J-A19011-07

2007 PA Super 250

CATHERINE ISAAC and JOHN ISAAC, INDIVIDUALLY and as HUSBAND and WIFE,	:	IN THE SUPERIOR COURT OF PENNSYLVANIA
Appellants	:	
v.	:	
	:	
JAMESON MEMORIAL HOSPITAL and RIFAATT BASSALY, M.D.,	:	
Appellees	:	No. 1555 WDA 2006

Appeal from the Judgment Entered August 2, 2006
In the Court of Common Pleas, Civil Division
Lawrence County, No. 11238 of 1999 CA

BEFORE: HUDOCK, TODD, and TAMILIA, JJ.

OPINION BY TODD, J.: Filed: August 22, 2007

¶ 1 In this appeal, we are asked to determine, in an action alleging lack of informed consent, the relevance of Medicaid regulations which set forth the parameters of informed consent to sterilization procedures required for federal reimbursement of those procedures. For the reasons that follow, we hold that they are not relevant, and thus affirm the judgment entered against Catherine Isaac and John Isaac, wife and husband, and in favor of Appellees Jameson Memorial Hospital and Rifaatt Bassaly, M.D.

¶ 2 The factual background of this case was set forth by the trial court as follows:

> [Ms. Isaac] came under the care of [Appellee] Rifaatt Bassaly, M.D., on October 21, 1997. At this time, Ms. Isaac was in the eighth month of her fourth pregnancy. At that initial appointment in Dr. Bassaly's office, Dr. Bassaly determined that Ms. Isaac's due date was November 12, 1997. Also, at that initial office visit on October 21, 1997, Ms. Isaac executed an "Authorization for Surgery or Special Procedures" for a bi-lateral partial salpingectomy (the tubal litigation procedure to

> permanently prevent pregnancy) and a "[S]terilization Consent Form."
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> On November 21, 1997, Ms. Isaac was admitted to Jameson Memorial Hospital so that labor could be induced. During the course of labor, it was determined that it was medically necessary to deliver the unborn child by cesarean section. The cesarean section was accomplished on November 22, 1997, as the result of which, Ms. Isaac gave birth to a baby boy. Immediately following the cesarean section, Dr. Bassaly performed a bi-lateral salpingectomy (the tubal litigation).

(Trial Court Opinion, 7/26/06, at 2.)

¶ 3 At trial, held on March 21 to March 27, 2006, the Isaacs contended that the tubal ligation procedure was performed without Ms. Isaac's consent, and, specifically, that she had withdrawn any previous consent given at the time of her initial appointment with Dr. Bassaly on October 21, 1997. They filed a motion for directed verdict, asserting that the evidence was conclusive that she had withdrawn any previous consent given by her for the tubal ligation procedure upon her admission to the hospital on November 21, 1997, and that any subsequent consent obtained from her by Appellees, during labor and childbirth, was in violation of Medicaid regulations and thus ineffectual to constitute her informed consent to the tubal ligation procedure.

¶ 4 The trial court denied the Isaacs' motion for directed verdict, concluding that, under Pennsylvania law, Jameson Memorial Hospital could not be liable for any lack of informed consent. With respect to Dr. Bassaly, the court concluded that the Medicaid regulations had no relevance to an action for lack of informed consent.

¶ 5 Thereafter, the case was submitted to the jury on a theory of negligence as to Jameson Memorial Hospital, in allegedly failing, through its personnel, to communicate Ms. Isaac's withdrawal of her consent to the doctor, and on the theory of lack of informed consent as to Dr. Bassaly based on Ms. Isaac's testimony that she continuously advised Dr. Bassaly throughout the period of labor and prior to the performance of the cesarean section that she did not want to have the tubal ligation procedure.

