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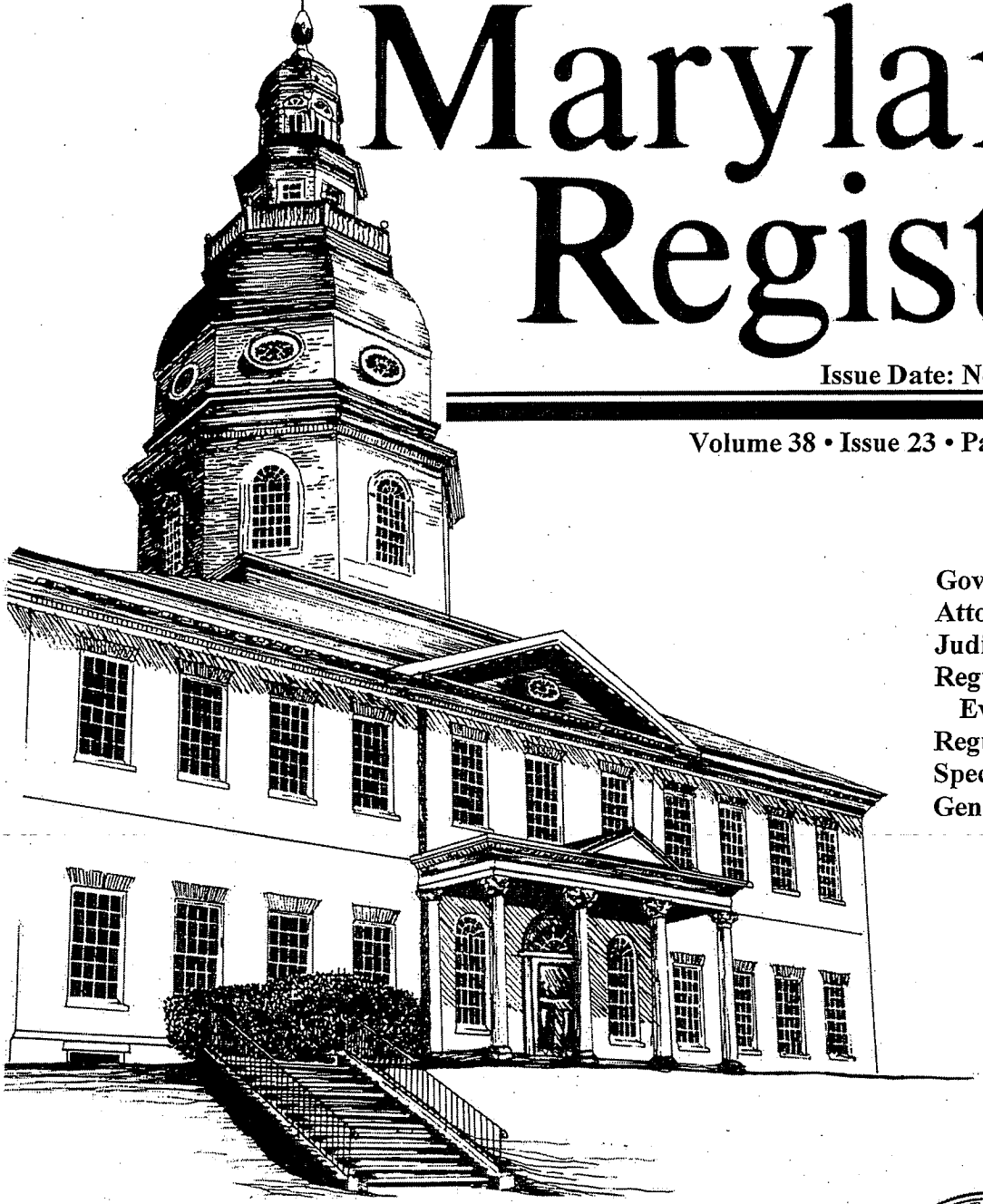

IN THIS ISSUE

Pursuant to State Government Article, §7-206, Annotated Code of Maryland, this issue contains all previously unpublished documents required to be published, and filed on or before October 17, 2011, 5 p.m.

