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Opinion No. 03-157

Off-Label Drug Use Statute

QUESTIONS

1. Tennessee Code Annotated Section 56-7-2352 provides, in pertinent part, that "[a]ny dispute about coverage for off-label [drug] uses brought to the commissioner of health shall be resolved by the appropriate court-approved grievance process authorized by the department." Tenn. Code Ann. § 56-7-2352(c)(6). What is/are the appropriate court(s) for approving the grievance process which is required by this paragraph?

2. What is the process by which the appropriate court(s) are to go about approving the off-label dispute grievance process which is required by Tenn. Code Ann. § 56-7-2352(c)(6)?

3. Is Tenn. Code Ann. § 56-7-2352 constitutional insofar as it requires court approval for the "grievance process authorized by the department" to resolve disputes about coverage for off-label drug uses?

OPINIONS

1-2. In our view, the meaning of the term, "court-approved grievance process," is ambiguous. Therefore, it is appropriate to examine the legislative history of the statute and the historical context of the passage thereof, in an effort to determine the Legislature's intention in enacting the provisions.

Our review of the legislative history has led us to several conclusions. First, the Legislature intended that the issues and matters to be addressed by the Commissioner in any "dispute" brought to him under Tenn. Code Ann. § 56-7-2352 be very circumscribed. If the Commissioner determines that an off-label use of a drug is approved of by the compendia and scientific literature described in the statute, he may direct that a patient's insurer pay for that use. If, however, the disputed use is not so approved, the Commissioner is not authorized to direct an insurer to pay for it. Second, the Legislature intended that the grievance process for handling off-label disputes brought to the Commissioner expend little or no additional state funds.

In view of the above considerations, we think that the Legislature used the term, "court-approved grievance process," in Tenn. Code Ann. § 56-7-2352, to refer to an already-existing process. And we think that the Legislature could have intended that the "court-approved grievance

process" refer to the contested case provisions of Tennessee's Administrative Procedures Act ("APA"), Tenn. Code Ann. §§ 4-5-301, *et seq*. These statutory provisions for the determination of parties' legal rights by state agencies have been held by the Court of Appeals for the Sixth Circuit to "scrupulously protect the fundamental right of notice and an opportunity to be heard," and thus have been "court-approved." *Watts v. Burkhart*, 978 F.2d 269, 275-78 (6th Cir. 1992) (*en banc*).

We view the APA's declaratory order processes as most obviously applicable to "disputes" under Tenn. Code Ann. § 56-7-2352. These declaratory order processes are set out at Tenn. Code Ann. §§ 4-5-223 through 4-5-225. If an insured individual seeks a directive from the Commissioner of Health requiring the former's insurer to pay for an off-label drug use, Tenn. Code Ann. § 56-7-2352 requires that the Commissioner or his designee determine whether the requested off-label use is one that must be approved under the statute. If so, the Commissioner may issue a directive to the insurer, ordering it to make payment(s) for the use. If the disputed use is not approvable under the terms of the statute, the Commissioner must deny issuance of a directive. Thereafter, in the event that there is an issue as to the validity or applicability of Tenn. Code Ann. § 56-7-2352 or the Commissioner's directive, the affected insured or insurer may bring a petition for a declaratory order to the Commissioner under Tenn. Code Ann. § 4-5-223(a). The Commissioner would either convene a contested case hearing and issue a declaratory order, or refuse to issue a declaratory order. Tenn. Code Ann. § 4-5-223(a)(1), (2). In either scenario, the matter may be reviewed in the Davidson County Chancery Court. *Id.* Any such contested case hearing would be handled under the "court-approved" contested case provisions of the APA; *i.e.*, Tenn. Code Ann. §§ 4-5-301, *et seq.*

3. In light of our response to your first two questions, this question is pretermitted.

ANALYSIS

1-2. Tennessee Code Annotated § 56-7-2352 became law in 1997. 1997 Acts, Pub. Chap. 277. Paragraph (a) of the statute contains a number of legislative findings and declarations, including:

> . . .
>
> (3) Some insurers deny payment for drugs that have been approved by the federal food and drug administration (FDA) when the drugs are used for indications other than those stated in the labeling approved by the FDA (off-label use) while other insurers with similar coverage terms do pay for off-label use;
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> (4) Denial of payment for off-label use can interrupt or effectively deny access to necessary and appropriate treatment for a person being treated for a life-threatening illness;
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> (5) Equity among employers who obtain insurance coverage for their employees and fair competition among insurance companies require that insurance companies assure citizens reimbursement for drugs in the same way and in

the way citizens expect;

