**NOTICE OF INTENT**

**Department of Health**
**Bureau of Health Services Financing**

**Pharmacy Benefits Management Program**
**(LAC 50:XXIX.Chapters 1-9)**

The Department of Health, Bureau of Health Services Financing proposes to amend LAC 50:XXIX.Chapters 1-9 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This proposed Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq.

The Department of Health, Bureau of Health Services Financing provides coverage and reimbursement for prescription drugs to Medicaid eligible recipients enrolled in the Medicaid Program. Act 10 of the 2009 Regular Session of the Louisiana Legislature provided that the department may redefine the reimbursement methodology for multiple source drugs in establishing the state maximum allowable cost (MAC) in order to control expenditures to the level of appropriations for the Medicaid Program. In accordance with the provisions of Act 10, the department promulgated an Emergency Rule to redefine the Louisiana maximum allowable cost (LMAC) (*Louisiana Register*, Volume 36, Number 1). In addition, the dispensing fee was increased for drugs with an LMAC.

The department subsequently determined that it was necessary to repeal the January 1, 2010 Emergency Rule in its entirety and amend the provisions governing the methods of payment for prescription drugs to redefine the LMAC (*Louisiana Register*, Volume 36, Number 2). The department promulgated an Emergency Rule to amend the February 1, 2010 Emergency Rule to revise the provisions governing the methods of payment for prescription drugs to further redefine the LMAC and increase the dispensing fee (*Louisiana Register*, Volume 36, Number 3). The department determined that it was necessary to repeal the March 1, 2010 Emergency Rule in its entirety and promulgated an Emergency Rule to amend the provisions governing the methods of payment for prescription drugs to revise the LMAC provisions (*Louisiana Register*, Volume 36, Number 3). The department subsequently promulgated an Emergency Rule to repeal the March 20, 2010 Emergency Rule in its entirety in order to revise the provisions governing the methods of payment for prescription drugs and the dispensing fee (*Louisiana Register*, Volume 38, Number 9).

The department promulgated an Emergency Rule which amended the provisions of the September 5, 2012 Emergency Rule to further revise the provisions governing the methods of payment for prescription drugs and the dispensing fee (*Louisiana Register*, Volume 38, Number 11). Upon further consideration and consultation with the U.S. Department of Health and Human

Services, Centers for Medicare and Medicaid Services (CMS) on the corresponding Medicaid State Plan Amendment, the department determined that it was necessary to rescind the provisions of the November 1, 2012 Emergency Rule governing the reimbursement methodology for services rendered in the Pharmacy Benefits Management Program, and to return to the reimbursement rates in effect on September 5, 2012, along with an increase in the dispensing fee, which is consistent with the currently approved Medicaid State Plan (*Louisiana Register*, Volume 40, Number 10).

The Department now proposes to amend the provisions governing the Pharmacy Benefits Management Program in order to clarify requirements regarding 340B-covered entities, and to revise the reimbursement methodology to include federal upper limits (FUL), new copayment exemptions and over-the-counter medications added for expansion benefits pursuant to CMS recently released regulations.

**Title 50**

**PUBLIC HEALTH-MEDICAL ASSISTANCE**
**Part XXIX. Pharmacy**

**Chapter 1. General Provisions**

**§105. Medicaid Pharmacy Benefits Management System Point of Sale—Prospective Drug Utilization Program**

A. ...

B. The Louisiana Department of Health reserves the right for ultimate decision making relative to certain drug class

information and drug contraindications or interactions.

C. Covered Drug List. The list of covered drugs is managed through multiple mechanisms. Drugs in which the manufacturer entered into the Medicaid Drug Rebate Program with CMS are included in the list of covered drugs. Average acquisition costs, federal upper payment limits (FUL) and usual and customary charges assist in managing costs on the covered drug list. Federal Upper Limits provide for dispensing of multiple source drugs at established limitations unless the prescribing practitioner specifies that the brand product is medically necessary for a patient. Establishment of co-payments also provides for management.

D. Reimbursement Management. The cost of pharmaceutical care is managed through Average Acquisition Cost (AAC) of the ingredient or through Wholesale Acquisition Cost (WAC) when no AAC is assigned, and compliance with FUL regulations, and the establishment of the professional dispensing fee, drug rebates and copayments. Usual and customary charges are compared to other reimbursement methodologies and the "lesser of" is reimbursed.

E. ...

F. Pharmacy Program Integrity. Program integrity is maintained through the following mechanisms:

1. - 2. ...

3. Surveillance and Utilization Review Systems (SURS)

Program processes which provide for on-going review for mis-utilization, abuse and fraud and audits of the pharmacy providers.