¶ 6 On March 27, 2006, the jury entered a verdict in favor of Appellees, finding that Jameson Memorial Hospital was not negligent, and that Dr. Bassaly did not perform the tubal ligation without Ms. Isaac's informed consent. The Isaacs filed post-trial motions seeking judgment notwithstanding the verdict, and a new trial on damages. The trial court denied the motions, and this appeal followed, in which the Isaacs ask:

> 1. Did the Trial Court err in refusing to grant [the Isaacs'] Motion for Directed Verdict in favor of [the Isaacs] and against [Appellees] as a matter of law, because [Appellees] failed to follow the state and federally mandated "informed consent" procedures required by [55] Pa. Code. 1101.11 *et seq.* and 42 C.F.R. 441.25[0] *et seq.*?
> 2. [Are the Isaacs] entitled to a new trial on damages only due to the trial Court's refusal to direct a verdict against [Appellees] as a matter of law?

(Appellants' Brief at 4.)

¶ 7 Our standard of review with respect to the denial of a directed verdict is as follows:

> [W]e may only ask whether the trial court's decision was an abuse of discretion or an error of law that controlled the outcome of the case. The trial judge, however, may only grant a directed verdict motion where "the facts are clear and there is no room for doubt." In so determining, the trial court "must consider the facts in the light most favorable to the nonmoving party and must accept as true all evidence which supports that party's contention and reject all adverse testimony."

Faherty v. Gracias, 874 A.2d 1239, 1246 (Pa. Super. 2005) (citations omitted).

¶ 8 The crux of the Isaacs' appeal is their contention that Appellees failed to obtain Ms. Isaac's informed consent to the tubal ligation because Appellees violated federal Medicaid regulations setting forth the parameters for obtaining that consent. Specifically, she asserts that she withdrew her prior written consent to the procedure, made in accordance with the regulations, upon her admission to Jameson Memorial Hospital and that, once her labor began, any further consent was invalid under the regulations which invalidate consent given during labor. Thus, the Isaacs assert that her consent was invalid as a matter of law. We need not address the factual issue of compliance with the regulations, as, for the following reasons, we reject the Isaacs' contention that the regulations were relevant to their lack of informed consent action against Appellees.

¶ 9 The Isaacs cite Medicaid regulations which indisputably govern sterilization procedures such as the tubal ligation performed on Ms. Isaac, and which applied to her as a participant in Pennsylvania's Medical

Assistance Program.[1] ***See*** 42 C.F.R. § 441.250 *et seq*.[2] These regulations specify the requirements that must be met in order for a health care provider to receive reimbursement for a sterilization procedure. ***See*** 42 C.F.R. § 441.252 ("A State plan must provide that the Medicaid agency will make payment under the plan for sterilization procedures and hysterectomies only if all the requirements of this subpart were met."); ***id.*** § 441.253 (federal financial participation "is available in expenditures for the

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[1] The federal Medicaid Act, 42 U.S.C. §§ 1396 *et seq.*, provides for

> federal-state collaboration in the provision of medical assistance. Specifically, the Act provides that states may elect to participate in the federal Medicaid program, as Pennsylvania has done, by preparing and submitting for federal approval a state Medicaid plan that complies with the Act and the regulations promulgated by the federal Department of Health and Human Services. ***See*** 42 U.S.C. § 1396a; 42 C.F.R. §§ 430-456. If the state plan is approved, the state will qualify for federal funding, which will cover part of the costs of the state's medical assistance program. ***See*** 42 U.S.C. § 1396b(a); ***id.*** § 1396d(b). Although "states are given considerable latitude in formulating the terms of their own medical assistance plans," their discretion is limited by the requirement that they must "fully comply with the federal statutes and regulations governing the program." ***Addis v. Whitburn,*** 153 F.3d 836, 840 (7th Cir.1998).