Pursuant to State Government Article, §7-206, Annotated Code of Maryland, I hereby certify that this issue contains all documents required to be codified as of October 17, 2011.

Brian Morris
Acting Administrator, Division of State Documents
Office of the Secretary of State

(2) "Gambling assistance message" means the phrase "Remember it's only a game. Please play responsibly. For confidential help or information at any time about gambling problems, please visit mdgamblinghelp.org or call 1-800-522-4700";

(3) "Printed advertisement" means an advertisement that appears in or on a sign, direct mailing, poster, brochure, or other written material and is intended to encourage video lottery terminal play.

(4) "Responsible gambling awareness materials" means a sticker, brochure, wallet card, or other material that conveys only problem gambling resource information.

(5) "Underage warning message" means the phrase "No person under the age of 21 is permitted on the casino floor".

B. A facility operator shall:

(1) Post signage provided by the Commission that prominently bears the gambling assistance message and the underage warning message at each entrance and exit of the gaming floor;

(2) Include the gambling assistance message on an advertisement that is intended to encourage video lottery terminal play at its facility;

(3) Ensure that a printed advertisement bears the gambling assistance message in a font height that is the greater of:

(a) The same size as the majority of the text used in the advertisement; or

(b) Two percent of the height or width of the size of the advertisement;

(4) Ensure that a billboard bearing a printed advertisement bears the gambling assistance message in a font height that is at least 5 percent of the height of the face of the billboard;

(5) Ensure that a television or video advertisement bears the gambling assistance message that and the gambling assistance message is:

(a) Displayed in a font that is at least two percent of the height of the image that will be displayed; and

(b) Visible for the entire time the television or video advertisement is displayed;

(6) Ensure that the gambling assistance message is printed on a paper product that is associated with player consumption of food or beverage if the paper product is:

(a) Special ordered; and

(b) Branded with the facility's logo;

(7) Ensure that the gambling assistance message is printed on ticket stock; and

(8) Shall place in the facility responsible gambling awareness materials according to its responsible gaming plan required under Regulation .09 of this chapter.

STEPHEN L. MARTINO
Director
State Lottery Agency

Subtitle 09 WORKERS' COMPENSATION COMMISSION

14.09.03 Guide of Medical and Surgical Fees

Authority: Labor and Employment Article, §§ 9-309, 9-663, and 9-731, Annotated Code of Maryland

Notice of Proposed Action

[11-305-P]

The Workers' Compensation Commission proposes to amend Regulations **.01** and **.04** and adopt new Regulation **.09** under **COMAR 14.09.03 Guide of Medical and Surgical Fees.** This action was considered at an open meeting on August 11, 2011, notice of which was given by publication in 38:15 Md. R. (July 15, 2011) pursuant to State Government Article, §10-506(c), Annotated Code of Maryland.

Statement of Purpose

The purpose of this action is to establish a uniform fee or pricing schedule for reimbursing prescription drugs required to treat an injured covered employee irrespective of the identity of the person or entity that dispenses the prescription drug. Specifically, the pharmaceutical fee schedule is designed to eliminate the existing disparity in reimbursement rates between physician-dispensed and pharmacy-dispensed prescriptions by establishing a single reimbursement rate tied to the average wholesale price ("AWP"). In a recent study, the Workers Compensation Research Institute found that "for several common physician-dispensed drugs, workers [in Maryland] received more prescriptions and pills than in other states where physician dispensing was not common. For these medications, physician-dispensers [in Maryland] were paid nearly double or triple the price paid to a pharmacy for the same prescription." Workers Compensation Research Institute, Prescription Benchmarks for Maryland, at 11 (March 2010). "Maryland physicians were paid an average of $2.59 per pill when they dispensed, while retail pharmacies were paid $0.67 per pill." Id., at 14.

