

The Duty of Care and the Quest for Payment

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the third-party payer and the prescriber. Can the same rationale be used to increase the legal duties of other caregivers as they navigate between patients, payers and other providers?

Yarushka Rivera, a MassHealth beneficiary, had a seizure disorder for which she was prescribed Topamax by her neurologist, Dr. Schoeck. When her family tried to renew the prescription, a Walgreens pharmacist informed them that MassHealth required a prior authorization form to be filled out and signed by the prescribing physician before the medication would be covered by MassHealth. Under MassHealth rules, it does not notify physicians of the need for prior authorization, but only the prescribing physician could submit the prior authorization form, not the pharmacist or patient.

In this case, there was no evidence that a Walgreens pharmacist notified Dr. Schoeck's office of the need for a prior authorization form for Rivera's medication, though there was testimony that a Walgreens pharmacist told Rivera's mother that Walgreens would do so. Testimony at trial indicated that Rivera's family contacted Schoeck's office seven times over the course of four months, ending in October of 2009, about the need for the prior authorization form and tried unsuccessfully four times to fill the prescription at Walgreens. The family could not afford the approximate \$400 out-of-pocket cost of the medication. Rivera's mother testified that at an appointment with Dr. Schoeck in the middle of October 2009, Rivera told her physician that she had not been able to take the medication since August because Schoeck's office had not processed the required paperwork. At the end of October, Rivera suffered a seizure and died.

The case went to the Supreme Judicial Court on an appeal from the trial court's grant of Walgreens's motion for summary judgment on the ground that it owed no legal duty to Rivera. In its decision, the SJC held: "In light of the evolving nature of the pharmacist-patient relationship, Walgreens's specific knowledge regarding the need for prior authorization, the industry-wide customs and practices of pharmacies handling prior authorization requests, and the foreseeability of the harm to Rivera, we conclude that Walgreens owed a limited duty to take reasonable steps to notify both Rivera and Schoeck of the need for prior authorization each time Rivera tried to fill her prescription." It is worth unpacking each element of this holding.

First, the evolving pharmacist-patient relationship. The court acknowledged that pharmacists are not required by statute or regulation to facilitate prior authorization processes for patients, but in light of other patient-service functions served by pharmacists, they are "well situated to assist patients with certain issues regarding their medications." This is an argument based on the placement of a caregiver in the complex relationships among the patient, the insurer and other caregivers. In principle, it could be used in a variety of

contexts to add to providers' legal duties owed to their patients.

Second, the court turned to the question of "specific knowledge"; in this case, that of the pharmacy regarding danger to a particular customer. Normally, under the "learned intermediary" doctrine as understood in Massachusetts, the legal duty of a drug manufacturer or a pharmacy to warn of such dangers runs only to the physician, who has the ultimate duty to warn his or her patient. One reason for this rule is that imposing a duty on pharmacists to, for example, warn a patient about a medication's general side effects would interfere with the patient-physician relationship. However, as in cases where a pharmacist is aware of contraindications related to other prescriptions a particular customer may be taking, conveying that information to the patient or to her physician facilitates that relationship. Here, that exception to the learned intermediary doctrine is applied not in the case of patient-specific clinical information, but regarding the requirements of that patient's insurance coverage.

The court then turned to industry practices to determine if a standard of care had been established among pharmacies to notify physicians and not patients of the need for prior authorization. Expert testimony at trial established that Walgreens pharmacists routinely notify prescribers' offices directly of the need for prior authorization and that this practice is typical in the pharmacy industry. Thus, the court concluded, "The skill and knowledge of pharmacists today involve more than the dispensing of pills. A pharmacist exercising the skill and knowledge normally possessed by members of the professional community ordinarily would notify a patient and the prescribing physician that prior authorization is needed."

Next, the court considered the foreseeability of the harm to Rivera. Under general principles of tort law, in order for there to be a duty to exercise reasonable care to avoid harm to others, the foreseeability of that harm must be reasonable. Presumably, the court felt that the fact that Rivera's prescription would ordinarily be paid for by MassHealth indicated that without MassHealth coverage, it would be reasonably foreseeable that Rivera would be unable to pay for the prescription. The court went further than establishing a pharmacist's duty to warn the patient of the need for prior authorization, so that the patient can then convey that requirement to her prescribing physician. That duty requires the pharmacist to notify the prescribing physician directly, since it is the pharmacist, not the patient, who has the relevant information and required forms.

The court took pains to establish that this duty is not unlimited. The pharmacist is not required to ensure that the physician received the request for authorization and will act on that request. Also, the pharmacist is able to choose whatever means of notification she or he deems reasonable. Moreover, the duty only applies where insurance coverage is denied specifically because a prior authorization form is required.

A dissent written by Justice Lowy in this case raises some broader issues. He describes the cause of Rivera's tragic death as a "systemic flaw" in the interactions among not just pharmacists, but also patients, physicians and health insurers. Justice Lowy was concerned that pharmacists, as opposed to health insurers, may not have the best means to control or avoid the risks in the prior authorization system. He asked whether the court's opinion might enable physicians and health insurers to delegate a portion of their responsibilities in that system to others.

We may ask similar questions about how expansive the duty of care might prove to be for providers acting within complex systems of care involving case management obligations and the integration of many types of caregivers. As the physician-patient relationship evolves within these complex structures, what specific knowledge regarding the prerequisites of insurance reimbursement, in the context of customs and practices developed within integrated systems of managed care, might the physician be required to understand and communicate in order to avoid liability?

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