G. ...

H. Point-of-Sale Prospective Drug Utilization Review System. This on-line point-of-sale system provides electronic claims management to evaluate and improve drug utilization quality. Information about the patient and the drug will be analyzed through the use of eight therapeutic modules in accordance with the standards of the National Council of Prescription Drug Programs. The purpose of prospective drug utilization review is to reduce in duplication of drug therapy, prevent drug-to-drug interactions, and assure appropriate drug use, dosage and duration. The prospective modules may screen for drug interactions, therapeutic duplication, improper duration of therapy, incorrect dosages, clinical abuse/misuse and age restrictions. Electronic claims submission inform pharmacists of potential drug-related problems and pharmacists document their responses by using interventions codes. By using these codes, pharmacists will document prescription reporting and outcomes of therapy for Medicaid recipients.

I. - I.2. ...

I.3. - I.4. Repealed.

5. Eligibility verification is determined at the

point of sale.

6. Pharmacy providers and prescribing providers may obtain assistance with clinical questions from the University of Louisiana at Monroe.

7. Prescribers and pharmacy providers will be required to participate in the educational and intervention features of the Pharmacy Benefits Management System.

J. Recipient Participation. Pharmacy patients are encouraged to take an active role in the treatment or management of their health conditions through participation in patient counseling efforts with their prescribing providers and pharmacists.

K. - L. ...

AUTHORITY NOTE: . Promulgated in accordance with R.S, 46:153, Title XIX of the Social Security Act, and the 1995-96 General Appropriate Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1053 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

**§107. Prior Authorization**

A. The medication must be prescribed by a practitioner who is authorized to prescribe under state law. The National Drug Code (NDC) must be identified on each pharmacy claim for

reimbursement. Prescription drugs considered for payment are subject to rebates from manufacturers as mandated by federal law and regulations.

B. Covered Drugs. Coverage of drugs shall be limited to specific drug products authorized for reimbursement by therapeutic category and listed by generic name, strength/unit, NDC, and brand name. Those drug products subject to mandatory coverage as a result of a rebate agreement with the federal government will be covered until written notice is received from the Centers for Medicare and Medicaid Services that coverage will be terminated. Providers will be given notice of termination of coverage.

C. Prior Authorization with a Preferred Drug List

1. A prior authorization process is established which utilizes a preferred drug list (PDL) for selected therapeutic classes. Drugs in selected therapeutic classes that are not included on the PDL shall require prescribers to obtain prior authorization. Lists of covered drug products, including those that require prior authorization, will be maintained on the Louisiana Medicaid web site.

2. The prior authorization process provides for a turn-around response by either telephone or other telecommunications device within 24 hours of receipt of a prior authorization request. In emergency situations, providers may

dispense at least a 72-hour supply of medication.

3. ...

D. Drugs Excluded from Coverage. As provided by §1927(d)(2) of the Social Security Act, the following drugs are excluded from program coverage:

1. experimental drugs and investigational drugs;

2. drugs used to treat weight loss, except Orlistat;

3. cough and cold preparations, except some prescription antihistamine/decongestant combination products;

4. cosmetic drugs, except Isotretinoin;

5. - 8. ...

9. vaccines covered in other programs, except influenza vaccine; and

10. ...

E. DESI Drugs. Those drugs that are subject to a Notice of Oppcrtunity for Hearing, as prescribed by Section 1927(k)(2)(A) of the Social Security Act for which the Food and Drug Administration has proposed to withdraw from the.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1054 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

**§109. Medicare Part B**

A. The Department of Health, Bureau of Health Services Financing pays the full co-insurance and the Medicare deductible on pharmacy claims for services reimbursed by the Medicaid Program for Medicaid recipients covered by Medicare Part B.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1055 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

**§111. Copayment**

A. Payment Schedule

1. ...

2. The pharmacy provider shall collect a copayment from the Medicaid recipient for each drug dispensed by the provider and covered by Medicaid. The following pharmacy services are exempt from the copayment requirements.

a. services furnished to pregnant women;

b. emergency services;

c. family planning services; and

d. preventive medications as designated by the U.S. Preventive Services Task Force's A and B recommendations;

e. Repealed.

B. The following population groups are exempt from copayment requirements:

1. individuals under the age of 21;

2. individuals residing in a long-term care facility;

3. individuals receiving hospice care;

4. Native Americans;

5. Women whose basis for Medicaid eligibility is breast or cervical cancer; and

6. waiver recipients.

C. In accordance with federal regulations, the following provisions apply.

1. The provider may not deny services to any eligible individual on account of the individual's inability to pay the copayment amount. However, this service statement does not apply to an individual who is able to pay, nor does an individual's inability to pay eliminate his or her liability for the copayment.

2. Providers shall not waive the recipient copayment liability.

3. Departmental monitoring and auditing will be conducted to determine provider compliance.

4. Violators of this §111 will be subject to a penalty such as suspension from the Medicaid Program.

AUTHORITY NOTE: Promulgated in accordance with R.S.

46:153 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 32:1055 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

**§113. Prescription Limit**

A. - B. ...

C. The four prescriptions per month limit can be exceeded when the prescriber determines an additional prescription is medically necessary and communicates the following information to the pharmacist in his own handwriting or by telephone or other telecommunications device:

1. ...

