

DEPT OF MEDICAL ASSISTANCE SERVICES

Prospective Drug Utilization Review

Page 1 of 7

12 VAC 30-10-650. Drug Utilization Review Program.

A. 1. The Medicaid agency meets the requirements of ~~Section~~ § 1927(g) of the Act for a drug use review (DUR) program for outpatient drug claims.

2. The DUR program assures that prescriptions for outpatient drugs are:

- Appropriate
- Medically necessary
- Are not likely to result in adverse medical results

B. The DUR program is designed to educate physicians and pharmacists to identify and to reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and patients or associated with specific drugs as well as:

- Potential and actual adverse drug reactions
- Therapeutic appropriateness
- Overutilization and underutilization
- Appropriate use of generic products
- Therapeutic duplication
- Drug disease contraindications
- Drug-drug interactions
- Incorrect drug dosage or duration of drug treatment
- Drug allergy interactions
- Clinical abuse/misuse

C. The DUR program shall assess data use against predetermined standards whose source materials for their development are consistent with peer-reviewed medical literature which has been critically reviewed by unbiased independent experts and the following compendia:

American Hospital Formulary Service Drug Information (~~1995~~ 2003, as amended)

United States Pharmacopeia-Drug Information (~~1995~~ 2003, as amended)

~~American Medical Association Drug Evaluations (1993, as amended)~~

MICROMEDEX (as updated monthly)

Drug Facts and Comparisons (as updated monthly)

Drug Information Handbook (2003, as amended in 2004)

D. DUR is not required for drugs dispensed to residents of nursing facilities that are in compliance with drug regimen review procedures set forth in 42 CFR 483.60. The state has nevertheless chosen to include nursing home drugs in retrospective DUR.

E. 1. The DUR program includes prospective review of drug therapy at the point of sale or point of distribution before each prescription is filled or delivered to the Medicaid recipient.

2. Prospective DUR includes screening each prescription filled or delivered to an individual receiving benefits for potential drug therapy problems due to:

- Therapeutic duplication
 - Drug disease contraindications
 - Drug-drug interactions
 - Drug-interactions with nonprescription or over-the-counter drugs
 - Incorrect dosage or duration of drug treatment
 - Drug allergy interactions
-
-

DEPT OF MEDICAL ASSISTANCE SERVICES

Prospective Drug Utilization Review

Page 2 of 7

- Clinical abuse/misuse

3. Prospective DUR includes counseling for Medicaid recipients based on standards established by State law and maintenance of patient profiles.

4. Prospective DUR may also include electronic messages as well as rejection of claims at point-of-sale pending appropriate designated interventions by the dispensing pharmacist or prescribing physician.

5. Designated interventions may include provider override, obtaining prior authorization via communication to a call center staffed with appropriate clinicians, or written communication to prescribers.

F. 1. The DUR program includes retrospective DUR through its mechanized drug claims processing and information retrieval system or otherwise which undertakes ongoing periodic examination of claims data and other records to identify:

- Patterns of fraud and abuse

- Gross overuse

- Inappropriate or medically unnecessary care among physicians, pharmacists, Medicaid recipients, or associated with specific drugs or groups of drugs.

2. The DUR program assesses data on drug use against explicit predetermined standards including but not limited to monitoring for:

- Therapeutic appropriateness

- Overutilization and underutilization

- Appropriate use of generic products

- Therapeutic duplication

- Drug disease contraindications

- Drug-drug interactions

- Incorrect dosage/duration of drug treatment

- Clinical abuse/misuse

3. The DUR program through its state DUR Board, using data provided by the board, provides for active and ongoing educational outreach programs to educate practitioners *and pharmacists* on common drug therapy problems to improve prescribing and dispensing practices.

4. In situations of conflict with these criteria, DMAS, pursuant to the DUR Board's criteria and requirements, shall reject or deny presented claims and require the dispensing pharmacist to intervene as specified through electronic messages in the point-of-sale system before the claim will be approved for payment.

5. Designated interventions may include provider override, obtaining prior authorization via communication to a call center staffed with appropriate clinicians, or written communication to prescribers.

G. 1. The DUR program has established a state DUR Board directly.

2. The DUR Board membership includes health professionals (one-third licensed actively practicing pharmacists and one-third but no more than 51 percent licensed and actively practicing physicians) with knowledge and experience in one or more of the following:

- Clinically appropriate prescribing of covered outpatient drugs.

- Clinically appropriate dispensing and monitoring of covered outpatient drugs.

- Drug use review, evaluation and intervention.

- Medical quality assurance.