Under the proposed fee schedule, the reimbursement rate a dispenser will be reimbursed for a brand drug is calculated by subtracting 10% of the AWP from the AWP and adding a $3 dispensing fee: BR = AWP – (0.10 x AWP) + 3. Similarly, the reimbursement rate a dispenser will be reimbursed for a generic drug is calculated by subtracting 10% of the AWP from the AWP and adding a $5 dispensing fee as follows: GR = AWP – (0.10 x GEAP) + 5. For repackaged or compounded drugs, the AWP utilized in calculating the reimbursement shall be the AWP and corresponding NDC (National Drug Code) number, or AWP of the primary underlying active drug product used in the repackaging or compounding. This action further directs the Commission to designate a nationally recognized pharmaceutical publication as the source of AWP pricing and recognizes that a pharmacy and payer, or a pharmacy and a pharmacy benefits manager ("PBM"), may continue to enter into private contracts for pharmaceutical reimbursement.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

I. Summary of Economic Impact. The proposed action is anticipated to have a small beneficial economic impact on self-insured businesses, self-insured governmental entities and insurance carriers, entities that directly bear the cost of pharmaceutical reimbursement, who may realize cost savings resulting from decreased pharmaceutical expenditures. National and independent pharmacies may experience a slight increase in revenues based on the mandated dispensing fee. Dispensing physicians and repackagers that provide physicians with pharmaceuticals may experience a slight decrease in revenues when reimbursement is limited to the same amount as a pharmacy.

II. Types of Economic Impact.	Revenue (R+/R-) Expenditure (E+/E-)	Magnitude
A. On issuing agency:		
Workers' Compensation Commission	(E-)	Minimal
B. On other State agencies:		
Other State Agencies	(E-)	Minimal
C. On local governments:		
Local Governments	(E-)	Minimal
	Benefit (+) Cost (-)	Magnitude
D. On regulated industries or trade groups:		
Insurance Carriers	(+)	Significant drop in costs
E. On other industries or trade groups:		
(1) Maryland Self-Insured Businesses	(+)	Minimal
(2) National Pharmacies	(+)	Minimal
(3) Small Independent Pharmacies	(+)	Slight gain
(4) Dispensing Physicians	(-)	Unable to estimate
(5) Repackagers	(-)	Significant loss
(6) Maryland Businesses	(+)	Significant drop in rates

III. Assumptions. (Identified by Impact Letter and Number from Section II.)

A. The State of Maryland and coordinate agencies may realize cost savings resulting from decreased pharmaceutical expenditures.

B. Self-insured employers including the State of Maryland, may realize cost savings resulting from decreased pharmaceutical expenditures.

C. Self-insured employers, including local governments and self-insured groups, may realize cost savings resulting from decreased pharmaceutical expenditures.

D. Insurance carriers are projected to realize significant cost savings resulting from decreased pharmaceutical expenditures.

E(1). Maryland businesses who are permitted to self-insure may realize cost savings resulting from decreased pharmaceutical expenditures.

E(2). National pharmacies may experience a slight increase in revenue based on dispensing fee.

E(3). Small independent pharmacies may experience a slight increase in revenue based on dispensing fee.

E(4). Dispensing physicians may experience a decrease in revenues when reimbursement is limited to the same amount as a pharmacy.

E(5). Repackagers may experience a decrease in revenues when reimbursement is limited to the same amount as a pharmacy.

E(6). Cost savings realized by insurance carriers stemming from contained pharmaceutical costs may result in reduced premiums for Maryland businesses.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Amy S. Lackington, Administrator, Workers' Compensation Commission, 10 E. Baltimore Street, Baltimore, MD 21202, or call 410-864-5300, or email to alackington@wcc.state.md.us, or fax to alackington@wcc.state.md.us. Comments will be accepted through December 5, 2011. A public hearing has not been scheduled.

.01 Definitions.