2. a valid diagnosis code that is directly related to each drug prescribed that is over the four prescription limit (literal descriptions are not acceptable).

D. - E. ...

F. An acceptable statement and ICD-10-CM, or its successor, diagnosis code are required for each prescription in excess of four per calendar month.

G. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health

and Human Resources, Office of Family Security, LR 14:88 (February 1988), amended by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 16: 313 (April 1990), LR 29:2115 (October 2003). Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1055 (June 2006), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 35:1901 (September 2009), LR 37:3270 (November 2011), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

**§115. Drug Coverage Limits**

A. Reimbursement for multi-source prescription drugs shall be limited in accordance with state and federal law and rules pertaining thereto, with the following exception: Reimbursement shall be provided for any drug prescribed by a prescribing provider that, in his professional judgment and within the lawful scope of his practice, he considers appropriate for the diagnosis and treatment of the patient with the following limitations.

1. - 3 ...

4. The prescribed drug is not methadone prescribed only for narcotic addiction.

5. - 5.c. ...

6. The prescribed drug is not a cosmetic drug, anorexic, cough and cold preparation, or selected nonprescription

drug.

7. The prescribed drug is not an experimental or investigational drug which are generally labeled: Caution - limited by federal law to investigational use, unless a specific exception has been granted by the federal government.

8. The prescribed drug is not an immunosuppresant drug prescribed and billed to Medicare within one year from the date of the transplant for a Title XIX recipient who has Medicare Part B coverage.

9. The prescribed drug is not an immunosuppressant drug covered by Medicare Part B which is prescribed for a nontransplant patient with Medicare Part B coverage and identified in the Title XIX provider manual as subject to special billing procedures. Payment shall be made only when billing requirements are met. Requirements may include provision of a physician statement (or copy) verifying the diagnosis attached to each claim submitted.

B. Drug Listing

1. The bureau's fiscal intermediary or agent will provide coverage information on any specific drug. Providers should contact the fiscal intermediary's or agent's provider/pharmacy relations unit when a specific coverage question arises.

2. The Title XIX provider manual shall include a

listing of examples of prescribed medications and/or supplies which are not payable under pharmaceutical services of the Medicaid Program.

C. Erectile Dysfunction Drugs. Prescription drugs for the treatment of sexual or erectile dysfunction shall not be covered or reimbursed under the Medicaid Program.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1055 (June 2006), LR 32:2083 (November 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

**§117. Time Limits**

A. Filling Prescriptions. Prescriptions for drugs covered by Medicaid other than a controlled substance shall expire one year after the date prescribed by a licensed prescriber. These prescriptions shall not be refilled more than 11 times in one year. A prescription for a controlled dangerous substance listed in Schedule II shall expire 90 days after the date written, and no refills are allowed. A prescription for a controlled dangerous substance listed in Schedule III, IV or V shall expire six months after the date written. Expired prescriptions shall not be refillable or renewable. Payment shall be made for prescriptions

refilled for controlled substances in Schedule III, IV and V not more than five times or more than six months after issue date and only tc the extent indicated by the prescriber on the original prescription, and is restricted by state and federal statutes.

B. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1056 (June 2006), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 38:368 (February 2012), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

**§119. Maximum Quantity**

A. - C. ...

D. Payment will not be made for narcotics other than opioid agonists/antagonists prescribed only for narcotic addiction.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1056 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

## Chapter 3. Lock-In Program

### §303. Recipient Placement in the Lock-In Mechanism

A. Potential lock-in recipients will be identified through review of various reports or by referral from other interested parties. Department of Health designee(s) who are medical professionals examine data for a consistent pattern of misuse/overuse of program benefits by a recipient. Contact with involved providers may be initiated for additional information. The medical professionals render a recommendation to place a recipient in the Physician/Pharmacy Lock-In Program or Pharmacy-Only Lock-In Program. The decision making authority rests solely with the Department of Health, Bureau of Health Services Financing.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1057 (June 2006), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:3268 (November 2011), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

### §307. Notification Directives

A. - A.4. ...

B. The department's contract designee shall be responsible

for the following:

1. initiate contact with the recipient in instances when the recipient fails to contact the department, or its contractor;

2. conduct a telephone interview when warranted with the recipient regarding the Lock-In Program and the recipient's rights and responsibilities;

3. ...

4. notify Lock-In providers of their selection.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1057 (June 2006), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:3268 (November 2011), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

**§309. Restrictions**

A. Recipients shall be prohibited from choosing physicians and pharmacists who overprescribe or oversupply drugs. When the agency cannot approve a recipient's choice of provider(s), the Lock-In recipient shall be required to make another selection.

A.1. - B. ...

AUTHORITY NOTE: Promulgated in accordance with R.S.

