

DEPARTMENT OF HEALTH

PETITION FOR DECLARATORY ORDER

NOTICE OF HEARING

(As required under Tenn. Code Ann. § 4-5-224)

1. **Petitioner's Name:** Janet Leach Richards

2. **Petitioner's Attorney:** Michael Reynolds
Address: Baker, Donelson, Bearman,
Caldwell & Berkowitz, P.C.
165 Madison Avenue
Suite 2000
Memphis, Tennessee 38103
Telephone: (901) 577-2214

Petitioner's Attorney: Jamie Whitney
Address: Tx. Bar No. 24056202
Fulbright & Jaworski, LLP
600 Congress Avenue #2400
Austin, Texas 78701
Telephone: (512) 536-5298

3. **Agency rule, order, or statutory provision on which declaratory order is sought:** Tenn. Code Ann. § 56-7-2352(c)(1)
Tenn. Code Ann. § 56-7-2352(c)(7)

4. **Summary of Relief Requested:**

Petitioner states that she was diagnosed with Stage IV ovarian cancer in 2002 and was treated successfully through high dose chemotherapy and a stem cell transplant. Petitioner states that her cancer has reoccurred. Petitioner states that her treating physician has determined that the most effective treatment for Petitioner would be small, daily ("metronomic") doses of an oral chemotherapy drug, Hycamtin (topotecan), coupled with a second oral drug, Votrient (pazopanib). Petitioner states that insurance coverage is necessary to allow her access to these chemotherapy drugs. Petitioner states that her insurance carrier, CVS CareMark, has declined coverage. Petitioner requested that the Commissioner of the Department of Health direct coverage of these drugs pursuant to Tenn. Code Ann. § 56-2352, and the Commissioner denied the request.

Petitioner requests a declaratory order: finding that Petitioner's proposed treatment regimen is a covered off-label treatment regimen under Tennessee law; declaring that the Commissioner of the Department of Health direct Petitioner's insurance carrier to cover and provide the prescribed treatment; and providing all other relief to which Petitioner may be entitled.

5. Summary of Statute or Regulation at Issue:

Tenn. Code Ann. § 56-7-2352(c)(1) provides that no insurance policy or contract regulated under [title 56] that provides coverage for drugs shall exclude coverage of any such drug for a particular indication on the ground that the drug has not been approved by the FDA for that indication, if the drug is recognized for treatment of the indication in one (1) of the standard reference compendia, or in the medical literature; provided, that nothing in this section shall be construed to authorize the commissioner of health to approve any drug or direct any person that issues an insurance policy to make payments for the drug for a particular indication unless the drug is recognized for treatment of the indication in one (1) of the standard reference compendia or in the medical literature. Tenn. Code Ann. § 56-7-2352(c)(7) provides that the commissioner of health shall have the authority to direct any person who issues an insurance policy to make payments required by this section.

6. Hearing:

The Petitioner has requested an expedited hearing. The contested case hearing in this matter will be conducted by an administrative law judge sitting for the Commissioner of the Department of Health; the administrative law judge will schedule the hearing date. If you are interested in intervening or participating in this case in any way or think you may be affected by the possible outcome of this case, you must file a Petition to Intervene pursuant to Tenn. Code Ann. § 4-5-310 and Tenn. Comp. R. & Regs. 1360-04-01-.12, stating your specific interest(s) in the case and your legal position/argument regarding those interests. The Petition must be submitted in writing to:

Administrative Procedures Division
Office of the Secretary of State
312 Rosa L. Parks Avenue
8th Floor, William R. Snodgrass Tennessee Tower
Nashville, Tennessee 37243
(615) 741-2078

A copy of the Petition must be mailed to:

Christy Allen, Special Counsel to the Commissioner
Department of Health
Bureau of Health Licensure and Regulation
220 Athens Way, Suite 104
Plaza I MetroCenter
Nashville, Tennessee 37243
(615) 741-8404

7. Administrative Procedures

Docket Number: 17.00-112820J

CERTIFICATE OF SERVICE

A true and correct copy of this Notice is being mailed via first class mail to the following persons in compliance with Tenn. Code Ann. § 4-5-224(a)(2):

Mary Kennedy, Deputy General Counsel
Department of Health
425 5th Avenue North
3rd Floor, Cordell Hull Building
Nashville, Tennessee 37243

Michael Reynolds, Esq.
Baker, Donelson, Bearman, Caldwell & Berkowitz, P.C.
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Memphis, Tennessee 38103

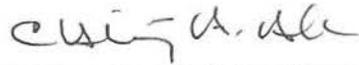
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5th Floor, Davy Crockett Tower
Nashville, Tennessee 37243

CVS CareMark
Attn: Jonathan Friedman, Esq.
CT Corporation System
530 Gay Street
Knoxville, Tennessee 37902

The original has been filed with the Office of the Secretary of State, Administrative Procedures Division, 3122 Rosa L. Parks Avenue, 8th Floor William R. Snodgrass Tennessee Tower, Nashville, Tennessee 37243 on this the 13th day of June 2011.



Christy A. Allen, BPR No. 015967
Special Counsel to the Commissioner
Tennessee Department of Health