant.	)	**CASE NO. CV-03-04943** MEMORANDUM DECISION AND ORDER IN RE: MOTION FOR SUMMARY JUDGMENT

Respondent/Defendant found Petitioner/Plaintiff ineligible for Medicaid coverage under certain rules. Petitioner/Plaintiff (a) seeks declaratory and injunctive relief; and (b) appeals from a decision of Respondent/Defendant. Petitioner/Plaintiff filed a Motion for Summary Judgment. Motion granted.

Alan Wasserman, IDAHO LEGAL AID SERVICES, INC., attorneys for Petitioner/Plaintiff.

Willard Abbott, Deputy Attorney General, OFFICE OF THE ATTORNEY GENERAL, attorneys for Respondent/Defendant.

I

FACTUAL BACKGROUND

Certain facts are undisputed. The Petitioner/Plaintiff, Burnice Hauser, was diagnosed with breast cancer in the Spring of 2001. Since then she has been under the care of Dr. Alan Grosset of the North Idaho Cancer Center in Coeur d'Alene, Idaho.

Ms. Hauser's treatment began with surgery. It then proceeded to a course of Adriamycin and Cytoxan. That was followed by Femara (after an unsuccessful month of Tamoxifen). Her Femara therapy is ongoing and, according to Dr. Grosset, is currently scheduled to continue for a total of five years.

In 2000, Congress adopted the Breast and Cervical Cancer Prevention and Treatment Act ("BCCPTA"). The Act amended the federal Medicaid statute to provide that each state's Medicaid program may offer Medicaid coverage to women with breast or cervical cancer if they met certain criteria.[1] For purposes of Ms. Hauser's lawsuit, the critical language of the federal Medicaid statute calls for Medicaid eligibility for women who "need treatment for breast cancer" (***42 U.S.C. § 1396(a(aa)(3)***) "during the period in which such an individual requires treatment" (***42 U.S.C. § 1396a(a)(10)(G)(XIV)***).

In turn, the State of Idaho adopted this Medicaid option effective July 1, 2001, in the form of a state Medicaid regulation at ***IDAPA 16.03.05.802***. The critical language of this regulation provides that a woman's Medicaid coverage is available "for the duration of her cancer treatment." ***IDAPA 16.03.05.802***.

Because Ms. Hauser met all the requirements for Medicaid eligibility under ***IDAPA 16.03.05.802***, she was afforded Medicaid eligibility by the Department of Health and Welfare ("the Department") once that provision was adopted in 2001. At that time, she had already completed her surgery and her treatment with Adriamycin and Cytoxan and had begun her treatment with Femara. In other words, Ms. Hauser was considered by Idaho's Medicaid program to be in "cancer treatment" when she was treated with Femara therapy for her breast cancer after the provision went into effect in 2001.

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[1] This new state option was codified in four places: ***42 U.S.C. § 1396a(a)(10)(A)(ii)(XVIII); § 1396(a)(xiii); § 1396a(aa); and § 1396a(a)(10(G)(XIV)***.

Not quite a year later, on June 18, 2002, the Department initiated Rulemaking Docket No. 16-0309-0209, which included a new, emergency ("temporary") rule in connection with Medicaid eligibility for women with breast or cervical cancer. The temporary rule was adopted as ***IDAPA 16.03.09.013*** and was made effective on July 1, 2002. The new rule, also sometimes referred to as Temporary Rule 013, defined when a woman is in cancer treatment for purposes of ***IDAPA 16.03.05.802***.[2] Temporary Rule 013 became "final and effective" at the close of the 2003 Session of the Idaho State Legislature on May 3, 2003.

Based on the temporary rules and without any change in Ms. Hauser's on-going course of treatment, the Department determined that her cancer treatment had ended. In a letter dated June 10, 2002, the Department notified Ms. Hauser that her Medicaid eligibility would end on June 30, 2002. The Department wrote Ms. Hauser that Medicaid coverage for treatment continued until a physician indicated that a woman was in the "surveillance, follow-up, or maintenance phase" of her cancer treatment. Because she was not eligible for Medicaid on any other ground, her Medicaid coverage was terminated.[3]

A timeline for the first half of 2002 preceding the termination of Ms. Hauser's Medicaid benefits is as follows. On March 15, 2002, Dr. Grosset had written that Ms. Hauser "showed no evidence of breast cancer." Even so and in line with normal medical practice, Dr. Grosset prescribed Femara, which is a substance that is believed to inhibit the production of estrogen and reduce the risk for relapse in estrogen positive cancer

[2] At the same time, a temporary amendment to Rule 802, which made reference to the new Rule 013, was adopted.
[3] Ms. Hauser was not eligible on other grounds because her income exceeded $600.00 per month and she was not totally disabled.

patients. On May 15, 2002, Dr. Grosset submitted a status report to the Department that Ms. Hauser had completed chemotherapy and was undergoing maintenance therapy to maintain her in a stable condition and prevent relapse. On June 19, 2002, Ms. Hauser received the letter telling her that her Medicaid coverage would terminate on June 30, 2002. On July 1, 2002, the temporary "end-of-treatment" rules went into effect and Ms. Hauser's Medicaid coverage terminated.

