

Department of Health and Hospitals Bureau of Health Services Financing

March 17, 2011

Re: Quantity Limits, Maximum Dosages and ICD-9-CM Diagnosis Code Requirement for C-II Narcotics Quantity Limits on Triptans and Carisoprodol, and Maximum Dosage on Buprenorphine Patches

Dear Pharmacist:

The Louisiana Medicaid Pharmacy Benefits Management (LMPBM) Program in collaboration with its Drug Utilization Review (DUR) Board has established maximum quantity and dosage limits for selected medications used in the management of pain. These limits will become effective on March 30, 2011. These new limits are in addition to quantity and/or dosage limits which are currently in place. Most prescriptions for recipients who have a confirmed diagnosis of cancer will be exempt from the quantity limit. To accurately determine which prescriptions should be exempt, we are requiring all prescriptions for schedule II narcotic agents to have an ICD-9-CM diagnosis code documented on the hardcopy prescription.

Compliance associated with program policy will be verified through the pharmacy compliance audit program. Pharmacists are reminded to contact prescribers for authorization when overrides are billed. Quantity limits or maximum dosage overrides require prescriber approval before pharmacists may submit override codes. For claims billed with an override, pharmacists must continue to **document (1) NCPDP DUR override codes**, (2) ICD-9-CM diagnosis codes, and (3) reason for exceeding limits on the hardcopy prescription for review during the pharmacy audit process.

Summary charts are provided in the appendices of this document. These charts address quantity limitations and maximum daily dosages. Products which contain acetaminophen continue to have a maximum dosage of four (4) grams of acetaminophen daily, while products which contain aspirin continue to have a maximum dosage of six (6) grams of aspirin daily.

The Louisiana Board of Medical Examiners published rules regarding the use of medications used in the treatment of non-cancer related chronic or intractable pain. These rules are included in Title 46: Professional and Occupational Standards. Subchapter B – Medications Used in the Treatment of Non-Cancer-Related Chronic or Intractable Pain – are enclosed for your review. For more information, see http://www.lsbme.la.gov/46v45MedicalProfessionsSeptember2009practice.htm#_Toc243144086

If you have concerns or comments regarding this correspondence, you may contact Melwyn B. Wendt at 225-342-9768 or send a fax to 225-342-1980. Your continued cooperation and support of LMPBM Drug Utilization Review (DUR) efforts are greatly appreciated.

Sincerely,

Rodney Wise, MD

Medicaid Medical Director

RW/MJT/mbw

Enclosure

Quantity Limits

Schedule II (C-II) Narcotic Agents

- Quantity limits for the Schedule II narcotic agents are listed in Table 1.
- Quantity limits are cumulative and are based on a rolling thirty (30) days.
- Unless otherwise specified, quantity limits apply to all strengths of an agent.
- An ICD-9-CM diagnosis code indicating the reason for use must be documented on the hardcopy prescription for **ALL Schedule II narcotic agents**, even for those Schedule II narcotic agents not subject to a quantity limit.
- With the exception of the fentanyl buccal and sublingual products, recipients receiving the agents listed in Table 1 for the management of cancer pain are not subject to a quantity limit.
- A list of cancer-related ICD-9-CM diagnosis code ranges is provided in Appendix A.

Table 1. Schedule II Narcotic Agents Subject to a Quantity Limit

Description	Dosage Form	Route	Quantity Limit per 30 Rolling Days	Sample Brand Name
Fentanyl	Patch 12, 25, 50 mcg/hr	Transdermal	10 units ea strength	Duragesic [®]
Fentanyl	Patch 75, 100 mcg/hr	Transdermal	20 units ea strength	Duragesic [®]
Fentanyl Citrate Immediate	Tab Sublingual,	Sublingual,	120 units	Abstral [®] ,* Actiq [®] ,*
Release	Lozenge HD, Tab Effervescence, Film	Buccal		Fentora [®] ,* Onsolis [®] *
Hydromorphone HCl ER	Tab ER 24 hr	Oral	30 units	Exalgo [®]
Morphine Sulfate SR	CPMP 24 hr	Oral	30 units	Avinza®
Morphine Sulfate SR	Cap SR Pellet	Oral	60 units	Kadian®
Morphine Sulfate SA	Tab SA	Oral	60 units	MS Contin [®]
Morphine Sulfate/Naltrexone SR	Cap SR Pellet	Oral	60 units	Embeda [®]
Oxycodone HCl SR	Tab SR 12 hr	Oral	60 units	Oxycontin [®]
Oxycodone, Oxycodone/Acetaminophen, Oxycodone/Aspirin	Tab, Capsule	Oral	120 units	Magnacet [®] , Percocet [®] , Percodan [®] , Roxicet [®] , Roxicodone [®] , Tylox [®] , Xolox [®]
Oxycodone/Ibuprofen	Tab	Oral	28 units	
Oxymorphone HCl SR	Tab SR 12 hr	Oral	60 units	Opana ER®