Dep't of Pub. Welfare v. Devereux Hosp. Texas Treatment Network, 579 Pa. 313, 320 n.7, 855 A.2d 842, 846 n.7 (2004). Pennsylvania's Medical Assistance Program was designed to provide medical assistance to those that cannot afford it and was created pursuant to the Public Welfare Code, 62 P.S. §§ 441.1 to 449, and in accordance with the Medicaid Act. 579 Pa. at 320-21, 855 A.2d at 846; ***see also*** 55 Pa. Code. § 1101.11(b) ("The [Medical Assistance] Program is authorized under Article IV of the Public Welfare Code (62 P. S. §§ 401--488) and is administered in conformity with Title XIX of the Social Security Act (42 U.S.C.A. §§ 1396-- 1396q) and regulations issued under it."). Ms. Isaac was enrolled in Pennsylvania's Medical Assistance Program. Jameson Memorial Hospital asserts, however, that there is no evidence that the hospital was ever reimbursed by Medicaid for Ms. Isaac's tubal ligation.

[2] Although the Isaacs rely on these Medicaid regulations, we note that the trial court, in its analysis, mistakenly cites the regulations for federal financial assistance programs administered by the Public Health Service. ***See*** 42 C.F.R. §§ 50.201 *et seq.* For purposes of our review of the trial court's determination, this error is immaterial as the two sets of regulations are substantially the same.

sterilization of an individual only if" certain requirements are met). Specifically, Section 441.253 provides:

> **§ 441.253 Sterilization of a mentally competent individual aged 21 or older.**
>
> FFP [(Federal financial participation)] is available in expenditures for the sterilization of an individual only if—
>
> (a) The individual is at least 21 years old at the time consent is obtained;
>
> (b) The individual is not a mentally incompetent individual;
>
> (c) The individual has voluntarily given informed consent in accordance with all the requirements prescribed in §§ 441.257 through 441.258; and
>
> (d) At least 30 days, but not more than 180 days, have passed between the date of informed consent and the date of the sterilization, except in the case of premature delivery or emergency abdominal surgery. An individual may consent to be sterilized at the time of a premature delivery or emergency abdominal surgery, if at least 72 hours have passed since he or she gave informed consent for the sterilization. In the case of premature delivery, the informed consent must have been given at least 30 days before the expected date of delivery.

42 C.F.R. § 441.253. Furthermore, Section 441.257 specifies the content of any consent form, 42 C.F.R. § 441.257(a), and specifically states that informed consent may not be obtained when the individual to be sterilized is: "(1) *In labor or childbirth*; (2) Seeking to obtain or obtaining an abortion; or (3) Under the influence of alcohol or other substances that affect the individual's state of awareness," ***id.*** § 441.257(b) (emphasis added).[3]

[3] These regulations were adopted in 1979 following protracted litigation and several cases of sterilization abuse involving minors and mentally incompetent individuals

¶ 10 As noted above, the Isaacs contend that these regulations were not adhered to in Ms. Isaac's case. Thus, they contend, as a matter of law, her tubal ligation was performed without her informed consent. We begin with a review of the legal principles underlying a cause of action for lack of informed consent.

¶ 11 In a claim alleging lack of informed consent,

> it is the conduct of the unauthorized procedure that constitutes the tort. ***Moure v. Raeuchle,*** 529 Pa. 394, 604 A.2d 1003, 1008 (1992). A claim of a lack of informed consent sounds in the intentional tort of battery because an operation performed without the patient's consent is deemed to be the equivalent to a technical assault. ***Smith v. Yohe,*** 412 Pa. 94, 194 A.2d 167, 174 (1963). To obtain a patient's informed consent, doctors must provide patients with "material information necessary to determine whether to proceed with the surgical or operative procedure or to remain in the present condition." ***Duttry v. Patterson,*** 565 Pa. 130, 771 A.2d 1255, 1258 (2001) (*quoting* ***Sinclair by Sinclair v. Block,*** 534 Pa. 563, 633 A.2d 1137, 1140 (1993)). This information must give the patient "a true understanding of the nature of the operation to be performed, the seriousness of it, the organs of the body involved, the disease or incapacity sought to be cured, and the possible results." ***Id.*** (*quoting* ***Gray v. Grunnagle,*** 423 Pa. 144, 223 A.2d 663, 674 (1966)). While doctors are not required to disclose "all known information," they are required to "advise the patient of those material facts, risks, complications and alternatives to surgery that a reasonable person in the patient's situation would consider significant in deciding whether to have the operation." ***Gouse v. Cassel,*** 532 Pa. 197, 615 A.2d 331, 334 (1992) (emphasis omitted).