46:153 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1057 (June 2006), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:3269 (November 2011), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

**§311. Appeals**

A. Administration Reconsideration. A recipient may request an administrative reconsideration of the department's determination to place the recipient in the Lock-In Program. An administrative reconsideration is an informal telephone discussion among the Bureau of Health Services Financing staff, the LDH contract designee, and the recipient. An explanation of the reason for recommending the recipient to be placed in the Lock-In Program will be provided to the recipient. An administrative reconsideration is not in lieu of the administrative appeals process and does not extend the time limits for filing an administrative appeal under the provisions of the Administrative Procedure Act. The designated official shall have the authority to affirm the decision, to revoke the decision, to affirm part or revoke in part, or to request additional information from either the department or the recipient.

B. Administrative Appeal Process. Upon notification of LDH's determination to place the Medicaid recipient into the Lock-In Program, the recipient shall have the right to appeal such action by submitting a written request to the Division of Administrative Law within 30 days of said notification. If an appeal is timely made, the decision to Lock-In is stayed pending the hearing of the appeal.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1057 (June 2006), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:3269 (November 2011), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

**§313. Changing Lock-In Providers**

A. Recipients may change lock-in providers every year without cause. With good cause, they may change lock-in providers only with the bureau's approval. Recipients may change providers for the following "good cause" reasons:

1. - 2. ...

3. the Lock-In provider(s) request(s) that the recipient be transferred; or

4. the Lock-In provider(s) stop(s) participating in

the Medicaid Program and does not accept Medicaid as reimbursement for services.

a. The recipient may still receive other program services available through Medicaid such as hospital, transportation, etc., which are not controlled or restricted by placing a recipient in Lock-In for pharmacy and physician services. No recipient on Lock-In status shall be denied the service of a physician or pharmacist on an emergency basis within program regulations. In instances in which a recipient is referred by his Lock-In physician to another enrolled Medicaid physician who is accepting Medicaid recipients, reimbursement shall be made to the physician to whom the recipient was referred.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1058 (June 2006), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:3269 (November 2011), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

## Chapter 5. Narcotics and Controlled Substances

### §501. Schedule II Narcotic Analgesic Prescriptions

A. Schedule II narcotic analgesic prescriptions covered

under the Louisiana Medicaid Program shall be filled within 90 days of the date prescribed by a physician or other prescribing practitioner. Also, in accordance with guidance from the drug enforcement agency, the prescriber has the ability to issue multiple prescriptions for the same Schedule II medication to the same patient on the same day. All prescriptions must be dated and signed on the date issued. The prescriber may issue dispensing instruction, e.g., "do not dispense until a specified date."

B. Payment will not be made for narcotics other than opioid agonists/antagonists prescribed only for narcotic addiction.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1058 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

**Chapter 7. Parenteral Nutrition Therapy**

**§703. Medical Necessity**

A. The department's published medical necessity criteria must be met.

B. - J.7. ...

AUTHORITY NOTE: Promulgated in accordance with R.S.

36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1058 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

**§705. Exclusionary Criteria**

Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1060 (June 2006), repealed by the Department of Health, Bureau of Health Services Financing, LR 43:

**§707. Prior Authorization**

A. Parenteral nutrition therapy may be approved by the Prior Authorization Unit (PAU) at periodic intervals not to exceed six months.

A.1. - B.6. Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1060 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

**§709. Intradialytic Parenteral Nutrition**

A. Intradialytic Parenteral Nutrition Therapy (IDPN) is parenteral nutrition therapy provided to a recipient with end stage renal disease (ESRD) while the recipient is being dialyzed. IPDN may be approved by the Prior Authorization Unit at periodic intervals not to exceed six months.

B. - D. Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1061 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

**§711. Additional Documentation**

Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1061 (June 2006), repealed by the Department of Health, Bureau of Health Services Financing, LR 43:

**§713. Equipment and Supplies**

A. ...

A.1. - D. Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1061 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

**Chapter 9. Methods of Payment**

**Subchapter A. General Provisions**

**§901. Definitions**

*Average Acquisition Cost (AAC)*-the average of net payments that pharmacists made to purchase a drug product, after taking into account such items as purchasing allowances, discounts and rebates as determined through the collection and review of pharmacy invoices and other information deemed necessary by the Medicaid Program, and in accordance with applicable state and federal law.

*Average Wholesale Price*—Repealed.

***

*Professional Dispensing Fee*-the fee paid by the Medicaid Program to reimburse for the professional services provided by a pharmacist when dispensing a prescription. Per legislative mandate, the provider fee assessed for each prescription filled in the state of Louisiana, or shipped into the state of Louisiana, will be reimbursed separately.

*Single Source Drug*-a drug mandated or sold by one manufacturer or labeler.

*Usual and Customary Charge*-a pharmacy's charge to the general public that reflects all advertised savings, discounts, special promotions or other programs, including membership-based discounts initiated to reduce prices for product costs available to the general public a special population or an inclusive category of customers.