3. The activities of the DUR Board include:

- *Prospective DUR*

- Retrospective DUR

- Application of Standards as defined in § 1927(g)(2)(C), and

DEPT OF MEDICAL ASSISTANCE SERVICES

Prospective Drug Utilization Review

Page 3 of 7

- Ongoing interventions for physicians and pharmacists targeted toward therapy problems or individuals identified in the course of retrospective DUR

4. The interventions include in appropriate instances:

- Information dissemination

- Written, oral, and electronic reminders

- Face-to-Face *and telephonic* discussions

- Intensified monitoring/review of prescribers/ dispensers

- *Rejected or denied claims, as appropriate, to prevent the violation of the DUR Board's predetermined criteria.*

- *Provider override, obtaining prior authorization via communication to a call center staffed with appropriate clinicians, or written communication to prescribers.*

H. The state assures that it will prepare and submit an annual report to the secretary, which incorporates a report from the state DUR Board, and that the state will adhere to the plans, steps, procedures as described in the report.

The Medicaid agency ensures that predetermined criteria and standards have been recommended by the DUR Board and approved by ~~the~~ *either BMAS or the director, acting on behalf of the BMAS, pursuant to § 32.1-324 of the Code of Virginia* and that they are based upon documentary evidence of the DUR Board. The activities of the DUR Board and the Medicaid fraud control programs are and shall be maintained as separate. The DUR Board shall refer suspected cases of fraud or abuse to the appropriate fraud and abuse control unit with the Medicaid agency.

I. 1. The state establishes, as its principal means of processing claims for covered outpatient drugs under this title, a point-of-sale electronic claims management system to perform on-line:

a. Real time eligibility verification.

b. Claims data capture.

c. Adjudication of claims. *Such adjudication may include the rejection or denial of claims found to be in conflict with DUR criteria. Should such rejection or denial occur during the adjudication process, the dispensing pharmacist shall have the opportunity to resolve the conflict and resubmit the claim for readjudication.*

d. Assistance to pharmacists, etc., applying for and receiving payment.

2. Prospective DUR is performed using an electronic point of sale drug claims processing system.

J. Hospitals which dispense covered outpatient drugs are exempted *pursuant to federal law* from the drug utilization review requirements of this section when facilities use drug formulary systems and bill the Medicaid program no more than the hospital's purchasing cost for such covered outpatient drugs.

12 VAC 30-130-290. Scope and purpose.

A. DMAS shall implement and conduct a drug ~~use~~ *utilization* review program (DUR program) for covered drugs prescribed for eligible recipients. The program shall help to ensure that prescriptions are appropriate, medically necessary, and are not likely to cause medically adverse events. The program shall provide for ongoing retrospective DUR, prospective DUR and an educational outreach program to educate practitioners on common drug therapy problems with the aim of improving prescribing practices. *As needed, the program shall also provide for electronic messages as well as rejected or denied services when such claims are not consistent with DUR criteria and requirements.* The primary objectives shall be:

1. Improving in the quality of care;

2. Maintaining program integrity (i.e., controlling problems of fraud and benefit abuse); and

3. Conserving program funds and individual expenditures.

B. Certain organized health care settings shall be exempt from the further requirements of retrospective and prospective DUR process as provided for in § 4401 of OBRA 90.

C. The purpose of retrospective drug utilization review shall be to screen for:

1. Monitoring for therapeutic appropriateness;

2. Overutilization and underutilization;

3. Appropriate use of generic products;

DEPT OF MEDICAL ASSISTANCE SERVICES

Prospective Drug Utilization Review

Page 4 of 7

4. Therapeutic duplication;
5. Drug-disease/*health* contraindications;
6. Drug-drug interactions;
7. Incorrect drug dosage or duration of treatment;
8. Clinical abuse/misuse and fraud, and as necessary
9. Introduce to physicians and pharmacists remedial strategies to improve the quality of care rendered to their patients.

D. The purpose of prospective drug utilization review shall be to screen for:

1. Potential drug therapy problems due to therapeutic duplication;
2. Drug-disease/*health* contraindications;
3. Drug-drug interactions (including serious interactions with nonprescription or over-the-counter drugs);
4. Incorrect drug dosage or duration of drug treatment;
5. Drug-allergy interactions; and
6. Clinical abuse and misuse.

E. In instances where initial claims for reimbursement of covered services are determined to be in conflict with DUR criteria and requirements, such claims shall receive electronic messages or be rejected or denied, as appropriate, back to the dispensing pharmacist with notification as to the substance of the conflict. The dispensing pharmacist will be afforded the opportunity to provide an intervention, based on his professional expertise and knowledge, to modify the service to be claimed for reimbursement. If the modification no longer conflicts with the DUR criteria, the claim for the modified service shall be adjudicated for payment. If the modification requires additional information from the prescriber, the pharmacist shall advise the prescribing physician of the continuing conflict and advise the physician to seek prior authorization approval from either DMAS or the pharmacy benefits contractor for his treatment plans.

F. Designated interventions may include provider override, obtaining prior authorization via communication to a call center staffed with appropriate clinicians, or written communication to prescribers.