^{*}Refer to special cases on page 2.

ICD-9-CM Diagnosis Code Requirement

An ICD-9-CM diagnosis code <u>must</u> be written on the hardcopy prescription for agents listed in Table 1 and all other Schedule II narcotic agents. The diagnosis code must be written on the hardcopy prescription by the prescribing practitioner <u>or</u> by the pharmacist after consultation with the prescriber. Additionally, all claims for these agents require an ICD-9-CM diagnosis code in **NCPDP field 424-DO.** Claims submitted for these agents without a diagnosis code will deny with:

NCPDP rejection code 39 (Missing or invalid diagnosis code) mapped to **EOB Code 575** (Missing or invalid ICD-9-CM diagnosis code).

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Except for methadone, when the prescribing practitioner does not indicate a diagnosis code on the prescription and when the **prescriber cannot be reached**, a denial for a missing diagnosis code may be overridden if the pharmacist determines that the recipient cannot wait to receive the medication. The pharmacist may override the denial by

entering "03" in NCPDP field 418-DI (Level of Service) specifying an emergency.

Special Cases

Methadone: All prescriptions for methadone must have a diagnosis code for payment. There are no provisions for an override of methadone when a diagnosis code is omitted. Methadone products when used for the treatment of opioid addiction in detoxification or maintenance programs shall only be dispensed by opioid treatment programs certified by the Substance Abuse and Mental Health Services Administration.

Fentanyl: Claims for fentanyl buccal and sublingual agents (Abstral[®], Actiq[®], Fentora[®], and Onsolis[®]) must contain a cancer-related ICD-9-CM diagnosis code in order for the claim to process for payment through the Point of Sale (POS) System. These buccal and sublingual agents are subject to quantity limits.

Prescriber Consultation Authorizing Quantity Limit Override

When the cumulative quantity for an agent listed in Table 1 is determined to be in excess of the quantity limit, the claim will deny with:

NCPDP rejection code 76 (Quantity or days supply exceeds program maximum) mapped to **EOB code 457** (Quantity or days supply exceeds program maximum).

If the prescribing practitioner chooses to exceed the quantity limit, the prescribing practitioner must provide the reason why the quantity limit needs to be exceeded. The pharmacist may override the quantity limit after consultation with the prescriber. The pharmacist must document on the hardcopy prescription (1) the prescriber's reason why the quantity limit needs to be exceeded, and (2) the NCPDP DUR override codes used in submitting the claim. The pharmacist must submit the override at the Point of Sale in:

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NCPDP 439-E4 field (Reason for Service Code) – EX (Excessive Quantity)
NCPDP 440-E5 field (Professional Service Code) – MØ (Prescriber Consulted)
NCPDP 441-E6 field (Result of Service Code) – 1G (Filled with Prescriber Approval)
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Serotonin Agonists (Triptans)

- Quantity limits for the triptans are listed in Table 2.
- Quantity limits are cumulative and are based on a rolling thirty (30) days.
- Unless otherwise specified, quantity limits apply to all strengths of an agent.

When the cumulative quantity for an agent listed in Table 2 is determined to be in excess of the quantity limit, the claim will deny with:

NCPDP rejection code 76 (Quantity or days supply exceeds program maximum) mapped to **EOB code 457** (Quantity or days supply exceeds program maximum).