*Wholesale Acquisition Cost (WAC)*-the manufacturer's published catalog price for a drug product to wholesalers as reported to Medicaid by one or more national compendia on a weekly basis.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1061 (June 2006), amended LR 34:87 (January 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:1558 (July 2010), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

**Subchapter C. Estimated Acquisition Cost**

**§935. Estimated Acquisition Cost Formula**

A. *Estimated Acquisition Cost (EAC)* is the average

acquisition cost of the drug dispensed. If there is not an AAC available, the EAC is equal to the wholesale acquisition cost, as reported in the drug pricing compendia utilized by the department's fiscal intermediary/pharmacy benefits manager (PBM).

B. B. - B.4.c. Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1064 (June 2006), amended LR 34:88 (January 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:1561 (July 2010), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

**Subchapter D. Maximum Allowable Costs**

**§945. Reimbursement Methodology**

A. Maximum Pharmaceutical Price Schedule

1. The maximum payment by the agency for a prescription shall be no more than the cost of the drug established by the state plus the established professional dispensing fee.

2. Repealed.

B. Payment will be made for medications in accordance with the payment procedures for any fee-for-service (FFS) Medicaid

eligible person. On a periodic basis as ingredient costs change, the department will post a link on its website containing average acquisition cost of drugs.

C. - D. ...

E. Payment will be made to providers only for medications furnished to persons eligible for medical vendor payments on a prescription written by a practitioner who is authorized to prescribe in Louisiana and is enrolled in FFS Medicaid.

F. Payments will be made only for the drugs covered under Louisiana Medicaid's Pharmacy Program.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1064 (June 2006), amended LR 34:88 (January 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:1561 (July 2010), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

**§947. Payments to Dispensing Physician**

A. Payment will be made for medications dispensed by a physician on a continuing basis only when his main office is more than five miles from a facility which dispenses drugs.

1. Under the above circumstances, vendor payments

(when the treating prescriber dispenses his own medications and bills Medical Assistance Program under his own name will be made on the same basis as a pharmacist as specified in §945.A.1-2.

B. A prescriber who has a sub-office in an area more than five miles from a pharmacy or other facility dispensing medications will not be paid for medications he dispenses if his main office is within five miles of a pharmacy or other facility dispensing medications.

C. When a prescriber bills Medicaid for medications he dispenses, he shall certify that he himself, or a pharmacist, dispensed the medications and he shall maintain the same records as required of the pharmacist.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1065 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

**§949. Cost Limits**

A. Brand Drugs. The department shall make payments for single source drugs (brand drugs) based on the lower of:

1. average acquisition cost (AAC):

a. If no AAC is available, use the wholesale acquisition cost (WAC) plus the professional dispensing fee; or

b. Repealed.

2. the provider's usual and customary charges to the general public not to exceed the department's "maximum payment allowed."

a. For purposes of these provisions, *general public* is defined as all other non-Medicaid prescriptions, including:

i. third-party insurance;

ii. pharmacy benefit management; or

iii. cash.

A.3. - A.3.c. Repealed.

B. Generic Drugs. The department shall make payments for multiple source drugs (generic drugs), other than drugs subject to "physician certifications", based on the lower of:

1. AAC:

a. If no AAC is available, use the WAC plus the professional dispensing fee;

2. federal upper payment limits plus the professional dispensing fee; or

3. the provider's usual and customary charges to the general public not to exceed the department's "maximum payment allowed."

a. For purposes of these provisions, *general public* is defined as all other non-Medicaid prescriptions,

including:

i. third-party insurance;

ii. pharmacy benefit management; or

iii. cash.

C. Federal Upper Payment Limits for Multiple Source Drugs

1. Except for drugs subject to "physician certification", the Medicaid Program shall utilize listings established by the Centers for Medicare and Medicaid Services (CMS) that identify and set upper limits for multiple source drugs that meet the following requirements.

a. All of the formulations of the drug approved by the Food and Drug Administration (FDA) have been evaluated as therapeutically equivalent in the most current edition of their publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (including supplements or in successor publications).

b. At least three suppliers list the drug, which has been classified by the FDA as category "A" in the aforementioned publication based on listings contained in current editions (or updates) of published compendia of cost information for drugs available for sale nationally.

2. Medicaid shall utilize the maximum acquisition cost established by CMS in determining multiple source drug cost.

3. The Medicaid Program shall provide pharmacists who participate in Medicaid reimbursement with updated lists

reflecting:

a. the multiple source drugs subject to federal multiple source drug cost requirements;

b. the maximum reimbursement amount per unit; and

c. the date such costs shall become effective.

4. Repealed.

D. Physician Certifications

1. Limits on payments for multiple source drugs shall not be applicable when the prescriber certifies in his own handwriting that a specified brand name drug is medically necessary for the care and treatment of a recipient. Such certification may be written directly on the prescription or on a separate sheet which is dated and attached to the prescription. A standard phrase in the prescriber's handwriting, such as "brand necessary" will be acceptable.

D.2 - D.2.c. ...

E. 340B Purchased Drugs. The department shall make payments for drugs that are purchased by a covered entity through the 340B program at the actual acquisition cost which can be no more than the 340B ceiling price plus the professional dispensing fee. Drugs that 340B covered entities purchase outside of the 340B program shall not be reimbursed by Medicaid. 340B contract pharmacies are not permitted to bill 340B stock to Medicaid.