A. (text unchanged)

B. Terms Defined.

(1)—(2) (text unchanged)

(3) "Average wholesale price (AWP)" means a figure reported by a commercial publisher of drug pricing data, based on wholesale pricing information provided by drug manufacturers including repackagers and relabelers.

[(3)] (4) (text unchanged)

(5) "Compounded drug" means a prescription drug that has been prepared by a pharmacist who mixes or adjusts drug ingredients to customize a medication to meet a patient's individual needs.

[(4)] *(6)*—[(8)] *(10)* (text unchanged)

(11) "Food and Drug Administration (FDA)" is a federal agency housed within the United States Department of Health and Human Services and is charged with a myriad of tasks including protecting the public health by assuring that foods are safe, wholesome, sanitary and properly labeled and that human and veterinary drugs, and vaccines and other biological products and medical devices intended for human use are safe and effective.

[(9)] *(12)* (text unchanged)

(13) "Generic Equivalent Drug" or "generic drug" means a drug that is identical, or bioequivalent, to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use.

[(10)] *(14)*—[(15)] *(19)* (text unchanged)

(20) "National Council for Prescription Drug Programs ("NCPDP") is a non-profit, American National Standards Institute accredited, standards development organization which creates and promotes standards for electronic healthcare transactions.

(21) "National Drug Code (NDC)".

(a) "National drug code" means the unique, three-segment number that identifies the labeler, product, and trade package size of human drugs.

(b) The NDC is comprised of three segments:

(i) The first segment, the labeler code, is assigned by the FDA and identifies the manufacturer (including repackagers or relabelers), or distributor of the drug;

(ii) The second segment, the product code, identifies a specific strength, dosage form, and formulation for a particular firm; and

(iii) The third segment, the package code, identifies package sizes and types.

(22) "Pharmacy Benefits Manager (PBM)" means a third party administrator of a prescription drug program that may process and pay prescription drug claims, contract with pharmacies, and negotiate discounts and rebates with drug manufacturers.

(23) Prescription Drug.

(a) "Prescription drug" means any drug required by federal law or regulation to be dispensed only by a prescription.

(b) "Prescription drug" includes:

(i) A biological product; and

(ii) Finished dosage forms and bulk drug substances subject to § 503(b) of the Federal Food, Drug, and Cosmetic Act.

(c) "Prescription drug" does not include blood and blood components intended for transfusion or biological products that are also medical devices.

(24) Repackage.

(a) "Repackage" means to repackage or otherwise change the container, wrapper, or labeling of a prescription drug to further the distribution of the prescription drug.

(b) "Repackage" does not include changes to a container, wrapper, or labeling of a prescription drug completed by the pharmacist responsible for dispensing the prescription drug to a patient.

[(16)] *(25)*—[(18)] *(27)* (text unchanged)

.04 MRA or Fee Not Established.

A. The Commission has not established a medical fee schedule for dental services, *and* durable medical equipment[, and pharmaceuticals].

B. For products and services for which the Commission has not established an MRA or medical fee schedule, including dental services, *and* durable medical equipment, [and pharmaceuticals,] the insurance carrier shall assign a relative value to the product or service.

C.—F. (text unchanged)

.09 Pharmaceutical Fee Schedule.

A. Scope.

(1) The pharmaceutical fee schedule applies to all prescription drugs required to treat an injured covered employee regardless of whether the prescription drugs are dispensed by a pharmacist, physician, dentist, or podiatrist.

(2) Unless a pharmacy and payer, or a pharmacy and a pharmacy benefits manager (PBM) with whom the payer contracts, have a contractual agreement governing pharmaceutical reimbursement, the pharmaceutical fee schedule shall govern the reimbursement of prescription drugs.

(3) Unless the pharmacy and payer, or a pharmacy and a PBM with whom the payer contracts, have a contractual agreement authorizing network discounts, network discounts do not apply.