(6) Off-label use of an FDA-approved drug is legal when prescribed in a medically appropriate way and is often necessary to provide needed care. Approximately fifty percent (50%) of cancer drug treatment is for off-label indications. The FDA and the federal department of health and human services recognize the wide variety of effective uses of FDA-approved drugs for off-label indications. Information on the appropriate off-label use of FDA-approved drugs is obtained from compendia published by the United States Pharmacopeail Convention, the American Medical Association, and the American Society of Hospital Pharmacists. In addition, scientific studies of off-label use of drugs published in recognized peer-reviewed professional journals provide information on appropriate use of drugs for off-label indications. The Omnibus Budget Reconciliation Act of 1990 recognizes these three (3) compendia and peer-reviewed literature as appropriate sources for reimbursement, and requires Medicaid agencies to pay for off-label use of drugs prescribed for Medicaid patients if the use is stated in any of such sources. The Onmibus [sic] Budget Reconciliation Act of 1993 applies the same criteria and coverage to Medicare patients. Twenty (20) states have also passed similar legislation, most based on uniform legislation. The National Association of Insurance Commissioners has also adopted a model act based on the ACCC model legislation;

. . .

(8) Reimbursement for off-label indications of FDA-approved drugs is necessary to conform to the way in which appropriate medical treatment is provided, to make needed drugs available to patients, and to contain health care costs; and

(9) The provisions of this section shall not apply to a governmentally funded health care program, if such program requires the provision of medically necessary services.

Tenn. Code Ann. § 56-7-2352(a). Paragraph (b) of the statute defines several terms used therein; *i.e.*, "insurance policy," "medical literature," and "standard reference compendia." Paragraph (c) provides as follows:

(1) No insurance policy or contract regulated under this title which 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 such drug is recognized for treatment of such 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 such drug or direct any person which issues an insurance policy to make payments for such drug for a particular

> indication unless such drug is recognized for treatment of such indication in one (1) of the standard reference compendia or in the medical literature.
>
> (2) Any coverage of a drug required by this section shall also include medically necessary services associated with the administration of the drug.
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> (3) This section shall not be construed to alter existing law with regard to provisions limiting the coverage of drugs that have not been approved by the FDA.
>
> (4) This section shall not be construed to require coverage for any drug when the FDA has determined its use to be contra-indicated.
>
> (5) This section shall not be construed to require coverage for experimental drugs not otherwise approved for any indication by the FDA.
>
> (6) Any dispute about coverage for off-label uses brought to the commissioner of health shall be resolved by the appropriate court-approved grievance process authorized by the department.
>
> (7) The commissioner of health shall have the authority to direct any person who issues an insurance policy to make payments required by this section.

Tenn. Code Ann. § 56-7-2352(c).

Concerning the matters about which you inquire, the statutory provisions may be summarized as authorizing the Commissioner of the Department of Health to approve off-label uses for drugs and to direct issuers of insurance policies to make payments for those uses when the uses are recognized in one of the standard reference compendia or in medical literature, as defined and described at Tenn. Code Ann. § 56-7-2352(b)(2), (3). This authority applies to insurance policies issued, amended, delivered or renewed in Tennessee, or which provide insurance for Tennessee residents. It does not, however, apply to governmentally funded health care programs which require the provision of medically necessary services; *e.g.*, the TennCare program.

The statute provides that in the event a "dispute" about coverage for off-label uses is brought to the Commissioner of the Department of Health, it "shall be resolved by the appropriate court-approved grievance process authorized by the department." Your questions concern these "dispute" provisions, and particularly the requirement that the Department of Health authorize use of an "appropriate court-approved grievance process" for resolution of such disputes.

Our research reveals that the Legislature's use of the term, "court-approved grievance process," is unique to Tenn. Code Ann. § 56-7-2352. The term does not appear in any other provision of the Tennessee Code. The Legislature did not define the term in the statute; nor did it define the term, "grievance process."

In our view, the meaning of the term is ambiguous. Therefore, it is appropriate to examine the legislative history of the statute and the historical context of the passage thereof, in an effort to determine the Legislature's intention in enacting the provisions. *See Chapman v. Sullivan County*, 608 S.W.2d 580, 582 (Tenn. 1980).