E.1. - E.2. Repealed.

F. Fee-For-Service Drugs. Drugs acquired at federal supply schedule (FSS) and at nominal price shall not be reimbursed by Medicaid.

G. Indian Health Service All-Inclusive Encounter Rate. Pharmacy services provided by the Indian Health Service (IHS) shall be included in the encounter rate. No individual pharmacy claims shall be reimbursed to IHS providers.

H. Mail Order, Long-Term Care and Specialty Pharmacy. Drugs dispensed by mail order, long-term care and/or specialty pharmacies (drugs not distributed by a retail community pharmacy) will be reimbursed using the brand/generic drug reimbursement methodology.

I. Physician Administered Drugs. Physician-administered drugs will be reimbursed based on the applicable fee schedule posted on the Louisiana Medicaid website.

J. Clotting Factor. Pharmacy claims for clotting factor will be reimbursed using the brand/generic drug reimbursement methodology.

K. Investigational or Experimental Drugs. Investigational or experimental drugs shall not be reimbursed by Medicaid.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health

and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1065 (June 2006), amended LR 34:88 (January 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:1561 (July 2010), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

**Subchapter E. 340B Program**

**§961. Definitions**

*Actual Acquisition Cost*—the covered entity's net payment made tc purchase a drug product.

*Contract Pharmacy*—a pharmacy under contract with a covered entity that lacks its own pharmacy whereby the contract pharmacy is authorized to dispense 340B-discounted drugs on behalf of the covered entity in accordance with 1996 Health Resources and Services Administration (HRSA) guidelines (61 FR 43549, August 23, 1996). Contract pharmacies are not allowed to bill Medicaid for pharmacy claims.

*Covered Entity*—a provider or program that meets the eligibility criteria for participating in the 340B Program as set forth in Section 340B(a)(4) of the Public Health Service Act. Covered entities include eligible disproportionate share hospitals that are owned by, or under contract with, state or local government, community health centers, migrant health centers, health centers for public housing, health centers for

the homeless, AIDS drug assistance programs and other AIDS clinics and programs, black lung clinics, hemophilia treatment centers, native Hawaiian health centers, urban Indian clinics/638 tribal centers, 340s school-based programs, Title X family planning clinics, sexually-transmitted disease clinics and tuberculosis clinics.

*Dispensing Fee*—Repealed.

*Estimated Acquisition Cost (EAC)*-the average acquisition cost of the drug dispensed. If there is not an AAC available, the EAC is equal to the wholesale acquisition cost, as reported in the drug pricing compendia utilized by the department's fiscal intermediary.

***

*Professional Dispensing Fee*-the fee paid by Medicaid for the professional services provided by a pharmacist when dispensing a prescription. Per legislative mandate, the $.10 provider fee assessed for each prescription filled in the state of Louisiana will be paid separately.

*Wholesale Acquisition Cost (WAC)*-the manufacturer's published catalog price for a drug product to wholesalers as reported to Medicaid by one or more national compendia on a weekly basis.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1066 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

**§963. Reimbursement**

A. Self-administered drugs that are purchased by a covered entity through the 340B program and dispensed to patients who are covered by Medicaid shall be billed to Medicaid at actual acquisition cost (can be no more than the 340B ceiling price) unless the covered entity has implemented the Medicaid carve-out option, in which case 340B drugs should not be billed to Medicaid. All other drugs shall be billed in accordance with existing Louisiana Medicaid reimbursement methodologies. Indian Health Service, tribal and urban Indian pharmacy claims will be reimbursed in the encounter rate.

B. Contract Pharmacies. Contract pharmacies are not allowed to bill 340B drugs to Medicaid; therefore, they should carve cut.

C. Professional Dispensing Fees. The covered entity will be reimbursed at the appropriate ingredient cost plus the maximum allowable professional dispensing fee or the usual and customary charge, whichever is less.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1066 (June 2006), amended LR 34:88 (January 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:1561 (July 2010), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

**Subchapter F. Antihemophilia Drugs**

**§971. Reimbursement**

A. Anti-hemophilia drugs purchased by a covered entity through the 340B program and dispensed to Medicaid recipients shall be billed to Medicaid at actual acquisition cost and the professional dispensing fee.

B. Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, amended LR 34:881 (May 2008), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

Implementation of the provisions of this Rule may be contingent upon the approval of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS),

if it is determined that submission to CMS for review and approval is required.

In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature, the impact of this proposed Rule on the family has been considered. It is anticipated that this proposed Rule will have no impact on family functioning, stability and autonomy as described in R.S. 49:972.

In compliance with Act 854 of the 2012 Regular Session of the Louisiana Legislature, the poverty impact of this proposed Rule has been considered. It is anticipated that this proposed Rule will have no impact on child, individual, or family poverty in relation to individual or community asset development as described in R.S. 49:973.