(4) The calculation of the reimbursement rate under the pharmaceutical fee schedule does not apply to an injured worker's direct purchase of prescription medications and does not limit an injured worker's right to reimbursement for actual out-of-pocket expenses.

B. Generic and Brand Name Drugs.

(1) A pharmacist may dispense generic equivalent drugs to injured covered employees in accordance with Health Occupations Article, §12-504(c), Annotated Code of Maryland.

(2) A physician, dentist, or podiatrist may dispense generic equivalent drugs to injured covered employees in accordance with Health Occupations Article, §12-102, Annotated Code of Maryland.

C. Rules Regarding Payment of Maximum Allowable Fee.

(1) A physician, dentist or podiatrist that dispenses prescription drugs shall be reimbursed based on the drug dispensed.

(2) A pharmacy or other entity for which a pharmacist dispenses prescription drugs shall be reimbursed based on the drug dispensed.

(3) In calculating the reimbursement rate for a prescription drug, the parties shall utilize the NDC number and the AWP for the dispensed drug set forth in the nationally-recognized pharmaceutical publication designated by the Commission.

(4) The Commission shall post on its website, under the fee schedule link of its homepage, the name of the nationally-recognized pharmaceutical publication designated by the Commission as the source of AWP pricing.

D. Determination of AWP.

(1) For prescription drugs, the average wholesale price is the AWP established by the manufacturer that produces the drug, as validated by the corresponding NDC number.

(2) In calculating the reimbursement rate for a prescription drug, the parties shall determine the AWP on the date the drug is dispensed based on the pricing published in the most recent issue, as updated quarterly, of the pharmaceutical publication designated by the Commission.

(3) For compounded drugs, the AWP utilized in calculating the reimbursement shall be the AWP, and corresponding NDC, of the primary underlying active drug product used in the compounding.

(4) For repackaged drugs, the AWP utilized in calculating the reimbursement shall be the AWP that corresponds to the NDC of the original drug manufacturer/labeler, and not the entity that repackaged the drug.

(5) If information concerning the original labeler of the underlying drug product is not provided or unknown, the payer may select the AWP, and corresponding NDC number, as published in the nationally-recognized pharmaceutical publication designated by the Commission, to use in calculating reimbursement for a repackaged or compounded drug.

(6) If the quantity (number of tablets or pills) of the dispensed prescription drug is different than the quantity published in the pharmaceutical publication, the parties shall adjust the AWP to reflect the ratio between the quantity of drug dispensed and quantity of drug published.

E. Calculation of Reimbursement.

(1) For generic prescription drugs dispensed after the effective date of this regulation, the parties shall calculate the generic reimbursement rate by subtracting 10 percent of the AWP from the AWP and adding a $5 dispensing fee as follows: GR = AWP – (0.10 x AWP) + 5.

(2) For brand name prescription drugs dispensed after the effective date of this regulation, the parties shall calculate the brand name reimbursement rate by subtracting 10 percent of the AWP from the AWP and adding a $3 dispensing fee as follows: BR = AWP – (0.10 x AWP) + 3.

F. Reimbursement Procedures.

(1) Physicians, Dentists, and Podiatrists. To obtain reimbursement under this section, a physician, dentist, or podiatrist shall:

(a) Complete Form CMS-1500 in accordance with the written instructions posted on the Commission's website and in compliance with the reimbursement procedures governing reimbursement for medical services if prescription drugs were dispensed in conjunction with the provision of medical services;

(b) Include on the CMS-1500, in the description field, the relevant NDC as set forth above; and

(c) Submit the completed CMS-1500 to the employer or insurer.

(2) Pharmacies. To obtain reimbursement under this section, a pharmacy shall submit to the employer or insurer, on the most current National Council for Prescription Drug programs (NCPDP) form, a complete electronic claim.

(3) Time for Reimbursement. Reimbursement by the employer or insurer shall be made within 45 days of the date on which the Form CMS-1500 or NCPDP form was received by the employer or insurer, unless the claim for pharmaceutical reimbursement is denied in full or in part under §5 of this regulation.