12 VAC 30-130-310. Prospective DUR.

A. Patient medication profile. On and after January 1, 1993, pharmacists shall make a reasonable effort to maintain a patient medication record system for persons covered under Title XIX of the Social Security Act for whom prescriptions are dispensed. For purposes of this regulation, a reasonable effort shall have been made if the information set forth in subdivision 1 of this subsection is requested by the pharmacist or the pharmacist's designee from the patient or the patient's agent.

1. A reasonable effort shall be made by the participating pharmacist to obtain, record, and maintain at least the following information on each patient's profile:

- a. *Patient's* name, address, telephone number;
- b. Date of birth (or current age) and gender;
- c. Medical history
 - (1) Significant patient health problems known to the pharmacist,
 - (2) Prescription drug reactions or known allergies,
 - (3) A comprehensive list of prescription and nonprescription medications and legend drug administration devices known by the pharmacist to have been used by the patient; and
- d. *Prescriber information to include, but not necessarily be limited to, name, address, and Medicaid and Drug Enforcement Agency (DEA) provider numbers.*
- ~~e.~~ e. Pharmacist's comments relevant to the patient's drug use, including any failure to accept the pharmacist's offer to counsel.

2. Such information may be recorded in any system of records and may be considered by the pharmacist in the exercise of his professional judgment concerning both the offer to counsel and content of counseling. DMAS or its designated agent is authorized to survey pharmacists' patients in order to determine compliance with and report on the mandates of federal and state law and regulations.

DEPT OF MEDICAL ASSISTANCE SERVICES

Prospective Drug Utilization Review

Page 5 of 7

3. The information for patient profiles may be obtained from a patient's prescribing physician, hospital medical records, interviews with the patient, patient's family or agent, or a combination of the above.

4. Patient medication profiles shall be maintained for a period of not less than two years from the date of last entry or as necessary to comply with state or federal law.

B. Pharmacist's responsibilities. Upon receipt of each prescription and before dispensing the medication, a pharmacist shall perform prospective DUR based on his professional knowledge and the criteria and standards approved by the DUR Board, using the information contained in the patient's profile.

~~Each pharmacy is required to have DMAS' DUR Board approved criteria readily available for pharmacists to use in performing prospective DUR. If an exception to one or more prospective DUR criteria is identified, a message will be transmitted to the pharmacist. Claims may be rejected due to the exceptions to one or more criteria. Pharmacists may be required to obtain prior authorization, defined as the process of reviewing drugs to determine if medically justified prior to the submission of a claim for payment by Medicaid, in order to dispense the medications.~~

Designated interventions may include provider override, obtaining prior authorization via communication to a call center staffed with appropriate clinicians, or written communication to prescribers.

C. Patient counseling. Consistent with federal law and regulation a pharmacist must offer to discuss in person, whenever practicable, or through access to a telephone service which is toll-free for long-distance calls with each individual receiving benefits or the caregiver of such individual who presents a prescription, matters which in the exercise of the pharmacist's professional judgment are deemed to be significant. The offer to counsel shall be made consistent with the requirements in § 54.1-3319 B of the Code of Virginia.

The specific areas of counseling shall include those matters listed below that, in the exercise of his professional judgment, the pharmacist considers significant:

1. Name and description of the medication;
2. Dosage form and amount, route of administration, and duration of therapy;
3. Special directions for preparation, administration and use by the patient as deemed necessary by the pharmacist;
4. Common or severe side or adverse effects or interactions that may be encountered which may interfere with the proper use of the medication as was intended by the prescriber, and the action required if they occur;
5. Techniques for self-monitoring drug therapy;
6. Proper storage;
7. Prescription refill information;
8. Action to be taken in the event of a missed dose.
9. Any other matters the pharmacist considers significant.

Alternative forms of patient information may be used to supplement, but not replace, oral patient counseling.

A pharmacist shall not be required to provide oral consultation when a patient or a patient's agent refuses the pharmacist's attempt to consult.

When prescriptions are delivered to the patient or patient's agent who resides outside of the local telephone calling area of the pharmacy, the pharmacist shall either provide a toll free telephone number or accept collect calls from such patient or patient's agent.

Patient counseling as described in this part shall not be required for inpatients of a hospital or institution where a nurse or other person authorized by the Commonwealth is administering the medication.

D. Compliance monitoring. An ongoing program shall be developed for the purpose of monitoring pharmacists' compliance with the prospective DUR requirements of this part.

The director may establish the compliance monitoring program through agreements with other state agencies, the DUR Board or other organizations.