As originally proposed by its sponsors in 1997, Senate Bill No. 834/House Bill No. 772 placed state authority over ensuring compliance with the off-label use coverage requirements of the proposed legislation with the Commissioner of the Department of Commerce and Insurance. The bill included the following provisions:

> (c)(6) The commissioner of commerce and insurance shall create a panel of seven (7) medical experts to review off-label uses not included in any of the three (3) standard references or in the medical literature and to advise him in such instances whether a particular off-label use is medically appropriate. The panel shall make such recommendation from time to time and whenever a particular dispute about payment for such off-label use is brought to the commissioner. This seven-member panel shall include: (a) three (3) medical oncologists selected by the state medical oncology association, (b) two (2) specialists in the management of AIDS patients, selected by the state AIDS medical provider organization, (c) one (1) specialist in heart disease appointed by the Tennessee medical association, and (d) one (1) physician selected by the Tennessee medical association.
>
> (7) The commissioner of commerce and insurance shall have the authority to direct any person which issues an insurance policy to make payments required by this section.

The fiscal note (March 24, 1997) prepared by the Fiscal Review Committee for the bill estimated that enactment thereof would result in increased state expenditures exceeding $100,000. The fiscal note included the following assumptions for this estimate: "Assumes an increased use of such drugs in TennCare with an eventual increase in capitation rates. Assumes an increase in administrative cost in the Department of Commerce and Insurance to regulate health insurance plan coverage of such drugs. . .." The fiscal note also estimated that enactment of the bill would increase local government expenditures and health insurance industry expenditures by more than $100,000 in each instance.

During the Senate Commerce Committee's review of the bill, legislators expressed concerns about the above fiscal projections, and elicited comments thereupon from interested persons. Senate Commerce Committee Debate, March 5, 1997. These concerns led to the adoption of amendments to the bill. The first amendment specifically excluded governmentally funded health care programs which require the provision of medically necessary services. This amendment was intended to exclude the TennCare program from the bill. Senate Commerce Committee, March 5, 1997 (Comments of Senator Cooper). The second amendment[1]: (1) deleted all references to the Commissioner of the Department of Commerce and Insurance, replacing them with references to the Commissioner of the Department of Health; (2) deleted the provisions of the original bill which had

[1]These two amendments were subsequently renumbered as Amendments Nos. 2 and 3, respectively.

established a 7-member expert panel to make recommendations to the Commissioner of the Department of Commerce and Insurance in instances of disputes about off-label uses not included in any of the three (3) standard references or in the medical literature; and (3) enacted language providing for resolution of disputes about coverage for off-label uses brought to the Commissioner of the Department of Health by the appropriate court-approved grievance process authorized by the department.[2]

Senator Rochelle also identified the need for a third amendment, based upon comments of the bill's sponsors and supporters which indicated that they had no intention of authorizing the Commissioner of Health to approve the off-label use of any drug, unless that off-label use was identified in the compendia and scientific literature cited in the bill. Senate Commerce Committee, March 5, 1997 (Comments of Senator Rochelle). That third amendment (later renumbered as Amendment No. 4) was eventually passed, adding the following language to the bill:

> Provided, however, nothing in this section shall be construed to authorize the Commissioner of Health to approve any such drug or direct any person which issues an insurance policy to make payments for such drug for a particular indication unless such drug is recognized for treatment of such indication in one of the standard reference compendia or in the medical literature.

Our review of the above legislative history has led us to several conclusions relevant to construing the Legislature's intent in enacting the provisions concerning the off-label dispute grievance process and the Commissioner of Health's attendant authority to direct payment for such off-label uses. First, the Legislature intended that the issues and matters to be addressed by the Commissioner in any such dispute be very circumscribed. If the Commissioner determines that an off-label use of a drug is approved of by the compendia and scientific literature described in Tenn. Code Ann. § 56-7-2352, he may direct that a patient's insurer pay for that use. If, however, the disputed use is not so approved, the Commissioner is not authorized to direct an insurer to pay for it. Second, the Legislature intended that the grievance process for handling off-label disputes brought to the Commissioner cause little or no additional expenditure of state funds.

In view of the above considerations, we think that the Legislature used the term, "court-approved grievance process," in Tenn. Code Ann. § 56-7-2352, to refer to an already-existing process. We are aware of at least two such possible processes.

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[2]An amended fiscal note (March 25, 1997) analyzing the effect of the two amendments was submitted by the Fiscal Review Committee. Noting that the proposed amendments would (1) delete the bill's applicability to any governmental funded health care program; and (2) make the Commissioner of Health responsible for administration of the program and resolution of disputes about drug usage, rather than the commissioner of Commerce and Insurance, the amended fiscal note deleted previous estimates that the bill, if enacted, would increase state and local government expenditures by more than $100,000 each.