A woman becomes presumptively eligible for Medicaid when she is referred to Medicaid by an outside clinic authorized to screen for breast cancer. The Department knows only that the woman has been referred to the program by a clinic authorized to do so, but it does not have detailed information about the course of her treatment when the referral occurs. Although women entering this program must be uninsured, they do not have to otherwise qualify for Medicaid.[4]

II

PROCEDURAL BACKGROUND

After she was advised that her Medicaid benefits would terminate, Ms. Hauser requested an administrative hearing on grounds that she was unable to pay for her prescribed medication and tests without Medicaid assistance. The Hearing Officer, Edward C. Lockwood, affirmed the termination in written Findings of Fact, Conclusions of Law, and Preliminary Decision. Mr. Lockwood specifically noted, however, that "an administrative hearing officer is granted no authority to invalidate federal or state statutes, rules or regulations pursuant to IDAPA 16.05.03.131." He further noted that "the hearing officer must accept the validity of the rule as published." Ms. Hauser then

[4] For example, women do not have to otherwise qualify for Medicaid through lack of income or disability.

appealed to the Director of the Department, who also affirmed the decision and issued a Final Order.[5]

Ms. Hauser filed her Petition for Judicial Review and Complaint in the instant lawsuit on July 10, 2003. First, Ms. Hauser seeks declaratory and injunctive relief to invalidate the "end of treatment" rules that the Department relied upon for authority to terminate her eligibility for Medicaid coverage. Second, Ms. Hauser appeals from the final decision of the Department to terminate her Medicaid eligibility.

Ms. Hauser filed a Motion for Summary Judgment. The Motion is supported by:

Brief in Support of Motion for Summary Judgment;
Addendum of Statutory and Regulatory Materials;
Affidavit of Burnice Hauser;
Affidavit of Alan B. Grosset, M.D.;
Affidavit of Haluk Tezcan, M.D.;
Affidavit of Alan Wasserman;
Second Affidavit of Haluk Tezcan, M.D.; and
Reply Brief.

The Department responded to Ms. Hauser's Motion for Summary Judgment with the following:

Brief on Summary Judgment with attachments; and
Affidavit of David Lehman.

A hearing was held on the Motion for Summary Judgment and both parties presented oral argument. At the conclusion of the hearing, Plaintiff's Motion for Summary Judgment was granted as to the first issue presented by Plaintiff.

III

ISSUES PRESENTED

1. Were the Department's rules concerning Medicaid eligibility for women with breast and cervical cancer that were made effective on July 1, 2002, void and

[5] The Department paid for Ms. Hauser's medical bills from the date she became eligible for Medicaid in June of 2001 until she exhausted her administrative remedies.

unenforceable until they became final on May 3, 2003, because they were adopted as temporary rules in violation of the Idaho Administrative Procedure Act?

2. Are the Department's rules concerning Medicaid eligibility for women with breast and cervical cancer void and unenforceable, both in their temporary and final forms, because they are in conflict with controlling federal Medicaid law?

3. Even if they were validly adopted and even if they are not in conflict with controlling federal law, did the Department misinterpret and misapply the Department's relevant Medicaid rules when it determined that Burnice Hauser was no longer in cancer treatment as of July 1, 2002?

IV

STANDARDS FOR SUMMARY JUDGMENT

Summary judgment must be granted when there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. In order to make that determination, the court looks to "the pleadings, depositions, and admissions on file, together with the affidavits, if any. . . ." ***Rule 56(c), Idaho Rules of Civil Procedure***.

On a motion for summary judgment, the facts in the record are to be liberally construed in favor of the party opposing the motion. If the court will be the ultimate trier of fact and if there are no disputed evidentiary facts, the judge is not constrained to draw inferences in favor of the party opposing the motion for summary judgment; rather, the trial judge is free to arrive at the most probable inferences to be drawn from uncontroverted evidentiary facts. ***Bonz v. Sudweeks***, 119 Idaho 539, 808 P.2d 876 (1991); ***Loomis v. City of Hailey***, 119 Idaho 434, 807 P.2d 1272 (1991).

If there are no genuine issues of material fact, the court will determine whether a party is entitled to judgment as a matter of law. ***Zumwalt v. Stephan, Balleisen & Slavin***, 113 Idaho 822, 758 P.2d 406 (Ct.App. 1987), ***rev. denied*** (1988).