In compliance with House Concurrent Resolution (HCR) 170 of the 2014 Regular Session of the Louisiana Legislature, the provider impact of this proposed Rule has been considered. It is anticipated that this proposed Rule will have no impact on the staffing level requirements or qualifications required to provide the same level of service, no direct or indirect cost to the provider to provide the same level of service, and will have no impact on the provider's ability to provide the same level of service as described in HCR 170.

Interested persons may submit written comments to Jen Steele, Bureau of Health Services Financing, P.O. Box 91030,

Baton Rouge, LA 70821-9030 or by email to MedicaidPolicy@la.gov. Ms. Steele is responsible for responding to inquiries regarding this proposed Rule. A public hearing on this proposed Rule is scheduled for Monday, February 27, 2017 at 9:30 a.m. in Room 118, Bienville Building, 628 North Fourth Street, Baton Rouge, LA. At that time all interested persons will be afforded an opportunity to submit data, views or arguments either orally or in writing. The deadline for receipt of all written comments is 4:30 p.m. on the next business day following the public hearing.

Rebekah E Gee MD, MPH

Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

Person Preparing Statement: Robert Andrepont
Phone: 342-8769

Dept.: Health
Office: Bureau of Health Services Financing

Return Address: P.O. Box 91030
Baton Rouge, LA

Rule Title: Pharmacy Benefits Management Program

Date Rule Takes Effect: April 20, 2017

SUMMARY

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment. The following summary statements, based on the attached worksheets, will be published in the Louisiana Register with the proposed agency rule.

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL UNITS (SUMMARY)

*It is anticipated that the implementation of this proposed rule will result in estimated state general fund programmatic savings of $10,746 for FY 16-17, $69,209 for FY 17-18 and $73,846 FY 18-19. It is anticipated that $4,104 ($2,052 SGF and $2,052 FED) will be expended in FY 16-17 for the state's administrative expense for promulgation of this proposed rule and the final rule. The numbers reflected above are based on a blended Federal Medical Assistance Percentage (FMAP) rate of 62.26 percent in FY 16-17 and 63.34 percent in FY 17-18 and 18-19.*

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

*It is anticipated that the implementation of this proposed rule will reduce federal revenue collections by approximately $19,062 for FY 16-17, $119,578 for FY 17-18 and $127,590 for FY 18-19. It is anticipated that $2,052 will be expended in FY 16-17 for the federal administrative expenses for promulgation of this proposed rule and the final rule. The numbers reflected above are based on a blended Federal Medical Assistance Percentage (FMAP) rate of 62.26 percent in FY 16-17 and 63.34 percent in FY 17-18 and 18-19.*

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS (Summary)

*This proposed Rule amends the provisions governing the reimbursement methodology in the Pharmacy Benefits Management Program to revise the reimbursement methodology, and to include federal upper limits (FUL), new copayment exemptions and over-the-counter medications added for expansion benefits pursuant to CMS recently released regulations. It is anticipated that implementation of this proposed rule will reduce programmatic expenditures for pharmacy payments by approximately $33,912 for FY 16-17, $188,787 for FY 17-18 and $201,436 for FY 18-19.*

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

*It is anticipated that the implementation of this proposed rule will no effect on competition and employment.*

Signature of Agency Head or Designee

Legislative Fiscal Officer or Designee

Jen Steele, Medicaid Director
Typed name and Title of Agency Head or Designee

1/10/2017
Date of Signature

LDH/BHSF Budget Head

01/10/17
Date of Signature

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

The following information is required in order to assist the Legislative Fiscal Office in its review of the fiscal and economic impact statement and to assist the appropriate legislative oversight subcommittee in its deliberations on the proposed rule.

A. Provide a brief summary of the content of the rule (if proposed for adoption or repeal) or a brief summary of the change in the rule (if proposed for amendment). Attach a copy of the notice of intent and a copy of the rule proposed for initial adoption or repeal (or, in the case of a rule change, copies of both the current and proposed rules with amended portions indicated).

*This proposed Rule amends the provisions governing the reimbursement methodology in the Pharmacy Benefits Management Program to revise the reimbursement methodology, and to include federal upper limits (FUL), new copayment exemptions and over-the-counter medications added for expansion benefits pursuant to CMS recently released regulations.*

B. Summarize the circumstances that require this action. If the action is required by federal regulations, attach a copy of the applicable regulation.

*The Department of Health, Bureau of Health Services Financing provides Medicaid coverage of prescription drugs through its Pharmacy Benefits Management Program. The Department now proposes to amend the provisions governing the Pharmacy Benefits Management Program in order to clarify requirements regarding 340B-covered entities, and to revise the reimbursement methodology to include federal upper limits (FUL), new copayment exemptions and over-the-counter medications added for expansion benefits pursuant to CMS recently released regulations.*

C. Compliance with Act 11 of the 1986 First Extraordinary Session.

(1) Will the proposed rule change result in any increase in the expenditure of funds? If so, specify amount and source of funding.