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in the early 1970s under prior regulations which merely required that the procedure be deemed "voluntary." ***See generally Haverhill Mun. Hosp. v. Comm'r of Div. of Med. Assistance***, 699 N.E.2d 1, 3 (Mass. App. 1998); ***Relf v. Weinberger,*** 372 F. Supp. 1196, 1199-1200 (D.D.C. 1974), *vacated as moot*, 565 F.2d 722 (D.C. Cir. 1977).

Valles v. Albert Einstein Med. Ctr., 569 Pa. 542, 551, 805 A.2d 1232, 1237 (2002). Moreover, since the tort founded upon lack of informed consent is an intentional tort, i.e. a battery, negligence principles generally do not apply. ***Montgomery v. Bazaz-Sehgal***, 568 Pa. 574, 585, 798 A.2d 742, 748-49 (2002); ***Moure***, 529 Pa. at 404 n.8, 604 A.2d at 1008 n.8.[4]

¶ 12 We first address the Isaacs' lack of informed consent claim against Jameson Memorial Hospital. As the above discussion suggests, the informed consent doctrine principally concerns the actions of the physician performing the surgical procedure. Given the unique nature of the doctrine and its origins as a technical battery, hospitals cannot be held vicariously liable for a physician's failure to obtain informed consent because "a medical facility cannot maintain control over this aspect of the physician-patient relationship." ***Valles***, 569 Pa. at 554, 805 A.2d at 1239. The Isaacs, however, rely on an exception to this general rule enunciated by this Court in ***Friter v. Iolab Corp.,*** 414 Pa. Super. 622, 607 A.2d 1111 (1992). We find their reliance on ***Friter*** to be misplaced.

¶ 13 In ***Friter***, we addressed whether the defendant hospital was liable for lack of informed consent where the hospital was involved in a clinical investigation for the federal Food and Drug Administration to determine the

[4] The General Assembly codified the law of informed consent in 2002. ***See*** 40 P.S. § 1303.504; ***see generally Valles***, 569 Pa. at 551 n.10, 805 A.2d at 1237 n.10. This statute is inapplicable to the instant matter, however, as it became effective after the procedure at issue herein took place.

safety of an ocular lens implant. Federal regulations required the hospital, as an approved institution for conducting experimental studies, to obtain the informed consent of any patient participating in the study. Finding an exception to the general rule that health care institutions are not liable for lack of informed consent, we concluded that the hospital, "as a participant in a clinical investigation for the FDA," specifically assumed a duty to ensure that an informed consent was obtained by any patient participating in the study. ***Id.*** at 628, 607 A.2d at 1113.

¶ 14 By contrast, herein, the Medicaid regulations cannot be read to place an independent duty on Jameson Memorial Hospital to obtain Ms. Isaac's informed consent. Rather, the regulations set forth preconditions for federal reimbursement of the costs of a sterilization procedure. ***See*** 42 C.F.R. § 441.252 ("A State plan must provide that the Medicaid agency *will make payment* under the plan for sterilization procedures and hysterectomies *only if all the requirements* of this subpart were met." (emphasis added)); ***id.*** § 441.253 ("FFP is available in expenditures for the sterilization of an individual *only if*" the consent requirements are met. (emphasis added)). Thus, if a health care provider fails to ensure that the regulations are adhered to, it forfeits any right to reimbursement under Medicaid; only in this way is the hospital obliged to follow the regulations. ***See Rosson v. Coburn***, 876 P.2d 731, 736 (Okla. App. 1994) (holding that the Medicaid regulations do not impose a policy "prohibiting sterilization of those under

the age of 21 years," but "ensure that federal funding is not used to do so."). Accordingly, the exception announced in ***Friter*** to the general rule that hospitals cannot be held vicariously liable for a physician's failure to obtain informed consent is inapplicable, and the trial court correctly denied the Isaacs' motion for directed verdict against Jameson Memorial Hospital on this basis.