(4) Untimely Reimbursement. If an employer or insurer does not pay the fee calculated under this section or file a notice of denial of reimbursement, within 45 days of receipt of the CMS-1500 or NCPDP form, the Commission may assess a fine against the employer or its insurer, and award interest to the provider in accordance with Labor and Employment Article, §§9-663 and 9-664, Annotated Code of Maryland, and COMAR 14.09.01.22.

(5) Denial of Reimbursement.

(a) If an employer or insurer denies, in full or in part, a claim for pharmaceutical reimbursement, the employer or insurer shall:

(i) Notify the provider of the reasons for the denial in writing; and

(ii) Mail the notice of denial of reimbursement to the provider within 45 days of the date on which Form CMS-1500 or NCPDP form was received.

(b) An employer or insurer who fails to file a notice of denial of reimbursement within 45 days of receipt of the CMS-1500 or NCPDP form waives the right to deny reimbursement, and is subject to the provisions of Labor and Employment Article, §§9-663 and 9-664, Annotated Code of Maryland, and COMAR 14.09.01.22.

(6) Objection to Denial of Reimbursement.

(a) A physician, dentist, or podiatrist may contest a partial or total denial of reimbursement, by submitting to the Commission the following items:

(i) A "Claim for Medical Services" on a form provided by the Commission;

(ii) The Form CMS-1500 that relates to the unpaid claims; and

(iii) All correspondence relating to the unpaid claim.

(b) A pharmacy may contest a partial or total denial of reimbursement, by submitting to the Commission the following items:

(i) A "Claim for Pharmaceutical Reimbursement" on a form provided by the Commission;

(ii) The information contained on the submitted NCPDP form; and

(iii) All correspondence relating to the unpaid claim.

(c) The Commission shall review the items submitted, without hearing, and issue its decision in an Order Nisi.

(7) Hearing on Objection to Commission's Order Nisi.

(a) The pharmacy, physician, dentist, podiatrist, employer, or insurer may contest the Commission's Order Nisi by filing with the Commission a controversion of medical claim, on a form provided by the Commission, within 30 days of the date of the Order Nisi.

(b) The Commission shall schedule a hearing on the matter and render a decision.

R. KARL AUMANN
Chairman
Workers' Compensation Commission

Title 29
DEPARTMENT OF STATE POLICE

Subtitle 02 MOTOR VEHICLES

29.02.01 Vehicle Inspection

Authority: Transportation Article, §23-105, Annotated Code of Maryland.

Notice of Proposed Action

[11-318-P]

The Secretary of State Police proposes to amend existing Regulations **.01**, **.02**, **.11**, and **.14** under **COMAR 29.02.01 Vehicle Inspection**.

Statement of Purpose

The purpose of this action is to add the full name of the Department of State Police to Regulation .01; amend Regulation .02 to reflect that post-manufacture window tinting certifications will only be done by registered inspection mechanics; amend the criteria to certify vehicle glass as safe and the criteria associated with certifying post-manufacture window tinting under Regulation .11; and add to Regulation .14 the rear view mirror requirements for 1978 or newer motorcycles.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

The proposed action has no economic impact.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Thomas Vondersmith, Administrator, Maryland State Police, 1201 Reisterstown Road, Pikesville, MD 21208, or call 410-653-4253, or email to tvondersmith@mdsp.org, or fax to 410-653-4250. Comments will be accepted through December 5, 2011. A public hearing has not been scheduled.

.01 Certification of Safety *Equipment* Repair Orders.

Visual Inspection and Certification of Safety Equipment Repair Orders. In accordance with [the] Transportation Article, §23-105, Annotated Code of Maryland, the Automotive Safety Enforcement Division of the *Department of* State Police has established the following procedures for visual inspection and certification of certain equipment and mechanism defects on certain types of State-registered motor vehicles or trailers by the State Police and police departments.