If the prescribing practitioner chooses to exceed the quantity limit, the **prescribing practitioner must provide the reason why the quantity limit needs to be exceeded.** The pharmacist **may override the quantity limit** <u>after consultation</u> with the prescriber. The pharmacist must document on the hardcopy prescription (1) **the prescriber's reason why the quantity limit needs to be exceeded,** and (2) **the NCPDP DUR override codes used in submitting the claim**. The pharmacist must submit the override at the Point of Sale in:

NCPDP 439-E4 field (Reason for Service Code) – EX (Excessive Quantity)
NCPDP 440-E5 field (Professional Service Code) – MØ (Prescriber Consulted)
NCPDP 441-E6 field (Result of Service Code) – 1G (Filled with Prescriber Approval)

Table 2. Triptans Subject to a Quantity Limit

Description	Dosage Form	Route	Quantity Limit per	Sample Brand
			30 Rolling Days	Name
Almotriptan Maleate	Tab	Oral	12 units	Axert [®]
Eletriptan HBr	Tab	Oral	6 units	Relpax [®]
Frovatriptan Succinate	Tab	Oral	9 units	Frova®
Naratriptan HCl	Tab	Oral	9 units	Amerge®
Rizatriptan Benzoate	Tab, Tab rapid	Oral	12 units	Maxalt [®] ,
	dissolve			Maxalt MLT®
Sumatriptan Succ/Naproxen Na	Tab	Oral	9 units	Treximet [®]
Sumatriptan Succinate	Tab	Oral	9 units	Imitrex [®]
Zolmitriptan	Tab, Tab rapid	Oral	6 units	Zomig [®] ,
	dissolve			Zomig ZMT®

Carisoprodol

- The quantity limit for carisoprodol has been changed to ninety (90) tablets per rolling ninety (90) days.
- The quantity limit is cumulative and applies to all strengths and combinations of carisoprodol.
- Cumulative quantities in excess of the quantity limit will not process for payment through the Point of Sale (POS) System.
- Clinical Note: An example of a carisoprodol tapering schedule can be accessed at: http://pharmacy.oregonstate.edu/drug_policy/pages/dur_board/newsletter/articles/volume4/4_8.pdf

Maximum Daily Dosage

Buprenorphine Transdermal Patches (Butrans®)

An ICD-9-CM diagnosis code <u>must</u> be written on the hardcopy prescription for buprenorphine transdermal patches. The diagnosis code must be written on the hardcopy prescription by the prescribing practitioner <u>or</u> by the pharmacist after consultation with the prescriber. All claims for these agents require an ICD-9-CM diagnosis code in **NCPDP field 424-DO.** Claims submitted for buprenorphine patches without a diagnosis code or with a diagnosis code related to the management of addictive disorders or substance abuse will deny with:

NCPDP rejection code 39 (Missing or invalid diagnosis code) mapped to **EOB Code 575** (Missing or invalid ICD-9-CM diagnosis code).

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There is no provision to override the denial when a diagnosis code related to the management of addictive disorders or substance abuse is submitted. When the prescribing practitioner does not indicate a diagnosis code on the prescription and when the **prescriber cannot be reached**, a denial for a missing diagnosis code may be overridden if the pharmacist determines that the recipient cannot wait to receive the medication. The pharmacist may override the denial by

entering "03" in NCPDP field 418-DI (Level of Service) specifying an emergency.

When the cumulative daily dosages for the agents listed in Table 3 exceed the maximum daily dosage, the claims will deny with:

NCPDP rejection code 88 (DUR Reject Error) mapped to **EOB code 529** (Exceeds maximum daily dose).

There are no override provisions through the Point of Sale (POS) System for morphine ER (Avinza[®]) or buprenorphine transdermal (Butrans[®]) when the respective maximum daily dosages are exceeded.

If the prescribing practitioner chooses to exceed the maximum daily dosage for the other agents, the prescribing practitioner must provide the reason why the daily dosage limit needs to be exceeded. The pharmacist may override the dosage limit after consultation with the prescriber. The pharmacist must document on the hardcopy prescription (1) the prescriber's reason why the daily dosage limit needs to be exceeded, and (2) the NCPDP DUR override codes used in submitting the claim. The pharmacist must submit the override at the Point of Sale in:

NCPDP 439-E4 field (Reason for Service Code) – HD (High Dose) NCPDP 440-E5 field (Professional Service Code) – MØ (Prescriber Consulted) NCPDP 441-E6 field (Result of Service Code) – 1G (Filled with Prescriber Approval)