First, the TennCare program had a grievance and hearing process in place in 1997 which was, at that time, under the auspices of the Department of Health.[3] This process, which was set out in state regulation[4], was designed by the TennCare Bureau in response to a federal court order issued in *Daniels v. Wadley*, 926 F. Supp. 1305 (M.D. Tenn. 1996), *vacated in part, sub nom. Daniels v. Menke*, 145 F.3d 1330 (6th Cir. 1998) (unpub.). The court order required the TennCare Bureau to develop, for those TennCare enrollees whose requests for medical services were denied, delayed, reduced, suspended or terminated by their TennCare managed care organizations, procedural due process protections that comport with federal Medicaid fair hearing regulations. *Id.* However, it is our opinion that the Legislature did not intend to require the Commissioner of Health to use the *Daniels* processes in resolving disputes under Tenn. Code Ann. § 56-7-2352. The fact that the Legislature determined to exclude the TennCare program from the requirements of Tenn. Code Ann. § 56-7-2352 counsels strongly against any such conclusion.[5]

Alternatively, we think that the Legislature could have intended that the "court-approved grievance process" refer to the contested case provisions of Tennessee's Administrative Procedures Act ("APA"), Tenn. Code Ann. §§ 4-5-301, *et seq.* These statutory provisions for the determination of parties' legal rights by state agencies have been held by the Court of Appeals for the Sixth Circuit to "scrupulously protect the fundamental right of notice and an opportunity to be heard," and thus have been "court-approved." *Watts v. Burkhart*, 978 F.2d 269, 275-78 (6th Cir. 1992) (*en banc*).

We view the APA's declaratory order processes as most obviously applicable to "disputes" under Tenn. Code Ann. § 56-7-2352. These declaratory order processes are set out at Tenn. Code Ann. §§ 4-5-223 through 4-5-225. If an insured individual seeks a directive from the Commissioner of Health requiring the former's insurer to pay for an off-label drug use, Tenn. Code Ann. § 56-7-2352 requires that the Commissioner or his designee determine whether the requested off-label use is one that must be approved under the statute. If so, the Commissioner may issue a directive to the insurer, ordering it to make payment(s) for the use. If the disputed use is not approvable under the terms of the statute, the Commissioner must deny issuance of a directive. Thereafter, in the event that there is an issue as to the validity or applicability of Tenn. Code Ann. § 56-7-2352 or the Commissioner's directive, the affected insured or insurer may bring a petition for a declaratory order

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[3]In 1999, Governor Sundquist transferred the TennCare program and its related functions and administrative support to the Department of Finance and Administration. Executive Order No. 23 (October 19, 1999).

[4]In 1997, the process was set out at Tenn. Adm. Comp. R. & Regs. 1200-13-12-.11. More recently, and following additional litigation, it has been significantly amended.

[5]Additionally, we note that the *Daniels* grievance and hearing processes contained detailed requirements, including mandatory time frames, for "reconsideration" by managed care organizations. As of 1997 at least, we question whether the non-TennCare insurers governed by the provisions of Tenn. Code Ann. § 56-7-2352 had the wherewithal to perform such requirements.

to the Commissioner under Tenn. Code Ann. § 4-5-223(a).[6] The Commissioner would either convene a contested case hearing and issue a declaratory order, or refuse to issue a declaratory order. Tenn. Code Ann. § 4-5-223(a)(1), (2). In either scenario, the matter may be reviewed in the Davidson County Chancery Court. *Id.* Any such contested case hearing would be handled under the "court-approved" contested case provisions of the APA; *i.e.*, Tenn. Code Ann. §§ 4-5-301, *et seq*.

In summary, we think that the Commissioner of the Department of Health, who is authorized to construe and interpret statutes which he is charged with administering and enforcing (*see Nashville Mobilephone Co., Inc. v. Atkins*, 536 S.W.2d 335, 340 (Tenn. 1976)), may construe the term, "court-approved grievance process," as used in Tenn. Code Ann. § 56-7-2352, as referring to the contested case provisions of Tennessee's Administrative Procedures Act ("APA"), Tenn. Code Ann. §§ 4-5-301, *et seq*., as described above. Absent differing clarification from the Legislature, it is our opinion that this construction is reasonable and best effectuates the legislative intent in enacting Tenn. Code Ann. § 56-7-2352.

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[6]Tenn. Code Ann. § 4-5-223(a) provides, in pertinent part:

> Any affected person may petition an agency for a declaratory order as to the validity or applicability of a statute, rule or order within the primary jurisdiction of the agency. . ..

The Administrative Procedures Act defines the term, "order," as "an agency action of particular applicability that determines the legal rights, duties, privileges, immunities or other legal interests of a specific person or persons." Tenn. Code Ann. § 4-5-102(7).

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