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RESIDENT OWLERY

Welcome to the NEXT edition of "Resident Owlery," a newsletter developed by Professional Risk Management Services® to provide psychiatry residents in training with *owl* you need to help manage your risks as you prepare to start your psychiatric careers. Featuring risk management resources, educational articles, and the latest announcements and events from PRMS, this quarterly newsletter will share relevant news, useful tips, and important updates in the field of psychiatry to help keep you, your patients, and your practice safe, from residency to retirement.

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SOME PRACTICAL POINTERS FOR OFF-LABEL USE OF AN APPROVED DRUG

Off-label prescribing of medications is a widespread and well-accepted part of psychiatric practice. Off-label uses range from those that are clearly controversial (which may carry professional liability risk) to those which are considered the established of care (such as prescribing for children). Some typical off-label uses include prescribing a medication for a condition not indicated on its FDA-approved label, prescribing at a different dosage than indicated, or prescribing for a different patient population. With evidence to support efficacy and safety, off-label prescribing is not, in and of itself, a professional liability risk.

Malpractice allegations related to the off-label use of medications would most likely claim a deviation from the standard of care in prescribing, administering, and/or monitoring of the medication, and/or a lack of informed consent. Therefore, it is imperative that psychiatrists prescribing medications for off-label uses ensure that their practices in this area meet the applicable standard of care and that their documentation supports the medical treatment that was given.

Consider these risk management tips when prescribing medication for off-label use:

DO remember that prescribing a drug for any use other than that specifically approved by the FDA constitutes an off-label use. The off-label use of an approved medication is different than the use of non-FDA approved medications.

DO realize that the off-label use of a medication can increase liability risks, if relevant efficacy and safety information about the proposed off-label use is scarce or non-existent. Educate yourself about off-label uses and stay informed as new information about the medication and its uses becomes available. Understand your professional liability insurance policy's coverage for off-label prescribing.

DO maintain a file containing any relevant scientific literature on safety and efficacy supporting the specific off-label use. Keep this file separate from the patients' chart.

DO obtain the patient's informed consent, and as always, document the consent. The documentation should reflect that the patient was informed about and understood (1) the nature of the proposed treatment, (2) the risks, benefits, and potential side-effects of the proposed treatment, (3) any alternatives to the proposed treatment, (4) the risks and benefits of the alternatives, and (5) the risks and benefits of doing nothing.

DO clarify to the patient that the proposed treatment is an off-label use of the medication. Do not describe the use as "experimental" or "investigational" as these terms do not accurately reflect the status of medications that have been approved by the FDA and are being prescribed for off-label use. Keep copies in the patient's record of all written instructions or informational materials provided to the patient.

DO remember that informed consent is a continuous process. Document your discussions with the patient

about the medication, their response to the drug, any subsequent actions taken, and the reasoning behind your clinical decision-making process.

DO realize that the usual issues that are part of the on-going communication between the patient and psychiatrist when medications are prescribed may take on heightened importance with off-label use. Be sure to inquire about the use of other prescription medications, over-the-counter medications, herbal remedies, and any other treatments the patient uses. Clarify dietary and/or activity restrictions. Discuss potential allergic reactions, ways to identify them, and what to do if the patient experiences a reaction. Make sure that the patient knows whom to call if they have any questions or concerns.

DO use caution when "stacking" medications/using polypharmacy. Obviously, the greater the number of medications prescribed, the greater the potential for adverse interactions. The potential for problems can increase with off-label uses due to the possibility of unknown interactions. Educate yourself about off-label uses and stay informed as new information becomes available.

DO communicate with other health care providers about the medications that are being prescribed by all psychiatrists involved in the patient's treatment and about signs, symptoms, and responses to the medications. Communication is an important tool for providing quality care.

DO consider a professional consultation or a referral to another psychiatrist with appropriate training and expertise when appropriate.

DO remain aware of the potential for misuse or abuse of medications by the patient or those who may have access to the medication.

refer a colleague

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CASE OF THE QUARTER:
DOE VS. CHRIS GOMEZ, MD

Written by
Claims Department
Professional Risk Management Services (PRMS)

The "Case of the Quarter" column is a sample case study that highlights best practices in actual scenarios encountered through PRMS' extensive experience in litigation and claims management. Specific names and references have been altered to protect clients' interests. This discussion is for informational and education purposes only and should not be relied upon as legal advice.

FACTS:

John Doe was hospitalized for four days after attempting suicide to stop the voices in his head. While inpatient, his attending physician started him on Zyprexa. Dr. Gomez first treated John Doe two days after he was discharged from the hospital. Mr. Doe told Dr. Gomez that he was very worried about losing his job because he was sleepy from the medication. He denied hearing voices. Mr. Doe asked to be taken off Zyprexa. Dr. Gomez reluctantly agreed to a slow taper of the medication and lowered the dosage by 5mg/day. Dr. Gomez asked the patient to return in three weeks and to call before that if he experienced any problems. Dr. Gomez documented the patient's report of sleepiness and job concerns as well as his medication change and the recommended return visit. Three days later, Mr. Doe jumped from a bridge and died.

ALLEGATIONS:

Mr. Doe's wife filed suit alleging that Dr. Gomez was negligent in lowering the Zyprexa dosage; failing to recommend a follow-up visit sooner than three weeks; failing to further explore the job stressor; and failing to perform a suicide risk assessment.

DEFENSES:

We could not find expert support primarily because Dr. Gomez failed to document a suicide risk assessment. The expert we consulted with noted that the patient had been discharged from the hospital following a suicide attempt just two days before seeing Dr. Gomez so a suicide risk assessment should have been done and documented. The suicide risk assessment should have included exploration of the job concerns Mr. Doe expressed. The expert was also critical of the lack of documentation reflecting whether the patient was hearing voices or having other symptoms of psychosis before lowering the Zyprexa dosage.

OUTCOME:

It is extremely difficult to defend a case at trial without expert support, so this case was settled.

TAKEAWAY:

Performing and documenting a thorough evaluation are critical pieces to any defense. A claimant's attorney will pay particularly close attention to what a psychiatrist did and documented following a psychiatric hospital admission as the admission itself indicates some level of instability in the patient.

TEST YOUR KNOWLEDGE!
THE STANDARD OF CARE

A DEFENDANT PSYCHIATRIST WHO DEPARTED FROM AUTHORITATIVE GUIDELINES WILL _____

A) Be deemed per se negligent

B) Be expected to explain his or her reasoning for departure in court

C) Not have to justify reasoning for deviation

D) None of the above

Answer: B is correct!

In certain clinical situations, it may be necessary for psychiatrists to depart from established guidelines. In the event of such a departure, psychiatrists will be expected to explain and justify why it was necessary to do so, and they should document the basis for such a departure.



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