According to ***Berg v. Fairman***, 107 Idaho 441, 444, 690 P.2d 896 (1984), the "purpose of summary judgment proceedings is to eliminate the necessity of trial where facts are not in dispute and where existent and undisputed facts lead to a conclusion of law which is certain."

V

THE TEMPORARY RULES WERE VOID AND UNENFORCEABLE

The first issue is whether or not the temporary rules concerning Medicaid eligibility for women with breast and cervical cancer that were made effective on July 1, 2002, were void and unenforceable. Ms. Hauser is entitled to Summary Judgment on this issue. At the hearing, Ms. Hauser's Motion for Summary Judgment on this issue was granted. Therefore, it will not be discussed further here.

VI

THE PERMANENT RULES ARE IN CONFLICT WITH CONTROLLING FEDERAL MEDICAID LAW

Ms. Hauser claims that the Department's rule at ***IDAPA 16.03.09.013*** denies Medicaid coverage to women in Idaho who need and are receiving treatment for their breast or cervical cancer. Therefore, according to Ms. Hauser, the regulation is in direct conflict with controlling federal law and must be found, under ***42 U.S.C. § 1983***, to violate Ms. Hauser's right to Medicaid coverage the BCCPTA provides for her.

A. Background

The Medicaid program was enacted by Congress in 1965 as a companion to the Medicare program. Provisions governing the Medicaid program are found in Title XIX of the Social Security Act and begin at ***42 U.S.C. § 1396***. Generally speaking, the Medicaid program provides for medical assistance to families with dependent children

and aged, blind, or disabled individuals whose income and resources are insufficient to meet the costs of necessary medical services.

Federal funds are provided to the states to be combined with state funds for use in the state's Medicaid program. Funds are primarily used to pay medical providers.

Once a state chooses to participate in the Medicaid program, it must meet certain requirements imposed by the statute and by federal regulations promulgated by the U.S. Department of Health and Human Services. Idaho has chosen to participate in the Medicaid program. The Idaho Department of Health and Welfare administers Idaho's Medicaid program pursuant to Chapter 2 of Title 56 of the Idaho Code and specifically ***Idaho Code § 56-209b***.

A state's Medicaid program must offer coverage to the "mandatory categorically needy." The state may also offer Medicaid coverage to the "optional categorically needy." If a state chooses to cover an optional group or provide an optional service, it must follow the applicable federal requirements.

As noted above, Congress amended the Medicaid law with the optional BCCPTA in 2000. Idaho adopted Medicaid coverage for this optional group in 2001. It does not appear that the new statute has been interpreted and it does not appear that federal regulations have been issued yet on this coverage.

B. <u>Interpretation of Statutes</u>

The primary function of the court in interpreting a statute is to determine legislative intent and give effect to it. ***George W. Watkins Family v. Messenger***, 118 Idaho 537, 797 P.2d 1385 (1990). The court may examine the language used, the reasonableness of the proposed interpretations, and the policy behind the statute. ***Kelso***

& Irwin, P.A. v. State Insurance Fund, 134 Idaho 130, 997 P.2d 591 (2000); ***Kootenai Electric Co-op, Inc. v. Washington Water Power Co.***, 127 Idaho 432, 901 P.2d 1333 (1995).

The interpretation begins with the literal words of the statute. Those words must be given their plain, obvious, and rational meaning. ***Adamson v. Blanchard***, 133 Idaho 602, 990 P.2d 1213 (1999); ***Higginson v. Westergard***, 100 Idaho 687, 604 P.2d 51 (1979). To the extent that legislation is remedial, it must be liberally construed to accomplish its expressed intent. ***State v. Hobby Horse Ranch Tractor & Equipment Co.***, 129 Idaho 565, 929 P.2d 741 (1996).

Documents generated by a federal agency that interpret a federal statute regulated by the agency are to be given "considerable deference" by a court. ***U.S. v. Mead***, 533 U.S. 218; 121 S.Ct. 2164, 150 L.Ed.2d 292 (2001); ***Skidmore v. Swift***, 323 U.S. 134, 65 S.Ct. 161, 89 L.Ed. 124 (1944).

Therefore, a determination as to conflict between the federal statues and the state regulations must turn upon an examination of (1) the words of the statutory provisions themselves, and (2) the "technical guidance" provided by the federal agency on its internet homepage.

C. <u>The Language in the Federal Statutes</u>

The first federal statute at issue here provides for optional coverage for certain breast or cervical cancer patients. The individuals must "***have been screened*** for breast and cervical cancer . . . and must ***need treatment*** for breast or cervical cancer . . . ." ***42 U.S.C. § 1396a(aa)*** (emphasis added).[6]

[6] ***42 U.S.C. § 1396a(aa)*** sets forth four elements that are required for Medicaid eligibility under the breast and cervical cancer program. A person must: (1) not be Medicaid eligible under another category; (2) be

The second federal statute at issue here states that Medicaid eligibility for a person who qualifies under the breast and cervical cancer program "shall be limited to medical assistance provided ***during the period in which such an individual requires treatment*** for breast or cervical cancer." ***42 U.S.C. § 1396(a)(10)(G)(XIV)*** (emphasis added).