As determined to be appropriate by DMAS, the methods used to monitor compliance shall include but shall not be limited to:

1. On-site inspections,
 2. Patient surveys,
-
-

DEPT OF MEDICAL ASSISTANCE SERVICES

Prospective Drug Utilization Review

Page 6 of 7

3. Desk audits, or
4. Retrospective pharmacy profile reviews.
5. *Electronic messages as well as rejection or denial of claims until there is resolution of the conflict with DUR criteria.*

12 VAC 30-130-320. Criteria and standards for DUR.

The DUR Board shall establish and revise as necessary a list of approved criteria and standards which shall be consistent with the following:

1. Compendia which shall consist of at least the ~~(i) American Hospital Formulary Service Drug Information, (ii) United States Pharmacopeia Drug Information, (iii) American Medical Association Drug Evaluations;~~ *publications, as may be amended from time to time, that are referenced at 12 VAC 30-10-650 C.*
2. The peer-reviewed medical literature; and
3. Commonly accepted standards of medical practice as used by practitioners across the Commonwealth.

12 VAC 30-130-330. Educational program.

A. DMAS shall develop an educational program designed to further educate physicians and pharmacists to ensure that prescriptions are appropriate, medically necessary, and are not likely to cause adverse actions. The purpose of such program shall be to:

1. Identify and reduce the frequency of patterns of fraud, abuse, overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and patients, or associated with specific drugs or groups of drugs;
2. Identify and reduce the potential and actual severe adverse reactions to drugs; and
3. Improve prescribing and dispensing practices.

Such program shall include education on therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions and clinical abuse/misuse.

B. The educational program shall be accomplished through the use of interventions. The interventions shall be directed to physicians and pharmacists and shall address therapy problems or individuals identified in the course of *prospective and retrospective* drug use reviews as having exceptional drug utilization patterns. The educational program shall have at least four types of interventions which shall be used as appropriate. These interventions shall include:

1. Information dissemination sufficient to ensure the ready availability to participating physicians and pharmacists of information concerning the DUR Board's duties, powers, and basis for its standards;
2. Written, oral, ~~or~~ electronic, *and telephonic* reminders containing patient-specific or drug-specific (or both) information and suggested changes in prescribing or dispensing practices, which is communicated in a manner designed to ensure the privacy of patient-related information;
3. Face-to-face discussions between health care professionals who are experts in appropriate and medically necessary drug therapy and selected prescribers and pharmacists who have been targeted for intervention, including discussion of optimal prescribing, dispensing, or pharmacy care practices, and follow-up face-to-face discussions; and
4. Intensified review or monitoring of selected prescribers or dispensers.

C. DMAS may establish the educational program through contracts with accredited health care educational institutions, state medical societies or state pharmacists associations/societies or other organizations, *which may include, but shall not necessarily be limited to, a pharmacy benefits manager.* The educational program will use, but not be limited to, as a basis for its educational activities the compendia and literature referenced in these regulations and data obtained primarily from the *prospective and retrospective* DUR process, and provided by the DUR Board, on common drug therapy problems and other utilization and drug therapy issues listed in these regulations. The educational program shall be based on recommendations submitted by the DUR Board.

D. A report shall be prepared by the DUR Board and submitted to the director at least semi-annually evaluating the success of the interventions, determining if the interventions improved the quality of drug therapy, and making recommendations for modifications in the program, if appropriate.

DEPT OF MEDICAL ASSISTANCE SERVICES

Prospective Drug Utilization Review

12 VAC 30-130-335. Other interventions.

As permitted by all applicable federal and state laws and regulations, DMAS or its designee may intervene in the process of the adjudication of claims for payment of prescription drugs. Such interventions may entail, but shall not be limited to, electronic messages, rejecting claims pending further resolution, or requiring prior authorization for selected prospective DUR criteria.

Designated interventions may include provider override, obtaining prior authorization via communication to a call center staffed with appropriate clinicians, or written communication to prescribers.

12 VAC 30-130-400. Utilization review process.

A. The program shall provide, through its drug claims processing and information retrieval systems, for the ongoing periodic *retrospective* examination of claims data and other records for targeted facilities to identify patterns of inappropriate or medically unnecessary care for individuals receiving benefits under Title XIX of the Social Security Act.

B. The program shall, on an ongoing basis, assess data on drug use against predetermined standards (as described in this section) including, but not limited to, monitoring for therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug/drug interactions, incorrect drug dosage or duration of treatment, clinical abuse/misuse, fraud, and, as necessary, introduce to physicians and pharmacists remedial strategies in order to improve the quality of care.

C. The Department of Medical Assistance Services may assess data on drug use against such standards as *contained in the American Hospital Formulary Service Drug Information, United States Pharmacopeia Drug Information, American Medical Association Drug Evaluations, publications, as may be amended from time to time, that are referenced at 12 VAC 30-10-650 C and any other appropriate peer-reviewed medical literature.*

CERTIFICATION: I hereby certify that these final, adopted regulations are full, true, and correctly dated.

Date

Patrick W. Finnerty, Director
Dept. of Medical Assistance Services