Table 3. Agents with a Maximum Daily Dosage

Description	Units	Limit	Sample Brand Name	Age
Morphine ER (CPMP 24 hr)	1600 mg	Daily	Avinza [®]	
Tapentadol	700 mg	Daily	Nucynta [®]	
Tramadol Immediate-Release	400 mg	Daily	Ultram [®] , Rybix ODT [®]	< 76 y
Tramadol Immediate-Release	300 mg	Daily	Ultram [®] , Rybix ODT [®]	> 75 y
Tramadol Sustained-Release	300 mg	Daily	Ultram ER®	
Tramadol/Acetaminophen	8 tablets	Daily	Ultracet [®]	
Buprenorphine transdermal patches	20 mcg/hr (4	80 mcg/24 hr)*	Butrans®	

*Do not exceed a dose of one 20 mcg/hr buprenorphine patch. See prescribing information. Each buprenorphine patch is intended to be worn for 7 days.

Summary Charts

Summary charts for the limits discussed in this document are provided in Appendices. Agents with quantity limits are provided in Appendix B and agents with maximum daily dosages are provided in Appendix C. These charts are current as of March 30, 2011. Please visit **www.lamedicaid.com** for chart updates.

Appendix A. Cancer-Related ICD-9-CM Diagnosis Code Ranges

ICD-9-CM Diagnosis Code Range	Description
140 - 149.99	Malignant neoplasm of lip, oral cavity, and pharynx
150 – 159.99	Malignant neoplasm of digestive organs and peritoneum
160 – 165.99	Malignant neoplasm of respiratory and intrathoracic organs
170 – 176.99	Malignant neoplasm of bone, connective tissue, skin, and breast
179 – 189.99	Malignant neoplasm of genitourinary system
190 – 199.99	Malignant neoplasm of other and unspecified sites
200 - 208.99	Malignant neoplasm of lymphatic and hematopoietic tissue
209.0 – 209.39	Malignant carcinoid tumors

Appendix B: Products with Quantity Limits as of March 30, 2011

Products with Quantity Limits as of March 24, 2011					
Description	Dosage Form	Route	Units	Limit*	Sample Brand Name
Almotriptan Maleate	Tablet	Oral	12 units	30 days	Axert®
Buprenorphine HCl	Tablet SL	SL	16 mg	Daily	Subutex [®]
Buprenorphine HCl/Naloxone HCl	Tablet SL, Film	SL	24 mg**	Daily	Suboxone®
Carisoprolol, Carisoprodol/ASA, Carisoprodol/ASA/Codeine Phos	Tablet	Oral	90 units	90 days	Soma®
Eletriptan Hydrobromide	Tablet	Oral	6 units	30 days	Relpax [®]
Fentanyl	Patch 12, 25, 50 mcg/hr	Transdermal	10 units	30 days	Duragesic [®]
Fentanyl	Patch 75, 100 mcg/hr	Transdermal	20 units	30 days	Duragesic [®]
Fentanyl Citrate Immediate Release	Tablet sublingual, Lozenge HD, Tablet effervescence, Film	Sublingual, Buccal	120 units	30 days	Abstral [®] , Actiq [®] , Fentora [®] , Onsolis [®]
Frovatriptan Succinate	Tablet	Oral	9 units	30 days	Frova®
Hydromorphone HCl	Tablet ER 24 hr	Oral	30 units	30 days	Exalgo®
Ketorolac	Tablet	Oral	20 units	5 days	Toradol [®]
Morphine Sulfate	CPMP 24 hr	Oral	30 units	30 days	Avinza®
Morphine Sulfate	Cap SR pellet	Oral	60 units	30 days	Kadian ®
Morphine Sulfate	Tablet SA	Oral	60 units	30 days	MS Contin®
Morphine Sulfate/Naltrexone	Cap SR pellet	Oral	60 units	30 days	Embeda [®]
Naratriptan HCl	Tablet	Oral	9 units	30 days	Amerge®
Orlistat	Tablet	Oral	90 units	30 days	Xenical [®]
Oxycodone HCl	Tablet SR12hr	Oral	60 units	30 days	Oxycontin [®]
Oxycodone, Oxycodone/APAP, Oxycodone ASA	Tablet, Capsule	Oral	120 units	30 days	Magnacet [®] , Percocet [®] , Percodan [®] , Roxicet [®] , Roxicodone [®] , Tylox [®] , Xolox [®]
Oxycodone/Ibuprofen	Tablet	Oral	28 units	30 days	
Oxymorphone HCl	Tablet SR 12 hr	Oral	60 units	30 days	Opana ER [®]
Palivizumab	Vial	IM	5 doses	RSV season	Synagis [®]
Rizatriptan Benzoate	Tablet, Tablet rapid dissolve	Oral	12 units	30 days	Maxalt [®] , Maxalt MLT [®]
Sumatriptan Succ/Naproxen Sod	Tablet	Oral	9 units	30 days	Treximet®
Sumatriptan Succinate	Tablet	Oral	9 units	30 days	Imitrex [®]
Zolmitriptan	Tablet, Tablet rapid dissolve	Oral	6 units	30 days	Zomig [®] , Zomig ZMT [®]