Therefore, it can be concluded that the relevant language of the two statutes when viewed together provides for Medicaid eligibility for persons who "need treatment" for breast cancer "during the period in which such an individual requires treatment" for breast cancer.

D. Documents Interpreting the Federal Statutes

The Centers for Medicare and Medicaid Services ("CMS") provide technical guidance by responding to some of the issues that have been raised regarding the BCCPTA.[7] The April 2004 CMS Technical Guidance document sets forth the following relevant questions and answers.

> **Question 10. What is meant by the term "need treatment"?**
>
> **Answer:** The term "need treatment" means that, a CDC breast or cervical cancer screen indicates that the woman is in need of cancer treatment services. These services include diagnostic services that may be necessary to determine the extent and proper course of treatment, as well as *definitive cancer treatment* itself. Women who are determined to require only routine monitoring services for a precancerous breast or cervical condition (e.g., breast examinations and mammograms) are not considered to need treatment.
>
> **Question 17. The statute states that a woman is eligible for Medicaid under BCCPTA as long as she "requires treatment for**

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under the age of 65; (3) ***have been screened*** for breast and cervical cancer under a program . . . and must ***need treatment for breast or cervical cancer***; and (4) not have other creditable insurance coverage . . . . (Emphasis added).

[7] This technical guidance document must be distinguished from federal regulations; it does not appear that federal regulations pertaining to the BCCPTA have been adopted yet.

breast or cervical cancer". What is meant by the term "requires treatment"?

Answer: The term "requires treatment" relates to *duration of treatment* for purposes of the BCCPTA. States have the flexibility to define what constitutes "requires treatment." *States may establish reasonable limits or guidelines for determining when breast or cervical cancer treatment is completed and the person is no longer eligible for Medicaid* under the BCCPTA.

Question 18. When would a woman's eligibility under this provision end?

Answer: A woman determined eligible under this option would continue to be eligible as long as she is receiving treatment for breast or cervical cancer, is under age 65, and is not otherwise covered under creditable insurance coverage. *A state may presume that a woman is receiving such treatment during the duration of the period established by her treating health professional in her plan of care.* If that period extends beyond a year (or a shorter period at state option), the state must confirm eligibility consistent with standard Medicaid redetermination requirements. Care and service under this new option should be *consistent with optimal standards of practice* for items and services available under the state plan. The state may use utilization management techniques such as prior approval to monitor care and ensure that it is medically necessary and used efficiently.

Question 19a. Is a woman limited to one period of eligibility? What happens if a woman goes through treatment for breast or cervical cancer, and then two years after treatment is completed has a recurrence and needs treatment for breast or cervical cancer again?

Answer: No. A woman is not limited to one period of eligibility. A new period of eligibility and coverage would commence each time a woman is screened under a CDC program and found to need treatment for breast or cervical cancer, and meets all other eligibility criteria.

Question 19b. If a woman is treated for breast or cervical cancer during her first period of eligibility and is subsequently determined to have cancer that has spread to other parts of her body, would she be covered?

> **Answer:** Yes. If the recurrent metastasized cancer is either a known or presumed complication of breast or cervical cancer, and the woman is still in her first period of eligibility, i.e., she is still receiving treatment for the initial breast or cervical cancer diagnosis, she would continue to be eligible for additional treatment. If, however, her first treatment period is over and her Medicaid eligibility has been terminated, she must be screened again under a CDC program and found to be in need of treatment for breast or cervical cancer.

(Emphasis added.)

Thus, the term "need treatment" includes diagnostic services as well as "definitive cancer treatment," but it does not include routine monitoring for precancerous conditions. States may establish "reasonable" limits or guidelines for determining when the treatment is completed and the person is no longer eligible for Medicaid. In formulating "reasonable" limits, states can presume that a woman is receiving needed treatment "during the duration of the period established by her treating health professional in her plan of care." The care and service should be "consistent with optimal standards of practice."

