January 2022 – Pharmacy Rules

For Filing with CSI and JCARR

Stakeholder Feedback – Rule 4729:5-5-08 | Prospective drug utilization review.

COMMENT:

I would suggest that the regulation be less granular here:

D. Prior to dispensing an outpatient prescription for a controlled substance dangerous drug or a drug containing gabapentin, at a minimum, a pharmacist shall request and review an OARRS report covering at least a one year time period in any of the following circumstances:

(1) A patient adds a new or different controlled substance dangerous drug or a drug containing gabapentin to the patient's therapy that was not previously included;

(2) An OARRS report has not been reviewed for that patient during the preceding twelve months, as indicated in the patient profile;

(3) A prescriber is located outside the usual pharmacy geographic area;

(4) A patient is from outside the usual pharmacy geographic area;

(5) A pharmacist has reason to believe the patient has received prescriptions for controlled substance dangerous drugs or a drug containing gabapentin from more than one prescriber in the preceding three months, unless the prescriptions are from prescribers who practice at the same physical location;

Logic:

This language would resolve the current concern about Gabapentin; however, the language would require revision again, each time a new drug entity of concern is approved by the FDA.

Recommended Verbiage:

D. Prior to dispensing an outpatient prescription for a controlled substance dangerous drug or any OARRS reportable drug at a minimum, a pharmacist shall request and review an OARRS report covering at least a one year time period in any of the following circumstances:

(1) A patient adds a new or different controlled substance dangerous drug or any OARRS reportable drug to the patient's therapy that was not previously included;

(2) An OARRS report has not been reviewed for that patient during the preceding twelve months, as indicated in the patient profile;

(3) A prescriber is located outside the usual pharmacy geographic area;

(4) A patient is from outside the usual pharmacy geographic area;

(5) A pharmacist has reason to believe the patient has received prescriptions for controlled substance dangerous drugs or any OARRS reportable drug from more than one prescriber in the preceding three months, unless the prescriptions are from prescribers who practice at the same physical location;

There are also other verbiage phrases in use in other states, such as "drugs of concern"; as long as they obviate the need for regulatory revisions to include new drug entities, any such language would seem preferable.

*As an aside, I would suggest a board evaluation of Gabapentin to be included as a scheduled drug. About 30% of emergency department ODs have Gabapentin as a contributing drug. Considering that the purpose of scheduling drugs is to reflect a drug's potential for abuse, this is screaming, "**schedule me**"! Clearly, a drug encountered that often in ED ODs is being abused.*

Honestly, it reminds me of Soma. That was a known drug of abuse for decades before the DEA finally took action. WHY?

Rule 4729:5-5-08 | Prospective drug utilization review.

(A) Prior to dispensing any prescription, a pharmacist shall review the patient profile for the purpose of identifying the following:

(1) Over-utilization or under-utilization;

(2) Therapeutic duplication;

(3) Drug-disease state contraindications;

(4) Drug-drug interactions;

(5) Incorrect drug dosage;

(6) Drug-allergy interactions;

(7) Abuse/misuse;

(8) Inappropriate duration of drug treatment; and

(9) Food-nutritional supplements-drug interactions.

(B) Upon identifying any issue listed in paragraph (A) of this rule, a pharmacist, using professional judgment, shall take appropriate steps to avoid or resolve the potential problem. These steps may include, but shall not be limited to, the following:

(1) Requesting and reviewing an OARRS report or another state's prescription drug monitoring report;

(2) Consulting with the prescriber; or

(3) Counseling the patient.

(C) Prospective drug utilization review shall be performed using predetermined standards consistent with, but not limited to, any of the following:

(1) Peer-reviewed medical literature (i.e. scientific, medical, and pharmaceutical publications in which original manuscripts are rejected or published only after having been critically reviewed by unbiased independent experts);

(2) American hospital formulary service drug information; and

(3) United States pharmacopeia drug information.

(D) Prior to dispensing an outpatient prescription for a controlled substance dangerous drug **or a drug containing gabapentin**, at a minimum, a pharmacist shall request and review an OARRS report covering at least a one year time period in any of the following circumstances:

(1) A patient adds a new or different controlled substance dangerous drug **or a drug containing gabapentin** to the patient's therapy that was not previously included;

(2) An OARRS report has not been reviewed for that patient during the preceding twelve months, as indicated in the patient profile;

(3) A prescriber is located outside the usual pharmacy geographic area;

(4) A patient is from outside the usual pharmacy geographic area;

(5) A pharmacist has reason to believe the patient has received prescriptions for controlled substance dangerous drugs **or a drug containing gabapentin** from more than one prescriber in the preceding three months, unless the prescriptions are from prescribers who practice at the same physical location;

(6) Patient is exhibiting signs of potential abuse or diversion. This includes, but is not limited to, over-utilization, early refills, appears overly sedated or intoxicated upon presenting a prescription for a controlled substance dangerous drug, or an unfamiliar patient requesting a reportable drug by specific name, street name, color, or identifying marks.

(E) In the event an OARRS report is not immediately available, the pharmacist shall use professional judgment in determining whether it is appropriate and in the patient's best interest to dispense the prescription prior to reviewing a report.

(F) A pharmacist may use a delegate licensed or registered in accordance with Chapter 4729. of the Revised Code to request an OARRS report.

(G) Based upon information obtained during a prospective drug utilization review, a pharmacist shall use professional judgment when making a determination about the legitimacy of a prescription. A pharmacist shall not dispense a prescription of doubtful, questionable, or suspicious origin.

Rule 4729:9-1-01 | Schedule I controlled substances.