^{*} Maximum quantity limits are based on rolling days.

**Maximum quantity limit is based on buprenorphine content.

Appendix C. Products with Maximum Daily Dosages as of March 30, 2011

Products With Maximum Daily Dosages as of March 24, 2011					
Description	Maximum Dosage	Limit	Sample Brand Name	Age (Y = Year)	
Acetaminophen-containing products	4000 mg APAP	Daily	Î		
Aripiprazole	30 mg	Daily	Abilify [®]	18 Y And >	
Aripiprazole	5 mg	Daily	Abilify [®]	< 5 Y	
Aripiprazole	20 mg	Daily	Abilify [®]	5 - 12 Y	
Aripiprazole	30 mg	Daily	Abilify [®]	13 - 17 Y	
Asenapine	20 mg	Daily	Saphris [®]	18 Y And >	
Aspirin-containing products	6000 mg ASA	Daily			
Buprenorphine transdermal patches	20 mcg/hr (480 mcg /	24 hr)*	Butrans®		
Clozapine	900 mg	Daily	Clozaril [®]	18 Y And >	
Iloperidone	24 mg	Daily	Fanapt [®]	18 Y And >	
Morphine ER	1600 mg	Daily	Avinza®		
Olanzapine	40 mg	Daily	Zyprexa®	18 Y And >	
Olanzapine	10 mg	Daily	Zyprexa®	< 5 Y	
Olanzapine	20 mg	Daily	Zyprexa®	5 - 12 Y	
Olanzapine	30 mg	Daily	Zyprexa®	13 - 17 Y	
Olanzapine/Fluoxetine	18 mg / 75 mg	Daily	Symbyax®	18 Y And >	
Paliperidone	12 mg	Daily	Invega®	18 Y And >	
Paliperidone	3 mg	Daily	Invega®	< 5 Y	
Paliperidone	6 mg	Daily	Invega [®] Invega [®]	5 - 12 Y	
Paliperidone	9 mg	Daily	Invega®	13 - 17 Y	
Quetiapine	1200 mg	Daily	Seroquel [®]	18 Y And >	
Quetiapine	100 mg	Daily	Seroquel [®]	< 5 Y	
Quetiapine	600 mg	Daily	Seroquel [®]	5 - 12 Y	
Quetiapine	1000 mg	Daily	Seroquel [®]	13 - 17 Y	
Risperidone	16 mg	Daily	Risperdal [®]	18 Y And >	
Risperidone	3 mg	Daily	Risperdal [®]	< 5 Y	
Risperidone	6 mg	Daily	Risperdal [®]	5 - 12 Y	
Risperidone	8 mg	Daily	Risperdal [®]	13 - 17 Y	
Tapentadol	700 mg	Daily	Nucynta®		
Tramadol Immediate-Release	400 mg	Daily	Ultram [®] , Rybix ODT [®]	< 76 Y	
Tramadol Immediate-Release	300 mg	Daily	Ultram [®] , Rybix ODT [®]	> 75 Y	
Tramadol Sustained-Release	300 mg	Daily	Ultram ER®		
Tramadol/Acetaminophen	8 tablets	Daily	Ultracet [®]		
Ziprasidone	200 mg	Daily	Geodon [®]	18 Y And >	
Ziprasidone	30 mg	Daily	Geodon®	< 5 Y	
Ziprasidone	60 mg	Daily	Geodon®	5 - 12 Y	
Ziprasidone	120 mg	Daily	Geodon®	13 - 17 Y	

^{*}Do not exceed a dose of one 20 mcg/hr buprenorphine patch. See prescribing information. Each buprenorphine patch is intended to be worn for 7 days.