E. The Evidence Relating to "Need Treatment" and "Requires Treatment

Ms. Hauser has filed affidavits relating to the need for treatment, her health professional's plan of care, and the optimal standards of practice. Specifically, Ms. Hauser has filed the Affidavits of Alan B. Grosset, M.D., and Haluk Tezcan, M.D.[8]

Dr. Grosset is Ms. Hauser's physician treating her for breast cancer. Dr. Grosset avers that she is not undergoing "routine monitoringfor a pre-cancerous breast condition, nor can her care be said to be in surveillance, follow-up, or maintenance mode." Her

[8] Ms. Hauser has filed two Affidavits of Dr. Tezcan. The Department has not objected to the filing of the second Affidavit of Dr. Tezcan as part of Ms. Hauser's reply on the Motion for Summary Judgment. Therefore, both Affidavits of Dr. Tezcan will be considered. ***See Rule 56(c), Idaho Rules of Civil Procedure***. Also, the Exhibits attached to the Department's Brief will be considered here.

initial treatment was with surgery, followed by pharmaceutical therapy. Dr. Grosset states that the current standard practice for Femara[9] therapy is to administer a five (5) year course of treatment involving daily medication and close monitoring by a physician. He further states that this is the "optimal standard" of practice – the "gold standard" of care for women, such as Ms. Hauser, with "hormone receptor positive breast cancer." According to Dr. Grosset it would be a "clear dereliction of a health care provider's duty of care" if such women were not offered this treatment. He also avers that the Department's attempt to distinguish systemic chemotherapy from regimens of Tamoxifen and aromatase inhibitors is "medically unsupportable." Dr. Grosset states "unequivocally" that Ms. Hauser remains in active treatment for her breast cancer.

Dr. Tezcan is a Board Certified hematologist and medical oncologist with considerable education and experience. He avers that the current standard of care in the treatment of women with hormone receptive positive breast cancer is based on peer review and published clinical research. Based on those recommendations, he "unequivocally" states that the standard protocol for such women includes the administration of a five (5) year course of therapy of Tamoxifen or an aromatase inhibitor such as Femara. This treatment is the most effective component of breast cancer management for women with hormone receptor positive breast cancer. A course of treatment that is using "conventional treatment modalities" is to go from surgery to radiation and/or systemic chemotherapy to Tamoxifen or an aromatase inhibitor. Only under "extremely rare circumstances" would it be reasonable not to offer such therapy for women with this type of breast cancer. Even if a woman chooses to decline this form of treatment, it should be offered to her. Failure to make the offer would clearly violate the

[9] Femara is an aromatase inhibitor.

standard of care in Idaho and elsewhere and would, in his opinion, constitute professional malpractice. He avers that any rule which purports to provide payment for "treatment" of women with breast cancer, but which does not pay for the protocol, is no longer providing treatment and the program is "squarely at odds with any law that provides Medicaid coverage for women receiving treatment for breast cancer."

The Department does not dispute the evidence set forth in the Affidavits of Dr. Grosset and Dr. Tezcan. Thus, the undisputed evidence is that Ms. Hauser needs the treatment, that the treatment is part of her physician's five (5) year plan of care for her, and that the treatment is consistent with optimal standards of practice.

F. <u>The Idaho Regulations</u>

Certain regulations with regard to Medicaid coverage have been adopted in Idaho. ***IDAPA 16.03.05.802*** provides as follows:

> **WOMAN DIAGNOSED WITH BREAST OR CERVICAL CANCER.** A woman not otherwise eligible for Medicaid . . . is eligible for Medicaid for the duration of her cancer treatment. . . .
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> . . .
>
> **08. End of Treatment.** The division of Medicaid determines the end of treatment date according to IDAPA 16.03.09.013, "Rules Governing the Medical Assistance Program."

The regulation referred to is ***IDAPA 16.03.09.013***, which provides as follows:

> **DIAGNOSIS OF BREAST OR CERVICAL CANCER THROUGH THE WOMEN'S HEALTH CHECK.**
>
> Women eligible for Medical Assistnace as provided for in IDAPA 16.03.05.802, "Rules Governing Eligibility for Aid to the Aged, Blind and Disabled (AABD)" will be covered while receiving either primary or adjuvant cancer treatment, or both. The Division of Medicaid, or its successor, is responsible for determining when a woman's treatment has ended.

> **01. Primary Treatment.** The initial action of treating a patient medically or surgically for cancer using conventional treatment modalities.
>
> **02. Adjuvant Therapy.** Treatment that includes either radiation or systemic chemotherapy, or both, as part of the plan of care.
>
> **03. End of Treatment.** Cancer treatment ends:
>
> a. When the woman's plan of care reflects a status of surveillance, follow-up, or maintenance mode; or
>
> b. if the woman's treatment relies on an unproven procedure . . . in lieu of primary or adjuvant treatment.

When this regulation was adopted, the description stated that the "new rule is needed to provide definitions of cancer treatment and end treatment for women diagnosed with breast or cervical cancer . . . ." ***See*** Docket Number 16-0309-0209. The document went on to state that,

> [u]nless this new section is added, there will be no definitions in the rule of cancer treatment or end of treatment for women participating in the Breast and Cervical Cancer Program. This would allow some women to continue receiving Medicaid benefits for an indefinite period of time . . . .

These regulations have been referred to as the "end-of-treatment rules." Under the end-of-treatment rules, an individual's eligibility terminates when the "plan of care reflects a status of surveillance, follow-up, or maintenance mode . . . ." The Department found that Femara therapy was in the surveillance, follow-up, or maintenance mode.