*No, this proposed rule will result in a reduction in programmatic expenditures by approximately $29,808 for FY 16-17, $188,787 for FY 17-18 and $201,436 for FY 18-19. In FY 16-17, $4,104 is included for the state's administrative expense for promulgation of this proposed rule and the final rule.*

(2) If the answer to (1) above is yes, has the Legislature specifically appropriated the funds necessary for the associated expenditure increase?

(a) ____ If yes, attach documentation.
(b) _____ If no, provide justification as to why this rule change should be published at this time.

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

I. A. COST OR SAVINGS TO STATE AGENCIES RESULTING FROM THE ACTION PROPOSED

1. What is the anticipated increase or (decrease) in cost to implement the proposed action?

| COST | FY 16-17 | FY 17-18 | FY 18-19 |
|---|---|---|---|
| PERSONAL SERVICES | | | |
| OPERATING EXPENSES | $4,104 | $0 | $0 |
| PROFESSIONAL SERVICES | | | |
| OTHER CHARGES | ($33,912) | ($188,787) | ($201,436) |
| REPAIR & CONSTR. | | | |
| POSITIONS (#) | | | |
| **TOTAL** | **($29,808)** | **($188,787)** | **($201,436)** |

2. Provide a narrative explanation of the costs or savings shown in "A.1.", including the increase or reduction in workload or additional paperwork (number of new forms, additional documentation, etc.) anticipated as a result of the implementation of the proposed action. Describe all data, assumptions, and methods used in calculating these costs.

*The expenses reflected above are the estimated decreases in programmatic expenditures in the Medicaid program. In FY 16-17, $4,104 is included for the state's administrative expense for promulgation of this proposed rule and the final rule.*

3. Sources of funding for implementing the proposed rule or rule change.

| Source | FY 16-17 | FY 17-18 | FY 18-19 |
|---|---|---|---|
| STATE GENERAL FUND | ($10,746) | ($69,209) | ($73,846) |
| SELF-GENERATED | | | |
| FEDERAL FUND | ($19,062) | ($119,578) | ($127,590) |
| OTHER (Specify) | | | |
| **Total** | **($29,808)** | **($188,787)** | **($201,436)** |

4. Does your agency currently have sufficient funds to implement the proposed action? If not, how and when do you anticipate obtaining such funds?

*Yes, sufficient funds are available to implement this rule.*

B. COST OR SAVINGS TO LOCAL GOVERNMENTAL UNITS RESULTING FROM THIS PROPOSED ACTION.

1. Provide an estimate of the anticipated impact of the proposed action on local governmental units, including adjustment in workload and paperwork requirements. Describe all data, assumptions and methods used in calculating this impact.

*This proposed rule has no known impact on local governmental units.*

2. Indicate the sources of funding of the local governmental unit that will be affected by these costs or savings.

*There is no known impact on the sources of local governmental unit funding.*

II. EFFECT ON REVENUE COLLECTIONS OF STATE AND LOCAL GOVERNMENTAL UNITS

A. What increase or (decrease) in revenues can be expected from the proposed action?

| REVENUE INCREASE/DECREASE | FY 16-17 | FY 17-18 | FY 18-19 |
|---|---|---|---|
| STATE GENERAL FUND | | | |
| AGENCY SELF-GENERATED | | | |
| RESTRICTED FUNDS* | | | |
| FEDERAL FUNDS | ($19,062) | ($119,578) | ($127,590) |
| LOCAL FUNDS | | | |
| **Total** | ($19,062) | ($119,578) | ($127,590) |

***Specify the particular fund being impacted***

B. Provide a narrative explanation of each increase or decrease in revenue shown in "A". Describe all data, assumptions, and methods used in calculating these increases or decreases.

*The amounts reflected above are the estimated decreases in the federal share of programmatic expenditures for the Medicaid Program. In FY 16-17, $2,052 is included for the federal expense for promulgation of this proposed rule and the final rule.*

III. COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS

A. What persons or non-governmental groups would be directly affected by the proposed action? For each, provide an estimate and a narrative description of any effects on costs, including workload adjustments and additional paperwork (number of new forms, additional documentation, etc.)

*This proposed Rule amends the provisions governing the reimbursement methodology in the Pharmacy Benefits Management Program to revise the reimbursement methodology, and to include federal upper limits (FUL), new copayment exemptions and over-the-counter medications added for expansion benefits pursuant to CMS recently released regulations.*

B. Also, provide an estimate of any revenue impact resulting from this rule or rule change to these groups.

*It is anticipated that implementation of this proposed rule will reduce programmatic expenditures for pharmacy payments by approximately $33,912 for FY 16-17, $188,787 for FY 17-18 and $201,436 for FY 18-19.*

IV. EFFECTS ON COMPETITION AND EMPLOYMENT

Identify and provide estimates of the impact of the proposed action on competition and employment in the public and private sectors. Include a summary of any data, assumptions and methods used in making these estimates.

*It is anticipated that the implementation of this proposed rule will no effect on competition and employment.*