Title 46

PROFESSIONAL AND OCCUPATIONAL STANDARDS

Part XLV. Medical Professions

Subpart 3. Practice

Chapter 69. Prescription, Dispensation, and Administration of Medications Subchapter B. Medications Used in the Treatment of Non-Cancer-Related Chronic or Intractable Pain

§6915. Scope of Subchapter

A. The rules of this Subchapter govern physician responsibility for providing effective and safe pain control for patients with noncancer-related chronic or intractable pain.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 1270(B)(6) and 1285(B).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners LR 23:727 (June 1997), amended LR 26:693 (April 2000).

§6917. Definitions

A. As used in this Subchapter, unless the content clearly states otherwise, the following terms and phrases shall have the meanings specified.

Board—the Louisiana State Board of Medical Examiners.

Chronic Pain—pain which persists beyond the usual course of a disease, beyond the expected time for healing from bodily trauma, or pain associated with a long term-incurable or intractable medical illness or disease.

Controlled Substance—any substance defined, enumerated or included in federal or state statute or regulations 21 C.F.R. §§1308.11-15 or R.S. 40:964, or any substance which may hereafter be designated as a controlled substance by amendment or supplementation of such regulations and statute.

Diversion—the conveyance of a controlled substance to a person other than the person to whom the drug was prescribed or dispensed by a physician.

Intractable Pain—a chronic pain state in which the cause of the pain cannot be eliminated or successfully treated without the use of controlled substance therapy and, which in the generally accepted course of medical practice, no cure of the cause of pain is possible or no cure has been achieved after reasonable efforts have been attempted and documented in the patient's medical record.

Noncancer-Related Pain—that pain which is not directly related to symptomatic cancer.

Physical Dependence—the physiological state of neuroadaptation to controlled substance which is characterized by the emergence of a withdrawal syndrome if the controlled substance use is stopped or decreased abruptly, or if an antagonist is administered. Withdrawal may be relieved by readministration of the controlled substance.

Physician—physicians and surgeons licensed by the Board.

Protracted Basis—utilization of any controlled substance for the treatment of noncancer-related chronic or intractable pain for a period in excess of 12 weeks during any 12-month period.

Substance Abuse (may also be referred to by the term Addiction)—a compulsive disorder in which an individual becomes preoccupied with obtaining and using a substance, despite adverse social, psychological, and/or physical consequences, the continued use of which results in a decreased quality of life. The development of controlled substance tolerance or physical dependence does not equate with substance abuse or addiction.

Tolerance—refers to the physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect or a reduced effect is observed with a constant dose. Controlled substance

tolerance refers to the need to increase the dose of the drug to achieve the same level of analgesia. Controlled substance tolerance may or may not be evident during controlled substance treatment.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 1270(B)(6) and 1285(B).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners LR 23:727 (June 1997), amended LR 26:693 (April 2000).

§6919. General Conditions/Prohibitions

A. The treatment of noncancer-related chronic or intractable pain with controlled substances constitutes legitimate medical therapy when provided in the course of professional medical practice and when fully documented in the patient's medical record. A physician duly authorized to practice medicine in Louisiana and to prescribe controlled substances in this state shall not, however, prescribe, dispense, administer, supply, sell, give, or otherwise use for the purpose of treating such pain, any controlled substance unless done in strict compliance with applicable state and federal laws and the rules enumerated in this Subchapter.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 37:1270(B)(6) and 37:1285(B).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners LR 23:727 (June 1997), amended LR 26:694 (April 2000).