G. Determining the Enforceability of the Idaho Regulations

Initially, it must be noted that the Department does not contest that its Medicaid rules must comply with the federal Medicaid law. Furthermore, the Department does not challenge the medical facts set forth in the Affidavits of Dr. Grosset and Dr. Tezcan.

Ms. Hauser claims that the Idaho regulations are unenforceable because they are in conflict with the federal Medicaid statutes. The Department, on the other hand, contends that the end-of-treatment rules set reasonable limits, that they are not in conflict with the federal Medicaid statutes, and that they are valid.[10]

The question here is whether or not the standards in the Department's end-of-treatment regulations are in conflict with the BCCPTA with regard to setting medically reasonable limits for ending Medicaid eligibility. Otherwise stated, the test is whether or not the Department's end-of-treatment rules are reasonable in light of an individual's need for treatment and the period in which the individual requires treatment, with attention given to the duration of the period established by her treating health professional in her plan of care and to the optimal standards of practice. To answer the question presented here, the focus must be upon the facts concerning the medical reasonableness of the limits set by the Department in the regulations. Specifically, attention must be given to whether or not Tamoxifen or aromatase therapy such as Femara is cancer treatment such that the end-of-treatment rules which limit eligibility to surgery followed by radiation and/or systemic chemotherapy are in conflict with the BCCPTA.

Certain facts are set forth in the uncontroverted Affidavits of Dr. Grosset and Dr. Tezcan. Treatment for breast cancer in women with hormone receptor positive breast cancer continues from surgery and chemotherapy through hormone therapy such as Tamoxifen or other aromatase therapies such as Femara. There is no conceptual medical difference between systemic chemotherapy and hormone therapy in the treatment of

[10] For purposes only of her Motion for Summary Judgment, Ms. Hauser accepts that reasonableness is the standard for judging whether a state's rules comply with the BCCPTA.

women with hormone receptor positive breast cancer. Hormone therapy is not only less toxic and less costly than chemotherapy, but it is actually more effective. Under the Department's rules, however, chemotherapy is considered to be treatment while hormone therapy is not considered to be treatment.

The facts also indicate that, after surgery for early stage breast cancer, all women are essentially "disease free" with "no evidence of disease." All forms of post-surgery cancer treatment for women with hormone receptor positive breast cancer – radiation therapy, systemic chemotherapy, or hormone therapy – are used to reduce the substantial risk of recurrence. There is no medical basis for considering women receiving only radiation therapy and chemotherapy to be in treatment for their cancer and not considering women receiving the third form of hormone therapy not to be in treatment. All these women are being treated for their cancer and as such they all remain eligible for Medicaid under the BCCPTA.

The standard protocol for women with hormone receptive positive breast cancer includes the administration of a five (5) year course of therapy of Tamoxifen or an aromatase inhibitor such as Femara. This is the optimal standard of practice or, otherwise stated, the gold standard of care for women with hormone receptive positive breast cancer. Hormone therapy should be offered by the health professional as part of an individual's plan of care. Any program that does not pay for this protocol is in conflict with Medicaid coverage for women receiving treatment for breast cancer.

Basically, the Idaho "end-of-treatment" regulations seek to distinguish between various kinds of treatments and, while offering Medicaid coverage for some treatments, deny hormone treatment without any medical grounds for doing so. When the medical

facts set forth in the uncontroverted Affidavits of Dr. Grosset and Dr. Tezcan are considered, the Idaho "end-of-treatment" regulations are not reasonable with respect to the use of Tamoxifen or aromatase therapy. Therefore, the regulations are in conflict with the federal law.

The Department makes several arguments in support of its contention that the end-of-treatment rules are not in conflict with the federal Medicaid statutes and that they are valid and enforceable. First, the Department argues that the plain language of the statute suggests that a person needs treatment because a cancer was diagnosed or suspected in the screening. The "need for treatment" comes from the discovery of something that appears to the screening clinic to be cancerous. Conversely, when there is no detectable cancer, there is no need for treatment. According to the Department, the statute does not expressly or impliedly provide that a person who merely has cancer risk factors requires treatment. The language of the statute states that an eligible person is an individual who requires treatment for breast or cervical cancer. According to the Department's reading of the statute, the federal law intends to exclude persons who no longer "require" treatment for a cancer. Ms. Hauser has, however, provided evidence based upon medical standards to the effect that, after surgery, a five (5) year course of therapy of Tamoxifen or an aromatase inhibitor such as Femara is a required treatment for women with hormone receptor positive breast cancer. Furthermore, a distinction must be made between persons who have actually had cancer and embarked on a plan for its treatment from those who are undergoing routine monitoring services for precancerous conditions.