(For supporting materials to this rule, please refer to the Proposed Scheduling Action Document).

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(B) Narcotics-opiates

Any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted under federal drug abuse control laws, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation (for purposes of 3-methylthiofentanyl only, the term isomer includes the optical and geometric isomers):

(1) Acetyl-alpha-methylfentanyl (N-[1-(1-methyl-2-phenethyl)-4-piperidinyl]-N-phenylacetamide);

(2) Acetylmethadol;

(3) Acetyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide);

(4) Acryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide; other name: acryloylfentanyl);

(5) AH-7921 (3,4-dichloro-N-[(1-dimethylamino) cyclohexylmethyl]benzamide;

(6) Allylprodine;

(7) Alphacetylmethadol (except levo-alphacetylmethadol, also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM);

(8) Alphameprodine;

(9) Alphamethadol;

(10) Alpha-methylfentanyl (N-[1-(alpha-methyl-beta-phenyl)ethyl-4-piperidyl] propionanilide; 1- (1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine);

(11) Alpha-methylthiofentanyl (N-[1-methyl-2-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide);

(12) Benzethidine;

(13) Betacetylmethadol;

(14) Beta-hydroxyfentanyl (N-[1-(2-hydroxy-2-phenethyl-4-piperidinyl]-N-phenylpropanamide);

(15) Beta-hydroxy-3-methylfentanyl (other name: N-[1-(2-hydroxy-2-phenethyl)-3-methyl-4- piperidinyl]-N- phenylpropanamide);

(16) N-[1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl]-N-phenylpropionamide (other name: beta-Hydroxythiofentanyl);

(17) Betameprodine;

(18) Betamethadol;

(19) Betaprodine;

(20) Butyryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylbutyramide);

(21) Clonitazene;

(22) Dextromoramide;

(23) Diampromide;

(24) Diethylthiambutene;

(25) Difenoxin;

(26) Dimenoxadol;

(27) Dimepheptanol;

(28) Dimethylthiambutene;

(29) Dioxaphetyl butyrate;

(30) Dipipanone;

(31) Ethylmethylthiambutene;

(32) Etonitazene;

(33) Etoxeridine;

(34) 4-Fluoroisobutyryl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide; other name: para-fluoroisobutyryl fentanyl);

(35) Furanyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylfuran-2-carboxamide);

(36) Furethidine;

(37) Hydroxypethidine;

(38) Ketobemidone;

(39) Levomoramide;

(40) Levophenacylmorphan;

(41) 3-methylfentanyl (N-[3-methyl-1-(2-phenylethyl)-4-piperidyl]-N-phenylpropanamide);

(42) 3-methylthiofentanyl (N-[3-methyl-1-[2-(thienyl)ethyl]-4-piperidinyl]-N-phenylpropanamide);

(43) Morpheridine;

(44) MPPP (1-methyl-4-phenyl-4-propionoxypiperidine);

(45) MT-45 (1-cyclohexyl-4-(1,2-diphenylethyl)piperazine);

(46) Noracymethadol;

(47) Norlevorphanol;

(48) Normethadone;

(49) Norpipanone;

(50) Ocfentanil (N-(2-fluorophenyl)-2-methoxy-N-(1-phenethylpiperidin-4-yl)acetamide);

(51) Para-fluorofentanyl (N-(4-fluorophenyl)-N-[1-(2-phenethyl)-4-piperidinyl]propanamide;

(52) PEPAP (1-(2-phenethyl)-4-phenyl-4-acetoxypiperidine;

(53) Phenadoxone;

(54) Phenampromide;

(55) Phenomorphan;

(56) Phenoperidine;

(57) Piritramide;

(58) Proheptazine;

(59) Properidine;

(60) Propiram;

(61) Racemoramide;

(62) Tetrahydrofuranyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2- carboxamide);

(63) Thiofentanyl (N-phenyl-N-[1-(2-thienyl)ethyl-4-piperidinyl]-propanamide;

(64) Tilidine;

(65) Trimeperidine;

(66) U-47700 (3,4-Dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methylbenzamide);

(67) Except as otherwise provided in this chapter, any compound that meets all of the following fentanyl pharmacophore requirements to bind at the mu receptor, as identified by a report from an established forensic laboratory:

(a) A chemical scaffold consisting of both of the following:

(i) A five, six, or seven member ring structure containing a nitrogen, whether or not further substituted;

(ii) An attached nitrogen to the ring, whether or not that nitrogen is enclosed in a ring structure, including an attached aromatic ring or other lipophilic group to that nitrogen.

(b) A polar functional group attached to the chemical scaffold, including but not limited to, a hydroxyl, ketone, amide, or ester;

(c) An alkyl or aryl substitution off the ring nitrogen of the chemical scaffold; and

(d) The compound has not been approved for medical use by the United States food and drug administration.

(68) N,N-Diethyl-2-[[4-(1-methylethoxy)phenyl]methyl]-5-nitro-1H-benzimidazole-1-ethanamine (isotonitazene).

(69) 2-Methyl-AP-237 (1-[2-methyl-4-[(E)-3-phenylprop-2-enyl]piperazin-1-yl]butan-1-one).

(70) AP-237 (1-[4-(3-phenyl-2-propen-1-yl)-1-piperazinyl]-1-butanone).

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(G) For the purpose of complying with federal rule, all materials, compounds, mixtures or preparations which contain any substance temporarily placed in schedule I pursuant to 21 U.S.C. 811 by the United States drug enforcement administration **(INSERT DATE OF LATEST RULE FILING WITH JCARR).**