§6921. Use of Controlled Substances, Limitations

- A. Requisite Prior Conditions. In utilizing any controlled substance for the treatment of noncancer-related chronic or intractable pain on a protracted basis, a physician shall comply with the following rules.
- 1. Evaluation of the Patient. Evaluation of the patient shall initially include relevant medical, pain, alcohol and substance abuse histories, an assessment of the impact of pain on the patient's physical and psychological functions, a review of previous diagnostic studies, previously utilized therapies, an assessment of coexisting illnesses, diseases, or conditions, and an appropriate physical examination.
- 2. Medical Diagnosis. A medical diagnosis shall be established and fully documented in the patient's medical record, which indicates not only the presence of noncancer-related chronic or intractable pain, but also the nature of the underlying disease and pain mechanism if such are determinable.
- 3. Treatment Plan. An individualized treatment plan shall be formulated and documented in the patient's medical record which includes medical justification for controlled substance therapy. Such plan shall include documentation that other medically reasonable alternative treatments for relief of the patient's noncancer-related chronic or intractable pain have been considered or attempted without adequate or reasonable success. Such plan shall specify the intended role of controlled substance therapy within the overall plan, which therapy shall be tailored to the individual medical needs of each patient.
- 4. Informed Consent. A physician shall ensure that the patient and/or his guardian is informed of the benefits and risks of controlled substance therapy. Discussions of risks and benefits should be noted in some format in the patient's record.
- B. Controlled Substance Therapy. Upon completion and satisfaction of the conditions prescribed in §6921.A, and upon a physician's judgment that the prescription, dispensation, or administration of a controlled substance is medically warranted, a physician shall adhere to the following rules.
- 1. Assessment of Treatment Efficacy and Monitoring. Patients shall be seen by the physician at appropriate intervals, not to exceed 12 weeks, to assess the efficacy of treatment, assure that controlled substance therapy remains indicated, and evaluate the patient's progress toward treatment objectives and any adverse drug effects. Exceptions to this interval shall be adequately documented in the patient's record. During each visit, attention shall be given to the possibility of decreased function or quality of life as a result of controlled substance treatment. Indications of substance abuse or diversion should also be evaluated. At each visit, the physician should seek evidence of under treatment of pain.
- 2. Drug Screen. If a physician reasonably believes that the patient is suffering from substance abuse or that he is diverting controlled substances, the physician shall obtain a drug screen on the patient. It is within the physician's discretion to decide the nature of the screen and which type of drug(s) to be screened.
- 3. Responsibility for Treatment. A single physician shall take primary responsibility for the controlled substance therapy employed by him in the treatment of a patient's noncancer-related chronic or intractable pain.

- 4. Consultation. The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation, and consultation with or referral to an expert in the management of such patients.
- 5. Medications Employed. A physician shall document in the patient's medical record the medical necessity for the use of more than one type or schedule of controlled substance employed in the management of a patient's noncancer-related chronic or intractable pain.
- 6. Treatment Records. A physician shall document and maintain in the patient's medical record, accurate and complete records of history, physical and other examinations and evaluations, consultations, laboratory and diagnostic reports, treatment plans and objectives, controlled substance and other medication therapy, informed consents, periodic assessments, and reviews and the results of all other attempts at analgesia which he has employed alternative to controlled substance therapy.
- 7. Documentation of Controlled Substance Therapy. At a minimum, a physician shall document in the patient's medical record the date, quantity, dosage, route, frequency of administration, the number of controlled substance refills authorized, as well as the frequency of visits to obtain refills.
- C. Termination of Controlled Substance Therapy. Evidence or behavioral indications of substance abuse or diversion of controlled substances shall be followed by tapering and discontinuation of controlled substance therapy. Such therapy shall be reinitiated only after referral to and written concurrence of the medical necessity of continued controlled substance therapy by an addiction medicine specialist, a pain management specialist, a psychiatrist, or other substance abuse specialist based upon his physical examination of the patient and a review of the referring physician's medical record of the patient.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 37:1270(B)(6), and 37:1285(B).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 23:727 (June 1997), amended LR 26:694 (April 2000).

§6923. Effect of Violation

A. Any violation of or failure of compliance with the provisions of this Subchapter, §§6915-6923, shall be deemed a violation of R.S. 37:1285.A(6) and (14), providing cause for the board to suspend or revoke, refuse to issue, or impose probationary or other restrictions on any license held or applied for by a physician to practice medicine in the state of Louisiana culpable of such violation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 37:1270(B)(6), and 37:1285(B).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 23:728 (June 1997), amended LR 26:695 (April 2000).