Second, the Department argues that the documents interpreting the federal statutes indicate that the states have the flexibility to determine what constitutes "requires treatment." The document goes on, however, to indicate that states may establish limits, but those limits must be reasonable. In this case, the limits established by the Department were not medically reasonable and, therefore, are in conflict with the federal statutes and documents.

Third, the Department argues that the documents interpreting the federal statutes envision that eligibility will typically end within a year when they answer Question 18. A close reading of the Answer to Question 18, however, indicates that, if the period extends beyond a year or even a shorter period at a state's option, an individual's eligibility must be confirmed consistent with Medicaid redetermination requirements. Thus, at least once a year, the Medicaid program must check to see that a woman still meets all the requirements for coverage under the BCCPTA. This Answer actually contemplates multi-year treatments and provides for them. Furthermore, the Congressional Budget Office prepared an estimate in connection with the BCCPTA that reflects multi-year coverage broken down into costs for certain years of treatment.[11] This dispels any notion that the intention under the BCCPTA was to end coverage after chemotherapy or radiation therapy, which rarely extends more than one year after diagnosis.[12]

Fourth, the Department argues that the documents interpreting the federal statutes also envision a limited period of eligibility in the answers to Questions 19a and 19b. A

[11] For example, treatment in the first year after diagnosis is higher, treatment is subsequent years is less, and treatment in the last year of a patient's life is highest.

[12] In his Affidavit, Dr. Tezcan stated that chemotherapy or radiation therapy typically lasts only a few months and rarely extends beyond even one year after diagnosis.

reading of the Answers to Questions 19a and 19b indicates that they are addressing a recurrence of the cancer after completion of treatment or a spread of cancer to other parts of the body. In this case, needed treatment was not completed.

Fifth, the Department argues that it has the authority to limit the amount, duration, and scope of Medicaid services. In ***McCoy v. State of Idaho, Department of Health and Welfare***, 127 Idaho 792, 907 P.2d 110 (1995), the Idaho Supreme Court cited ***Beal v. Doe***, 432 U.S. 438, 97 S.Ct. 2366, 53 L.Ed.2d 494 (1977), for the proposition that states have broad discretion to adopt standards for determining the extent of medical assistance they will provide so long as such standards are reasonable and consistent with the objectives of Medicaid.[13] The evidence indicates that the standards adopted by the Department provide for eligibility for certain kinds of needed treatment for breast cancer, but do not provide for other kinds of needed treatment. Regulations that do not provide for eligibility for all forms of needed treatment during the period in which the individual requires treatment as established by treating health professionals and consistent with optimal standards of care are not reasonable. Furthermore, they are inconsistent with the objectives of the BCCPTA, which was to provide treatment for individuals who require such treatment for the duration of the treatment.

Sixth, the Department argues that, as Dr. Young testified at the Hearing before the Hearing Officer, the five (5) year hormone therapy is optional as the patient's choice.[14] Although patients may choose to decline such treatment, it must be offered to them.

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[13] In ***McCoy***, the applicant appealed the Department of Health and Welfare's denial of Medicaid coverage for gastric bypass surgery that was recommended by her doctor to treat her obesity. The Idaho Supreme Court held that the regulation denying Medicaid coverage for all medical procedures to treat obesity was fatally overbroad and inconsistent with Medicaid's objective of providing medical assistance to eligible individuals in need of such assistance.

[14] At the Hearing, Dr. Young acknowledged that hormone therapy is the standard of practice among physicians.

After reviewing the relevant statutes and rules and after considering the medical facts, it must be concluded that the Idaho regulations, both temporary and permanent, are in conflict with the federal BCCPTA. Therefore, they are void and unenforceable. The Department is enjoined from enforcing such rules that deny or terminate Medicaid eligibility to individuals described in the BCCPTA, including those receiving Tamoxifen or aromatase inhibitor therapy for so long as they remain in need of the treatment for breast or cervical cancer as determined by their treating health care professional and in accordance with optimal standards of care.

VII

ON APPEAL, THE DEPARTMENT'S DECISION MUST BE VACATED AND THE MATTER REMANDED

The Department advised Ms. Hauser that her eligibility for Medicaid benefits would terminate on June 30, 2002. Following an administrative hearing requested by Ms. Hauser, the Hearing Officer affirmed the termination. The Hearing Officer did not, however, rule upon the validity of the regulation. Rather, the Hearing Officer simply applied the regulation to the facts in Ms. Hauser's case.

The end-of-treatment regulations, which are found in ***IDAPA 16.03.09.813*** and ***IDAPA 16.03.05.802*** establish end-of-treatment limits that are void and unenforceable. Therefore, it must be determined whether or not Ms. Hauser is eligible for treatment under the BCCPTA.