¶ 15 We now turn to the relevance of the Medicaid regulations to the Isaacs' lack of informed consent claim against Dr. Bassaly. The trial court concluded that the regulations "relate to a procedure for payment for medical services, and the subject matter of the regulations does not address a legal standard relative to a cause of action against the doctor on the Doctrine of Informed Consent," adding that the regulations have "no application to the law as it currently exists in Pennsylvania relative to the Doctrine of Informed Consent." (Trial Court Opinion, 7/26/06, at 12.) We agree.

¶ 16 We first stress what the Isaacs do not argue. The Isaacs do not proffer the Medicaid regulations in support of a claim that Dr. Bassaly (or the hospital) was negligent or negligent *per se*. Their arguments are strictly tied to lack of informed consent, the intentional tort of battery. (***See*** Appellants' Brief at 10 ("As [consent was improperly obtained], [Appellees] are liable to [the Isaacs] for battery."), 22 (asserting that contributory negligence is not an issue in this case because Appellees liability is premised on battery; "the

battery that occurred was a result of the [Appellees'] failure to adhere to state and federal regulations [regarding Ms. Isaac's] informed consent to a sterilization procedure").) Accordingly, we need not and do not reach the question of whether these regulations may be asserted in support of a cause of action for negligence.

¶ 17 Instead, we are asked to assess the import of the regulations in the context of an informed consent claim. There are no decisions from the courts of this Commonwealth addressing these Medicaid regulations. Moreover, looking to other jurisdictions, we have located no decisions that address the application of these regulations to an informed consent action. While the Isaacs cite decisions from the trial courts of our sister states, the cited decisions concern negligence actions, not lack of informed consent. ***See, e.g., Hare v. Parsley***, 596 N.Y.S.2d 313 (N.Y. Sup. 1993) (violation of regulations constituted negligence); ***Butler v. Med. Ctr. of Delaware, Inc.***, 1993 WL 80616 (Del. Super. 1993) (unpublished decision) (in negligence action for failure to perform requested tubal ligation, court held that hospital was contractually prohibited from performing procedure where to do so in violation of Medicaid regulations would have rendered patient financially liable).

¶ 18 Upon review of the regulations, we agree with the trial court that they relate primarily to "a procedure for payment for medical services" and do not impose a legal standard relevant to an action for lack of informed consent.

(Trial Court Opinion, 7/26/06, at 12.) As discussed above, the regulations ostensibly impose prerequisites *for federal reimbursement* of a sterilization procedure. ***See*** 42 C.F.R. § 441.252; ***id.*** § 441.253. As the Oklahoma Court of Appeals reasoned in ***Rosson, supra***, in determining that the regulations could not support a negligence *per se* claim:

> The Medicaid Act is an administrative scheme providing medical assistance benefits to qualified recipients through states, implying no private right of action. ***Chalfin v. Beverly Enterprises, Inc.***, 741 F.Supp. 1162 (E.D.Pa.1990). Also see, ***Stewart v. Bernstein***, 769 F.2d 1088 (5th Cir.1985).
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> The Medicaid regulations themselves reveal that their purpose is not to impose a national policy prohibiting sterilization of those under the age of 21 years, but to ensure that federal funding is not used to do so.

Rosson, 876 P.2d at 736; ***but see Morinaga v. Vue***, 935 P.2d 637, 643 (Wash. App. 1997) (the regulations protect Medicaid patients "from being sterilized without being fully aware of the consequences and alternatives" and thus support negligence *per se* claim). Thus, fundamentally, the regulations impose administrative, not legal, obligations.