In this case, Dr. Grosset, who is Ms. Hauser's physician, has testified that, in addition to her surgery and chemotherapy, she requires hormone treatment. He has

prescribed Femara as the needed treatment that she requires. Dr. Grosset's prescription is standard protocol for women with hormone receptive positive breast cancer.

In conclusion, Ms. Hauser's appeal must be granted.[15] The Final Order is reversed and the matter is remanded to the Department for reinstatement of Medicaid coverage for Ms. Hauser from the last payment and continuing until such time as she no longer meets all the Medicaid requirements.

VIII

MS. HAUSER HAS A RIGHT TO BRING A 42 U.S.C. § 1983 ACTION

Ms. Hauser alleges that, under ***42 U.S.C. § 1983***, she has a right to challenge the state regulations that are in conflict with the federal statute. It is undisputed that ***§ 1983*** may be used in that manner. ***Maine v. Thiboutot***, 448 U.S. 1, 100 S.Ct. 2502, 65 L.Ed.2d 555 (1980). Section 1983 is not, however, available to enforce alleged rights that are only precatory or that are not substantive in nature. To be enforceable, a federally created right must arise from something more than congressional encouragement or preference. ***Pennhurst State School v. Halderman***, 451 U.S. 1, 101 S.Ct. 1531, 67 L.Ed.2d 694 (1981).

The United States Supreme Court has developed a three-part test for determining whether a statute creates enforceable rights within the meaning of § 1983. Thus, ***42 U.S.C. § 1983*** provides a cause of action to enforce a federal statutory right if (1) the statute was intended to benefit the plaintiff; (2) the statute imposes a congressional mandate rather than a preference; and (3) the plaintiff's interest in the statute is not vague

[15] There may be some question as to whether an appeal can be determined on a motion for summary judgment. Both parties have, however, addressed the issues presented in the appeal. This case is somewhat unusual in that the determination as to the enforceability of the Idaho regulations actually decided the appeal. Therefore, a decision is being made here.

and amorphous. ***Wilder v. Virginia Hospital Association***, 496 U.S. 198, 110 S.Ct. 2510, 110 L.Ed.2d 455 (1990); ***Westside Mothers v. Haveman***, 289 F.3d 852 (6th Cir. 2002).

Federally enforceable rights have routinely been found after applying the test in the Medicaid context. ***See Frew v. Hawkins***, 540 U.S. ___ No. 02-628 (January 14, 2004); ***Westside Mothers v. Haveman, supra; Miller v. Whitburn***, 10 F.3d 1315 (7th Cir. 1993).

In this case, Ms. Hauser's claim falls within the test. The Medicaid statute clearly intends to benefit individuals, such as Ms. Hauser, who have breast or cervical cancer. In states such as Idaho that have chosen this category of coverage, the Medicaid statute mandates coverage for women with breast or cervical cancer. Ms. Hauser's interest in the statute is not vague or amorphous because the BCCPTA provides explicit criteria describing the women to be covered.

IX

NO SANCTIONS WILL BE IMPOSED

Ms. Hauser seeks the imposition of sanctions on the Department pursuant to ***Idaho Code § 12-123*** and ***Rules 11(a)(1) and 54, Idaho Rules of Civil Procedure***. ***Rule 11*** sanctions are appropriate when, at the time that a pleading was signed, the party knew or shown have known that the facts were not well-grounded or the law was not supportive. ***Landvik v. Landvik***, 130 Idaho 54, 936 P.2d 697 (Ct.App. 1997). ***Idaho Code § 12-123*** provides for sanctions for frivolous conduct in a civil case. ***Rule 54(d)*** allows for costs to the prevailing party.

Based upon a review of the issues presented in this case, it cannot be found that sanctions should be imposed under ***Rule 11(a)(1) or Idaho Code § 12-123***. Costs should be awarded to Ms. Hauser as the prevailing party under ***Rule 54***.

IX

CONCLUSION AND ORDER

Based on the foregoing discussion, it is hereby ORDERED that the Petitioner/Plaintiff's Motion for Summary Judgment be and the same is granted as set forth herein. Based on the foregoing discussion and on the Petitioner/Plaintiff's Appeal, the Final Order of the Department of Health and Welfare be and the same is reversed as set forth herein and the matter is remanded to the Department for further action in accord herewith. Costs are awarded to Ms. Hauser as the prevailing party.

DATED this _____ day of May, 2004.

_____
John Patrick Luster
District Judge

CERTIFICATE OF MAILING

I hereby certify that a true and correct copy of the foregoing MEMORANDUM DECISION AND ORDER IN RE: MOTION FOR SUMMARY JUDGMENT was mailed, postage prepaid, sent by interoffice mail, or sent by facsimile transmission on the _____ day of May, 2004, to the following:

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ALL FIRST DISTRICT COURT JUDGES

DANIEL J. ENGLISH
Clerk of the District Court

_____
By: Deputy Clerk