¶ 19 We recognize the Isaacs' contention that the regulations, by setting forth preconditions for reimbursement, indirectly benefit patients by ensuring that they are able to fully consider a sterilization procedure, and thus reducing the risk of coercion. ***See Morinaga, supra***.[5] Nevertheless, in proffering the Medicaid regulations, the Isaacs seek to expand the doctrine of informed consent beyond that recognized in Pennsylvania. In

[5] ***See also supra*** note 3.

this Commonwealth, doctors obtain a patient's informed consent when they provide "material information" necessary for the patient to determine whether to proceed with a procedure; they are not required to disclose "all known information," but only to "advise the patient of those material facts, risks, complications and alternatives to surgery that a reasonable person in the patient's situation would consider significant in deciding whether to have the operation." ***Valles***, 569 Pa. at 551, 805 A.2d at 1237 (internal quotation marks omitted).[6] The Isaacs do not argue, however, that the alleged violation of Medicaid regulations had any bearing on the type or quality of information Ms. Isaac received from Appellees regarding her procedure — they argue only that the timing of the consent rendered it invalid under the regulations. The additional responsibilities the Isaacs seek to impose on physicians in obtaining a patient's informed consent exceed the exchange of "material information" our caselaw requires. The Isaacs seek the imposition of new duties more in line with a negligence claim, not a cause of action for lack of informed consent. ***See Montgomery***, 568 Pa. at 585, 798 A.2d at 748-49 (negligence principles generally do not apply to the intentional tort of lack of informed consent); ***Pollock v. Feinstein***, 917 A.2d 875, 878 (Pa. Super. 2007) ("Appellant correctly asserts that the established

[6] We note that Pennsylvania's informed consent statute, ***see supra*** note 4, retains these same basic requirements for a valid informed consent. ***See*** 40 P.S. § 1303.504(b) ("Consent *is informed if* the patient has been given a description of a procedure set forth in subsection (a) and the risks and alternatives that a

law of our Commonwealth considers a claim for a lack of informed consent to be a technical battery, and that negligence principles do not apply to this claim.").

¶ 20 Although the standard of care due a patient — ostensibly a negligence concept — may be relevant in a narrow class of informed consent cases where the type or quality of *information provided* is at issue, ***see Pollock***, 917 A.2d at 878-79 (holding that certificate of merit was required in informed consent case, as claim was based upon the failure of the defendant-doctors to adhere to an acceptable professional standard in providing patient with a full explanation of the medical risks involved in the procedure she was to undergo), here, the Isaacs' contention is not that Ms. Isaac's consent was not fully *informed*. Again, their argument is that, given the timing of her consent, it was invalid under the Medicaid regulations.

¶ 21 Finally, we agree with the concern expressed by the trial court that adopting the regulations as a legal standard in informed consent cases would lead to a perverse inequity. The court reasoned, and we agree, that if such a legal standard was adopted,

> then patients whose services are to be paid by Medica[id] would be treated differently than patients whose medical services would be paid by other forms of private or public insurance or self pay. It would be absurd to find that the standard for medical care should be determined by the method of payment

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reasonably prudent patient would require to make an informed decision as to that procedure." (emphasis added)).

> for the services as opposed to a legal standard applicable to all person[s] who receive medical care from a doctor or hospital."

(Trial Court Opinion, 7/26/06, at 12.) We will not expand the doctrine of informed consent where it would lead to this inequitable result.

¶ 22 Accordingly, we hold that the proffered Medicaid regulations pertaining to informed consent for sterilization procedures have no relevance to a lack of informed consent cause of action in Pennsylvania. As a result, we find that the trial court properly denied the Isaacs' motion for directed verdict against Dr. Bassaly on that basis.[7]

¶ 23 For all the foregoing reasons, we affirm the judgment entered below.

¶ 24 Judgment **AFFIRMED**.

[7] As a result of our determination that the trial court properly denied the Isaacs' motion for directed verdict, we need not address their contention that any remand should direct a new trial on damages alone.